

**THE TREATMENT OF POSTNATAL DEPRESSION WITH EXERCISE:
A RANDOMISED CONTROLLED TRIAL, QUALITATIVE STUDY
AND SYSTEMATIC REVIEW**

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ABSTRACT

This thesis investigated the effectiveness of exercise in the treatment of postnatal depression (PND). PND is highly prevalent, (1) affecting mothers, families and child development (2, 3). Exercise is currently recommended to mothers with PND, potentially offering fewer side effects than antidepressants and wider accessibility than psychological treatments (4).

This thesis reported three studies. A randomised controlled trial (RCT) investigated the effectiveness of an exercise counselling intervention, in addition to usual care, in treating PND. This intervention provided a moderate, non-significant decrease in depression compared to usual care alone.

A qualitative study found that exercise was viewed as acceptable and often preferable to antidepressants in the treatment of PND. A range of mechanisms via which exercise produced psychosocial benefits were proposed, including improving self-confidence and supporting personal identity after childbirth.

A systematic review with meta-analysis of RCTs of exercise interventions for PND concluded that exercise can be effective in reducing depression in general and depressed postnatal populations. Preliminary findings suggested the importance of social support within such interventions.

Exercise is likely to be effective in the treatment of PND and should therefore be recommended to mothers. However, further research investigating the relative effectiveness of different intervention designs would be valuable.

DEDICATION

To Stephen, for holding my hand during innumerable crises in confidence and for the life beyond this PhD that we'll share.

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LIST OF ABBREVIATIONS

7 Day PAR: Seven Day Physical Activity Recall Questionnaire

AEE: Activity Energy Expenditure

ANZCTR: Australian New Zealand Clinical Trials Registry

BDI: The Beck Depression Inventory

BEN PCT: Birmingham East and North Primary Care Trust

BMI: Body Mass Index

CBT: Cognitive Behavioural Therapy

CCBT: Computerised Cognitive Behavioural Therapy

CES-D: Centre for Epidemiologic Studies Depression Scale

CHS: The Child and Families Division of the NHS

CI: Confidence Interval

CIS-R: Clinical Interview Schedule Revised

DASS: The Depression Anxiety Stress Scale

DIT: Dietary Induced Thermogenesis

DSM IV: Diagnostic and Statistical Manual of Mental Disorders, fourth edition

DSM V: Diagnostic and Statistical Manual of Mental Disorders, fifth edition

DVD: Digital Versatile Disk

ECG: Electrocardiography

ECT: Electroconvulsive Therapy

EPDS: Edinburgh Postnatal Depression Scale

EQ-5D: The EuroQol 5D Questionnaire

GP: General Practitioner

HADS: Hospital Anxiety and Depression Scale

HAM-D: Hamilton Rating Scale for Depression

IAPT: Improving Access to Psychological Therapies

ICD-10: International Statistical Classification of Diseases and Related Health Problems 10th Revision

IMD: Index of Multiple Deprivation

IPAQ: International Physical Activity Questionnaire

IPT: Interpersonal Therapy

IQR: Interquartile Range

ISRCTN: International Standard Randomised Controlled Trial Number

ITT: Intention to treat Analysis

K Ohms: Kilo-ohms

kg/m²: Kilograms per Metre Squared

Kg: Kilogram

M: Metres

MCS-12: Mental Component Summary of the Short Form Health Survey

MD: Mean Difference

MeSH: Medical Subject Headings

MET: Metabolic Equivalent Task

MET-mins/wk: Minutes of activity per week at the specified MET level of intensity

Mins/wk: Minutes per week

Mins: Minutes

Mths: Months

MVPA: Moderate to Vigorous Physical Activity

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

NIHR: National Institute for Health Research

OCD: Obsessive Compulsive Disorder

PAEE: Physical Activity Energy Expenditure

PAF: Physical Activity Facilitator

PAL: Physical Activity Level

PCS-12: Physical Component Summary of the Short Form Health Survey

PCT: Primary Care Trust

PHQ-9: Patient Health Questionnaire-9

PMA: Postnatal Maternal Anxiety

PND: Postnatal Depression

PPQ: The Lederman Postpartum Self-Evaluation Questionnaire

RCT: Randomised Controlled Trial

REE: Resting Energy Expenditure

SB PCT: South Birmingham Primary Care Trust

SCID-1: Structured Clinical Interview for DSM-IV Axis I Disorders

SD: Standard Deviation

SEHS: The Self-efficacy and Exercise Habits Survey

SF-12: Short Form Health Survey-12

SF-36: Medical Outcomes Study 36-Item Short-Form Health Survey

SF-36v2: Short Form Health Survey-36 v2

SMD: Standardised Mean Difference

TEE: Total Energy Expenditure

UK: United Kingdom

V: Vertebra

WHO: The World Health Organisation

WIC: The U.S. Special Supplemental Nutrition Program for Women, Infants and Children

WMD: Weighted Mean Difference

CHAPTER ONE

1. INTRODUCTION AND BACKGROUND

1.1 Introduction

1.1.1 Purpose

The purpose of this thesis was to contribute to the body of scientific evidence regarding the effectiveness of exercise as a treatment for postnatal depression (PND). This was achieved through three principal methods; a randomised controlled trial (RCT) of an intervention designed to encourage exercise in clinically depressed mothers; a qualitative study exploring depressed mothers' views and experiences of exercise and their beliefs regarding the mechanisms by which exercise may improve mood; and a systematic review with meta-analysis of RCTs examining the effects of exercise on a range of postnatal psychological outcomes.

This introductory chapter will begin by discussing the definition, symptomatology, aetiology and epidemiology of PND. The influence of maternal depression on the bonding between mother and baby and the development of the child will then be explored. Current treatment recommendations for depression and PND will be discussed, including the evidence on which they are based. The definitions of exercise and physical activity will be considered and an exploration of the potential mechanisms by which exercise may influence psychological health will follow. Finally, current and previous literature surrounding the effects of exercise in treating depression in general adult populations, inpatient depressed populations and postnatal populations will be discussed.

1.2 Background

1.2.1 Defining postnatal depression

1.2.1.1 *Clinical definitions of PND*

PND is a common complication of the postnatal period, reportedly affecting 7-13% of mothers in the year after giving birth (1). It is known to have serious effects on the mother, the family as a whole and the development of the baby (3, 5-7). PND is, however, not a diagnosis in its own right. Within the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM V), the condition 'major depressive disorder' can be given the specifier 'with peripartum onset' (8). This categorisation is used whether the onset of mood symptoms occurs during pregnancy, or in the first four weeks following delivery (8). This combining of the prenatal and postnatal periods is based on the finding that 50% of postnatal major depressive episodes actually begin prior to delivery (8).

This definition could, however, be seen as counterintuitive in two respects. Firstly, the DSM V categorisation of depression represents a departure from the DSM IV, which included a specific diagnosis of major depression with postpartum, rather than peripartum onset (2). Although for some mothers depression may begin during pregnancy, for many it commences specifically after giving birth (1). The postnatal period represents a time of substantial psychological and practical adjustment for a mother and her wider family (9) and is known to involve a specific pattern of alterations in endocrine levels (10), something may therefore be lost by combining two periods of a process that have unique features. The present thesis focuses on depression in the postnatal period. Therefore within this thesis,

participants who would receive the clinical diagnosis of major depressive disorder with peripartum onset, will be referred to as having PND. The term postnatal depression (or postpartum depression in international literature) (11, 12) has been used in primary and secondary care as well as within research for several decades (11-19) and is generally applied to depressed postnatal women, regardless of the point of symptom onset. Postnatal depression was therefore felt to be an appropriate term to define the population studied in this thesis.

Secondly, research has shown that the incidence of postnatal depressive symptoms peaks around six weeks after birth (20), with more than half of those depressed at six weeks still depressed four months after giving birth (20). It is therefore unclear why the relatively restrictive timeframe of four weeks after birth has been applied to the diagnosis of 'major depressive disorder with peripartum onset' in the DSM V. The National Institute for Health and Care Excellence (NICE) have expressed surprise at the restriction of 'peripartum depression' to within four weeks of giving birth (4) and it is pertinent that the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) defines conditions of the puerperium as occurring up to six weeks after birth (21). In research, the postnatal period has often been defined as up to one year after giving birth; this is reflected in much of the previous literature relating to exercise and PND (11-19). The present thesis is concerned with pragmatic definitions of PND that will not exclude mothers who could potentially benefit from the treatment being studied; for the purposes of this research PND will therefore be classed as depression in women up to one year after giving birth.

1.2.1.2 *Definitions of PND within the health services and research*

Within UK primary care health services, screening questionnaires such as the Whooley questions (22) and the Edinburgh Postnatal Depression Scale (23) are used by health professionals to identify mothers at risk of depression (4). While such tools provide an indication of a mother's risk of PND, it is recognised that neither the Whooley questions nor the EPDS are diagnostic tools (22, 23). Within the research community, the current small number of trials that have investigated exercise in the treatment of PND have identified their populations using clinical judgement (14) or screening questionnaires such as the EPDS (11, 13-15). More recent studies investigating the effectiveness of antidepressants for PND have required mothers to have a DSM-IV or ICD-10 diagnosis of depression in the postnatal period (24-27). In the much more developed research field of exercise for depression in the general population, study populations have been recruited from a range of sources including clinical inpatient/out-patient hospital patients; participants scoring above a threshold on a screening questionnaire or participants receiving a DSM-IV, DMS-V or ICD-10 diagnosis of depression (28).

1.2.1.3 *Defining PND within this thesis*

The decision was taken within this PhD to study a clinically diagnosed population of mothers with depression in the postnatal period. As the aim of this research was to assess the effectiveness of exercise as a treatment for PND, a diagnosed population was chosen with the aim of providing a coherent clinical sample with a level of depression requiring treatment. PND will therefore be defined in this thesis as an ICD-10 diagnosis of depression in women up to one year after giving birth.

1.2.2 The symptoms of PND

Mothers with PND will typically experience the symptoms of a major depressive episode. As such they may experience a combination of depressive psychological and psychomotor symptoms on a daily basis (Figure 1). It is important to note that mothers may experience thoughts of self-harm and in some cases thoughts of harming their child (2), though in the vast majority of cases these are only thoughts and no action is taken.

Figure 1: The symptoms of a major depressive episode (DSM V) (8)

- Depressed mood most of the day
- Markedly diminished interest or pleasure in all, or almost all, activities most of the day
- Significant weight loss when not dieting or weight gain (e.g. a change of more than 5% of body weight in a month) or a decrease in appetite
- Insomnia or hypersomnia
- Psychomotor agitation or retardation
- Fatigue or loss of energy
- Feelings of worthlessness or inappropriate guilt
- Diminished ability to think or concentrate or indecisiveness
- Recurrent thoughts of death (not just fear of dying) recurrent suicidal ideation without a specific plan, or a suicide attempt or a plan for committing suicide

A relationship between insomnia, fatigue and PND has been found to remain even after the commonly reported increases in fatigue and sleep deprivation due to breastfeeding and childcare are taken into account, suggesting that insomnia and fatigue are in themselves indicative of PND (29, 30).

Qualitative research has suggested that mothers with PND may also experience altered thought processes. Qualitative literature has indicated that the

immense psychosocial changes a woman is subject to after giving birth may be associated with negative cognitions and emotions (9). Feelings of disconnection from the world have been associated with depression amongst postnatal women (9). Women may experience frustration and self-doubt as a result of the contrast between their expectations of motherhood and the reality of caring for an infant, breastfeeding, achieving sufficient sleep and experiencing changes in their relationship with a partner (9). Rapid alterations in a woman's role and her personal appearance have been perceived to cause a loss of control and an altered sense of personal identity in the postnatal period (9).

1.2.3 Depression in the postnatal period

A range of postnatal psychological conditions involve the experience of depressive symptoms. These conditions represent a spectrum of severity and require distinct treatment. The most common presentation of postnatal depressive symptoms is termed the 'baby blues' or 'postpartum blues'. This is experienced by between 26% and 45% of mothers, usually commencing three to five days and subsiding 10-12 days after giving birth (31, 32). These transient symptoms are of mild severity and often include dysphoric mood, crying, mood lability, anxiety, insomnia, loss of appetite and irritability (33). It has been postulated that the baby blues may reflect the hormonal adjustments of the postnatal period or factors such as anxiety and depression on the day of the birth itself (32).

The symptoms of PND are more persistent than those of the 'baby blues' and vary from mild to severe. PND can begin at any point in the postnatal period but the peak incidence has been found to be around six weeks after giving birth (20). For

some mothers, this may represent a continuation of depressive symptoms originating in the days after giving birth (33), for others, their symptoms may develop later in the postnatal period (20). Many mothers will gradually begin to recover, but for some their symptoms will persist beyond six months after the birth. Those who do recover are at an increased risk of further episodes of depression, particularly following subsequent pregnancies (5, 6).

For between 0.1% and 0.2% of mothers, postnatal psychotic symptoms will be experienced. Such symptoms are often defined as postnatal psychosis, postpartum psychosis, puerperal psychosis or bipolar disorder with postpartum onset (33). Postpartum psychosis is a psychiatric emergency requiring immediate treatment, often as an inpatient. This thesis will discuss neither the baby blues, due to its transient nature, nor postpartum psychosis, due to its low prevalence, severity and specific treatment requirements, but will focus solely on postnatal depression.

1.2.4 The aetiology and epidemiology of PND

The aetiology of PND has been explored in previous research, but has not yet been determined with any certainty. Several different factors have been found to be predictive of, or associated with, an increased risk of postnatal depressive symptoms. Cohort studies have found factors such as depressive or anxiety symptoms during pregnancy (7, 34), a family history of depression or a personal history of anxiety, depression or PND (5) to be amongst the strongest predictive factors of PND (6). Delayed perinatal care (7), poor infant health and unwanted pregnancy (6, 7) have also been found to be associated with PND.

Research has also revealed a range of psychosocial stressors that are associated with an increased risk of PND, including financial concerns, problems with family or friends, relocation, loss of loved ones, pregnancy, sexual, psychological or physical abuse, alcohol or drug related problems, work related problems and feeling continually overwhelmed by life (34). In particular, socioeconomic factors such as unemployment (34), a below average perception of household income, a lower level of education (5) or a husband with lower educational status (5, 7) have been suggested to increase the risk of a mother experiencing PND. Some cohort studies have found younger age to be associated with PND (34), however, other findings have contradicted this (5, 7). It has been postulated that young motherhood may not confer a risk of PND in cultures where motherhood at an early age is more socially acceptable (5). Postnatal depression has been consistently found to be more prevalent in developing countries (5, 7). This may be related to the association between PND, stressful life events (6) and low socioeconomic attainment (5, 34).

Social support from friends and family during stressful times has been found to be protective against PND, perhaps counteracting perceived social isolation, which has been strongly associated with PND (35, 36). In particular, emotional and instrumental (practical) support in pregnancy has been associated with a reduced likelihood of experiencing PND (36). However, differences have been found between a mother's perception of the social support she receives and what may be objectively observed, these differences are thought to relate to the negative mind-set found in depression (36).

The postnatal period is a time when the roles of a mother and a father in relation to childcare and working patterns may alter suddenly and significantly, potentially placing strain on relationships. Cohort studies have reported that marital conflicts and an unsupportive husband may increase a woman's risk of PND (35), whereas a supportive relationship with a partner is thought to be protective against PND (36). Similarly, if a mother has PND, paternal involvement has been suggested to have a protective effect on child development (37).

The lack of close proximity to extended family networks common in modern society may have reduced mothers' access to emotional, financial and instrumental support (38), perhaps resulting in poorer mental health for some mothers (38). This may be of particular importance for young mothers in developed countries, where support from extended families has been found to buffer against the effects of poor relationships with a child's father (39).

Evidence from cohort and case control studies has suggested an association between not breastfeeding and an increased risk of PND (40). From a medical perspective, breastfeeding influences the treatment advice provided by health professionals, with greater emphasis being given to psychological, rather than pharmacological therapies for PND (See chapter 1, section 1.2.9) (4). This differing treatment pattern may affect depression levels in mothers, however there is little evidence to suggest whether pharmacological or psychological therapies are more effective in the treatment of depression (41). Recent research has also suggested a psychological mechanism behind the relationship between not breastfeeding and PND risk, in the effect of unmet breastfeeding expectations (42). It has been

suggested that not successfully meeting a personal goal, such as the desire to breastfeed ones child, can result in ruminative self-focus and a negative affect (43).

The final potential facet of PND is thought to be the influence of chemical pathways in the body. Depression has been associated with dysregulation of several chemical pathways, including the hypothalamic-pituitary-adrenal axis (HPA axis), whose constituent organs form part of the neuroendocrine system which influences our reactivity to stress; the neurogenesis system, which regulates the production of neurones in the brain and the neuroimmune system, which produces neuroinflammatory factors protective against infection (44). Fluctuating levels of oestrogen and thyroid hormones in the postnatal period have also been explored in relation to PND (3). However, a recent review concluded that the evidence for the hormonal aetiology of PND remains equivocal and research into the possible influence of neuroendocrine and inflammatory processes remains in its infancy (3).

1.2.5 Mother and infant bonding

In 2010, Field et al. conducted a comprehensive review of studies exploring the interactions between depressed mothers and their infants (45). Depressed mothers were found to be less sensitively engaged with their child and took part in less facial and vocal interaction with them, compared to non-depressed mothers (45).

Depressed mothers also displayed more hostile, irritable behaviour than non-depressed mothers, demonstrating harsher use of punishment and behaving with less emotion and warmth (45). In particular, two different types of behavioural patterns were identified as more prevalent amongst depressed mothers; intrusive,

controlling, over-stimulating behaviour but also withdrawn, passive, under-stimulating behaviour (45).

A series of studies have suggested that mothers with depression may be less likely to perform certain behaviours important to the health and safety of their child. Depressed mothers may be less likely to breastfeed, or may cease breastfeeding sooner; they may also be less likely to place their baby to sleep on their back or use car seats and other home safety devices appropriately (45). A practical illustration of the potential effect of these altered behaviours is the finding that infants of mothers with PND have increased use of acute care and emergency visits in their later infancy (45).

1.2.6 Child development

The altered pattern of behavioural interactions between depressed mothers and their babies, as described above, has been found to be associated with long-term impairment in the bonding between mother and child (46). Such altered interactions between mother and child has been suggested to impact upon the child's social and cognitive development (47). Research has shown that children of depressed mothers may use less expressive language and perform more poorly on measures of cognitive-linguistic functioning (47). Physiological differences have also been found between the children of mothers with and without PND, with the children of mothers with PND showing greater activation of the right and decreased activation of the left frontal lobe (48). Activity in the right frontal lobe is associated with negative emotion and withdrawal (49). These patterns may result in the child being less attentive and engaged with their environment (48). The Children of mothers

with PND have also been found to have lower cardiac vagal tone, which has been associated with children being less facially and vocally expressive (49). Vagal regulation has also been found to support information processing in infants (50) and language and play development in toddlers (51). These physiological differences have been associated with the unpredictable and difficult behaviour sometimes found in the infants of parents with PND (52).

In 2011, Goodman et al. conducted a review of research into the association between maternal depression and children's psychological and behavioural outcomes (53). This review incorporated 193 trials with a total of 80,851 mother child dyads, with children ranging from nine years to 20 years old (mean 7.13 years, standard deviation (SD) 5.08) (53). Small but significant associations were found between maternal depression and children's internalizing problems (such as depressed mood, anxiety, social withdrawal); externalizing problems (such as aggression, conduct problems, oppositional defiant disorder, attention deficit hyperactivity disorder); negative affect/behaviour and positive affect/behaviour (53).

Research has also found that postnatal depression can affect the physical development of a child (54). A large cohort study conducted in the socioeconomically disadvantaged population of Johannesburg, South Africa (n=1035) reported that maternal depression was associated with 1.6 times the risk of child stunting at two years old (54). In turn, stunted growth was significantly associated with behavioural problems. PND was associated with child behavioural problems at two years old, independent of socioeconomic conditions. This association was primarily moderated by the nutritional status of the child (54). The association

between maternal depression and shorter child stature has also been found in developed countries such as the USA (55). It is possible that PND impairs a mother's ability to provide her child with suitable nutrition, regardless of socioeconomic status (54). Undernutrition may impair the neurological development and consequently the behavioural development of the child (54).

1.2.7 Screening for postnatal depression: current practice

The following sections will discuss the identification and treatment of PND. In 2007, prior to the commencement of this thesis, NICE recommended that health professionals working in primary care in England and Wales, including GPs, health visitors and nurses, use the Whooley questions during consultations with postnatal women to identify women at risk of depression (Figure 2) (4, 22). This is still current practice in England and Wales (4).

Figure 2: The Whooley Questions (22)

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?

If the answer to either of the above questions is yes, the following question can be asked.

3. Is this something you feel you need or want help with?

If further assessment is felt to be needed during routine screening, use of self-reported measures such as the EPDS, Hospital Anxiety and Depression Scale (HADS) (56) or Patient Health Questionnaire-9 (PHQ-9) (57) are recommended (4). No guidance is provided regarding appropriate cut off points for use in these questionnaires, though it is recognised that in research, a range of cut off points are used for the EPDS, including ≥ 10 to represent possible depression and ≥ 13 to represent probable depression (4). In Scotland, it is recognised that there is relatively weak evidence regarding the use of the EPDS and Whooley questions as accurate screening tools, however, their use in facilitating discussion of emotional issues with mothers and supporting clinical monitoring is recognised (40).

Internationally, there is huge variation in the degree of screening for PND. Within the USA, recent legislation from the National Centre for Education in Maternal and Child Health has recommended that paediatricians play a greater role in detecting maternal depression, however, research suggests that paediatricians are not generally using structured approaches to identify depression and that a lack of knowledge, training and willingness to provide treatment are limiting their effectiveness in screening for and managing PND (58).

In Brazil, there are no established protocols for PND screening (59). A lack of knowledge about the presentation of PND and a lack of desire to take responsibility for identifying and treating PND has also been found amongst health professionals in Brazil (59). Australian guidelines approved by their National Health and Medicines Research Council were issued in 2011 advising the use of the EPDS as a screening tool in the antenatal period and between six and 12 weeks postnatal (60). In Norway, guidance was first issued in 2003 addressing mental health issues for women during

pregnancy and the postnatal period. In response, an initiative in which public health nurses used the EPDS as screening tool for depression was evaluated qualitatively, reporting positive views from nurses regarding their training and the usefulness the EPDS as a screening tool (61). There is clearly room for greater creation and application of PND screening guidance internationally (4).

1.2.8 Current treatment for depression

NICE currently recommends a stepped care approach in the treatment of depression in adults (62) (Figure 3). This approach recommends that the least intrusive course of action is explored first and only if no benefit is achieved should a more intensive treatment be offered to a patient (62). Treatment for depression begins with 'active monitoring'; whereby a patient's mood and symptoms are monitored for a period of time to watch for changes or progression in the condition (62). If no improvement is seen, for example in patients with persistent sub-threshold depressive symptoms or in those with mild to moderate depression, low intensity psychosocial interventions should be offered (62). Suitable psychosocial interventions recommended by NICE include individual guided self-help based on cognitive behavioural therapy (CBT), computerised CBT (CCBT) and physical activity programmes (62). Group physical activity programmes consisting of three 45-60 minutes sessions per week over 10-14 weeks are currently recommended (62). If no improvement is obtained from such interventions, or the patients symptoms are felt to be severe, antidepressant medication, higher intensity psychological interventions (one to one CBT) or a combination of treatments is recommended (62). Finally, further treatments are advised for severe and complex depression. Complex depression is defined as

depression that shows an inadequate response to multiple treatments, is complicated by psychotic symptoms, and/or is associated with significant psychiatric comorbidity or psychosocial factors (62). For those with severe or complex depression, pharmacological treatments, high intensity psychological therapy, electroconvulsive therapy (ECT), a combination of treatments, use of the crisis service or inpatient care are recommended (62).

Figure 3: Stepped-care model for adult depression treatment (NICE CG 90) (62)

Focus of the interventions	Treatment
Step 4: Severe and complex depression; risk to life; severe self-neglect	Medication, high-intensity psychological interventions, electroconvulsive therapy, crisis service, combined treatments, multiprofessional and inpatient care
Step 3: Persistent sub-threshold depressive symptoms or mild to moderate depression with inadequate response to initial interventions; moderate and severe depression	Medication, high-intensity psychological interventions, combined treatments, collaborative care and referral for further assessment and interventions
Step 2: Persistent sub-threshold depressive symptoms; mild to moderate depression	Low-intensity psychosocial interventions, psychological interventions, medication and referral for further assessment and interventions
Step 1: All known and suspected presentations of depression	Assessment, support, psychoeducation, active monitoring and referral for further assessment and interventions

1.2.9 Postnatal mental health

The treatments currently recommended by NICE to mothers experiencing depression in the postnatal period are essentially the same as those recommended to adults suffering depression at any other point in their lives (4). However, the order in which these treatments are offered and the specific antidepressants recommended are altered by the balance of risk involving the mother and her infant. If a mother chooses to breastfeed, the neurodevelopmental risk associated with antidepressant medications must be weighed up with the risks of untreated depression and the possible benefits to the mother (and therefore the infant) of receiving antidepressant medication (4) (Figure 4).

Figure 4: NICE guidance for antenatal and postnatal mental health (NICE CG45) (4)

Health professional	Focus	Treatment
Step 5: Inpatient care, crisis teams	Risk to life, severe self-neglect	Medication, combined treatments, ECT
Step 4: Mental health specialists including perinatal and crisis teams	Psychosis, severe disorder	Medication, complex assessment and complex psychological interventions, combined treatments
Step 3: Primary care team, primary care mental health worker, clinical psychologists/therapists	Moderate or severe disorder	Medication, psychological interventions, social support
Step 2: Primary care team, primary care mental health worker, therapists	Mild disorder	Watchful waiting, guided self-help, computerised CBT, exercise, brief psychological interventions
Step 1: GP, practice nurse, midwife, obstetrician, health visitors	Recognition	Assessment

ECT: Electroconvulsive therapy
 CBT: Cognitive behavioural therapy
 GP: General practitioner

1.2.10 The evidence base behind the NICE guidance

1.2.10.1 *Pharmacological treatment of PND*

A recent review of pharmacological treatments in the postnatal period concluded that although the overall risk to the child of a mother taking antidepressants while breastfeeding was small, the varying degree to which different compounds pass into breast milk (and therefore through the blood brain barrier of the child) should be borne in mind (63) (Figure 5). In view of this consideration, citalopram, venlafaxine and fluoxetine should be avoided in breastfeeding mothers unless they have previously been particularly efficacious for that individual (63). It is advised that infants of mothers taking antidepressants should be monitored for increased agitation, crying, vomiting after feeds or signs of sedation (63). For moderate depression in the general adult population, NICE has recommended antidepressants in preference to psychological treatments, in view of their greater cost effectiveness (4). Due to the specific risks to the infant posed by breastfeeding mothers receiving antidepressants, this advice is not applicable to the perinatal period.

It should be borne in mind when considering the recommendation of NICE that only six RCT have been published investigating the use of SSRIs (Selective Serotonin Reuptake Inhibitors) in the treatment of PND (64). Greater reductions in depressive scores were registered by all trials, though these were not always statistically significant. The authors concluded that through SSRI antidepressants were well tolerated and initial evidence was supportive of their use in PND, further evidence was required to confirm their efficacy compared to other standard treatments (64).

1.2.10.2 *Psychological treatment of PND*

Psychological treatments are recommended by NICE to mothers with varying severities of PND (4) See Figure 5. Prior to the publication of the NICE guidance relating to the treatment of PND with psychological therapies, a systematic review by Dennis et al. found that six trials of CBT, Interpersonal therapy and psychodynamic therapy all reported positive effects in depression reduction compared to usual care (65). Although this review located a relatively small body of evidence, a review by Cuijpers et al. of psychological interventions in general adult depressed populations also reported a significant effect in favour of the interventions: SMD of 0.67 (95% CI: 0.60 to 0.75) (66). This review was based on 117 published trials, representing a far more substantial body of evidence which may have been taken into consideration by NICE when constructing their guidance. However, the lack of availability of psychological therapies in the UK on the NHS poses a continuing challenge to the viability of this treatment option (4).

1.2.10.3 *Psychosocial treatment of PND*

Psychosocial interventions are also recommended by NICE for mothers with mild moderate and severe PND (4) (Table 4). A review examining the effects of peer support and non-directive counselling interventions on PND compared to comparators found an overall statistically significant effect of peer support on reducing depressive symptoms (one trial) but not for non-directive counselling (four trials) (65). These findings indicate that the NICE guidance issued at the time this thesis was written (4) may have been premature.

Figure 5: Treatment of mental disorders in pregnant and breastfeeding women (NICE CG45) (4)

If a woman is taking an antidepressant and her latest presentation was a severe depressive episode, the following options should be discussed with the woman, taking into account previous response to treatment, her preference, and risk:

- combining drug treatment with psychological treatment, but switching to an antidepressant with lower risk
- switching to psychological treatment (CBT or IPT).

Pregnant or breastfeeding women who have a new episode of depression

For a woman who develops mild or moderate depression during pregnancy or the postnatal period, the following should be considered:

- self-help strategies (guided self-help, CCBT or exercise)
- non-directive counselling delivered at home (listening visits)
- brief CBT or IPT.

Antidepressant drugs should be considered for women with mild depression during pregnancy or the postnatal period if they have a history of severe depression and they decline, or their symptoms do not respond to, psychological treatments.

For a woman with a moderate depressive episode and a history of depression, or with a severe depressive episode during pregnancy or the postnatal period, the following should be considered:

- structured psychological treatment specifically for depression (CBT or IPT)
- antidepressant treatment if the woman has expressed a preference for it
- combination treatment if there is no response, or a limited response to psychological or drug treatment alone, provided the woman understands the risks associated with antidepressant medication.

Treatment-resistant depression

For pregnant women with treatment-resistant depression, a trial of a different single drug or ECT should be considered before combination drug treatment. Lithium augmentation should be avoided.

CBT: cognitive behavioural therapy

CCBT: computerised CBT

IPT: interpersonal therapy

1.3 Exercise, physical activity and depression

1.3.1 Exercise: how do we define exercise and physical activity?

The concepts of exercise and physical activity are central to this thesis. The discourse surrounding how we define exercise and physical activity in the fields of science and academia has been progressing for decades (67, 68). In 1978, Knuttgen provided the following definition of exercise which was subsequently adopted by the American College of Sports Medicine (67):

'Any and all activity involving generation of force by the activated muscle(s) that results in disruption of a homeostatic state. In dynamic exercise, the muscle may perform shortening (concentric) contractions or be overcome by external resistance and perform lengthening contractions. When muscle force results in no movement, the contraction should be termed isometric.'

This definition suggested that the term exercise does not relate to the context of the activity but is purely based on the contraction of muscles. In 1985, however, Caspersen et al. made reference to a person's intention and the context of the activity within their definition of exercise (69):

- 1. Body movement produced by skeletal muscles*
- 2. Resulting energy expenditure varying from low to high*
- 3. Very positively correlated with physical fitness*
- 4. Planned, structured and repetitive bodily movement*
- 5. The objective is to maintain or improve physical fitness*

Here the definition of exercise begins to diverge from the term physical activity, which Casperson et al. define as (69):

1. *Movement of the body produced by skeletal muscles*
2. *Resulting energy expenditure that varies from low to high*
3. *A positive correlation with physical fitness*

The suggestion is made that exercise is physical activity separated from the activities of daily living, whose intention is attaining physical fitness. This definition was confirmed by Biddle et al. in 2008, who referred to exercise as '*structured, leisure time physical activity*' (70). In 2009 however, after reviewing the application of these definitions in research, Winter et al. determined that the original definition by Knuttgen did not include certain 'exercises' where muscles are active, but the body remains still (isometric), such as bracing the body while sailing a boat (68). The authors therefore returned to a simple definition of exercise that encompassed all forms of muscular movement:

'A potential disruption to homeostasis by muscle activity that is either exclusively or in combination concentric, eccentric or isometric' (68)

This thesis relates to exercise or physical activity in the postnatal period; a time when muscular movement may more frequently relate to the activities of daily living than leisure time activities. If a mother chooses to walk more briskly to collect her children from school, this could be defined as physical activity (as it is an activity of daily living) or as exercise (if her intent is also to improve her fitness). Previous research in this field has incorporated both interventions based on structured group

exercise and also self-selected activity, often based on increasing the frequency and intensity of daily activities such as walking to the shops. Consequently, within this thesis, the terms 'exercise' and 'physical activity' will both be used. Where a term has been used by a previous author in their research, their choice will be respected; the choice of term will otherwise be based on the context of the activity in question.

1.3.2 Mechanisms by which exercise may effect depression

Many mechanisms have been postulated for the pathways by which exercise may improve psychological health. Several neurochemical pathways have been found to be affected by exercise in animal studies (71). The central nervous system (CNS) neurotransmitters norepinephrine (associated with state of alertness) dopamine (associated with pleasure and reward) and serotonin (associated with anxiety level) have been found to be modulated by exercise. Opioids and endocannabinoids, which stimulate a sense of euphoria, decreased anxiety and well-being, may also be released during exercise (71). As previously discussed, depression has been associated with the dysregulation of several neurochemical pathways including the HPA axis, the neurogenesis system and the neuroimmune system. Consequently it has been proposed that exercise may generate an antidepressant effect by stimulating neurogenesis in the hippocampus, the area of the brain that regulates the HPA axis (44), or by reducing neuroinflammatory mechanisms that lead to dysregulation of the HPA axis, monoamine dysfunction and neurogenesis dysfunction (72).

Psychological processes have also been postulated as the route by which exercise may influence depression, including improvements in self-efficacy for

exercise and for coping with daily life, which has received some empirical support (73, 74). Self-efficacy is defined as the belief in one's ability to perform a specific behaviour, here, exercise (75). The process of rumination, by which negative thoughts are dwelt on, is thought to be a feature of prolonged depression (76). The propensity of exercise to provide distraction from rumination has been suggested as a mechanism for its antidepressant effect, however, this has received little support from initial studies (74).

1.3.3 Exercise for depression in the general population

Unquestionably the most substantial body of high quality evidence in this field pertains to exercise as a treatment for depression in general adult populations. In 2013, Cooney et al. conducted a review of RCTs of exercise interventions in depressed adults (28). Exercise was defined as “planned, structured and repetitive bodily movement done to improve or maintain one or more components of physical fitness” (77). Trial comparator groups included; no treatment, placebo intervention, pharmacological and psychological interventions (28). (Of the 37 studies located by the authors, 35 provided data that could be meta-analysed.) Thirty five trials (1356 participants) presented exercise compared with no treatment or a control intervention (28). A moderate clinical effect with moderate heterogeneity was found in favour of exercise: combined standardised mean difference (SMD) for depressive symptoms -0.62 (95% Confidence Interval (CI): -0.81 to -0.42, I^2 statistic (I^2) 63%) (28). Only six trials (n=464) were reported to be at low risk of bias, with adequate allocation concealment, intention to treat analyses and blinded outcome assessment. The combined SMD for trials with a low risk of bias, although in the

same direction as the overall data set, was no longer statistically significant (SMD: -0.18, 95% CI: -0.47 to 0.11) (28). The relative paucity of high quality trials and the difference in efficacy reported between high quality trials and those at greater risk of bias, is an indication that although the body of research around exercise and depressive symptoms is both substantial and of longstanding, the design of further RCTs must be considered with greater attention to sources of bias. Further high quality trials would be useful in determining the size of the effect with greater certainty.

1.3.4 The comparative efficacy of current treatments for depression

A recent systematic review of CBT and other psychological therapies for adult depression reported an SMD of 0.67 (95% CI: 0.60 to 0.75) in favour of psychological therapy compared to control conditions (based on 175 comparisons between interventions and comparators) (66). This effect size is very similar to that reported for exercise in adult depressed populations (-0.62, 95% CI: -0.81 to -0.42) (28). There is a small body of evidence directly comparing the efficacy of exercise and psychological therapies for depressive symptoms. Cooney et al. located seven small trials (n=189) comparing exercise with psychological therapies and found no significant difference between the treatments (combined SMD: -0.03, 95% CI: -0.32 to 0.26), suggesting that they may be equally as effective in reducing depressive symptoms in adult populations (28).

In a review of the effectiveness of antidepressants in depressed adult populations, Arroll et al. reported an SMD of -0.49 (95% CI: -0.67 to -0.32) for Tricyclic antidepressants (TCAs) (12 studies) and an SMD of -0.24 (95% CI: -0.35 to

-0.12) for selective serotonin reuptake inhibitors (SSRIs) (four studies) compared to placebo (78). Similarly, these effect sizes are moderate in magnitude and comparable to that reported for physical activity (28). Exercise has also been compared directly to pharmacological treatment for depression in four trials, (n=300) (28), no significant difference was found between these treatments in adult populations (SMD -0.11, 95% CI: -0.34 to 0.12) (28). Although these early results are encouraging in their support of exercise when compared to other current treatments, further, high quality trials are required before any degree of certainty can be attached to these findings.

1.3.5 Exercise type and context

A recent Cochrane review compared the effectiveness of different types of exercise in reducing depression in the general adult population (28). An SMD of -0.55 (95% CI: -0.77 to -0.34) was reported for aerobic exercise compared to control group; a non-significant SMD of -0.85 (95% CI: -1.85 to 0.15) for mixed aerobic and anaerobic interventions compared to control group and an SMD of -1.03 (95% CI: -1.52 to -0.53) for resistance interventions compared to control group. It was noted that the confidence intervals attached to these results were wide, further reducing the certainty of these findings. This review highlighted a preliminary body of evidence indicating the potential usefulness of anaerobic exercise in the treatment of depression. (28).

In a recent review of exercise interventions in clinically depressed adults, the context of exercise (whether group or alone) did not significantly influence the overall effectiveness of the interventions in reducing depression (79). Though no

systematic reviews have examined this question in postnatal populations, a two arm trial by Armstrong in 2004 compared the effects of group exercise with group social support (80). Improvements in depression were seen in both intervention arms, though the improvement in the group exercise arm was significantly greater than in the social support arm, perhaps suggesting the value of interventions combining the social support provided through a group and exercise (80). No significant improvements in social support were reported in either arm, though the authors note that the high baseline levels of social support may have created a ceiling effect (80).

1.3.6 Exercise for inpatients with clinically diagnosed depression

In 2014, Stanton et al. published a review of exercise interventions in populations hospitalised due to psychological conditions such as depression, anxiety, schizophrenia and bipolar disorder (81). Four eligible trials (n=117) conducted in clinically depressed inpatient populations were included. Trials of moderate intensity running (compared to mixed activities), treadmill exercise (compared to placebo) and moderate intensity aerobic exercise (compared to control) reported significant effects on depressive symptoms in favour of the exercise interventions. One study of a pre post design (with no comparator group) investigating combined aerobic and non-aerobic activities found no significant effect on depression, though the participants were instructed to perform 'as well as they could'; consequently the intensity of the exercise was undefined (81). Overall, this limited evidence has begun to suggest that exercise can offer psychological benefits to those hospitalised with depressive disorders.

1.3.7 Exercise and anxiety

In 2014, Jayakody et al. completed a systematic review of exercise RCTs in populations with anxiety disorders (82). The authors located eight RCTs with sample sizes of between 18 and 170 participants (82). Comparator groups, however, included placebo, usual care, medication and CBT; as a result the weight of evidence for the use of exercise in comparison to any one treatment remains small. Currently, evidence suggests that exercise may be effective in decreasing anxiety and panic symptoms in those with diagnosed anxiety, generalised anxiety disorder (GAD) and panic disorder when compared to a placebo (83-86). The comparative efficacy of exercise, medication (87) and psychological therapies is unclear; more research is required to compare these treatments within populations diagnosed with anxiety. Current evidence gives an initial indication that the efficacy of exercise in reducing anxiety may be greater with increasing exercise intensity (88, 89); however, this suggestion is based on preliminary evidence. Similarly, there is an indication that aerobic and anaerobic exercise may be equally as effective in the treatment of anxiety symptoms (90). Larger, rigorous trials with comparator groups (such as usual care) are needed to provide a much greater evidence base around this question. Despite the relative paucity of evidence it is important to note that NICE currently advises that the benefits of exercise, as part of good general health, should be recommended to those with panic disorder (91).

1.3.8 Exercise and other psychological conditions

Research into the acceptability and effectiveness of exercise in the treatment of psychological conditions such as schizophrenia (92), obsessive compulsive disorder

(OCD) (93-95) and bipolar disorder (96-98) is in its infancy. There have been early indications of the potential usefulness of exercise as an adjunctive to usual care in alleviating obsessions and compulsions (93-95), anxiety (94, 95) and depression (94-98) within these populations. The quality of trials conducted thus far, however, has been low, with small, non-randomised trials without comparator groups providing the majority of data (99).

1.4 Exercise and PND

1.4.1 Exercise and postnatal depression: previous research

At the start of this thesis, the evidence base in the field of exercise and postnatal depression consisted of five trials that were heterogeneous in their design. The populations of all trials indicated a risk of depression on the EPDS screening questionnaire, however eligibility thresholds varied from ≥ 10 (11), to > 10 (15), to ≥ 12 (13, 80), to > 12 (14); with no trials recruiting women with a clinical diagnosis of depression. The definition of postnatal was also inconsistent with one trial recruiting participants up to 18 months after birth (80). Interventions ranged from pre-specified group exercise programmes (13), to group exercise and separate social support interventions (80), to combined group and home based exercise (15) and exercise counselling interventions where individualised exercise plans were created (11, 14). Objective assessment of physical activity was not included in any study (11, 13, 14, 80), introducing the possibility of recall bias within the physical activity data (100). As a group, these trials were also at risk of bias due to a lack of clarity regarding the blinding of outcome assessors (11, 13-15, 80) and a lack of intention to treat analyses (14, 15, 80). The trials were all relatively small in size, ranging from 20

(13) to 88 (11), introducing greater uncertainty to their results. Related psychological factors such as anxiety were not investigated in these studies. The results reported in these trials ranged from significant decreases in depression symptomatology in the intervention compared to comparators (13, 15, 80) to no significant differences in depression (11, 14). Long term follow up of outcomes was not conducted any study; maximum follow up ranging from immediately after the intervention (13, 15) to three months after completion (11, 14, 80). It is therefore unknown whether the benefits seen in some exercise trials were maintained over the long-term. For further details of these trials please refer to chapter six, section 6.3.

A systematic review and meta-analysis was conducted by Daley et al. in 2009 to bring together the evidence in the field of exercise and postnatal depression (101). The overall effect size of exercise interventions on PND symptoms was large, with a weighted mean difference (WMD) of -4.00 Edinburgh Postnatal Depression Scale (EPDS) points (23), however, confidence intervals were wide (95% CI: -7.64 to -0.35) (101). When the trial of an exercise and social support co-intervention (13) was removed from the analysis the differences in EPDS were no longer significant, suggesting the potential importance of social support. Interventions which successfully reduced depressive symptoms relative to comparators varied between those that were predominantly group based (13, 80) to those that were predominantly home based (15). However, high levels of adherence to exercise interventions were found, highlighting their acceptability. The authors concluded that the evidence base provided some support for the use of exercise in reducing the symptoms of PND. The designing of a large trial in a clinically diagnosed population

comparing exercise to standard treatments, including long term follow up, was consequently recommended (101).

1.4.2 The limitations in the evidence base addressed by the RCT in this thesis

To address the limitations seen in the evidence base for exercise in the treatment of PND, a larger, robustly designed RCT is required. Such a trial should only include women with an ICD-10 diagnosis of depression. This would ensure that all participants were clinically depressed, providing a coherent clinical sample and circumventing the lack of consensus regarding the indication of depression through various EPDS thresholds. To reduce recall bias, an objective measurement of exercise is required in addition to a self-reported measure (100). Investigation of relevant psychological factors including anxiety and perceived social support should be conducted in addition to the primary outcome of depression, in order to improve the evidence base related to these outcomes. To determine whether any effects reported from the intervention are maintained, follow up six months from completion of the intervention or comparator should be conducted. The RCT included in this thesis was designed to address these limitations found in previous studies and provide more robust evidence to inform clinical guidance and practice regarding the use of exercise as a treatment for PND.

1.4.3 Exercise and postnatal depression: Beyond the Daley review

Further to the publication of the review by Daley et al. and after the commencement of the RCT in this thesis, seven additional RCTs have been published investigating exercise as a treatment for PND (12, 16-19, 102, 103) (up to August 2014) The

interventions have ranged from structured group exercise classes to self-selected activities and incorporated a variety of activity intensities. These studies were based on two different populations; postnatal women indicating a risk of depression on a screening questionnaire (11, 13-15, 101) and general postnatal populations (12, 16, 18, 19, 102, 103). As previously described, the first studies in populations at risk of depression were generally small (101). The inclusion of all postnatal women may have been an attempt to achieve greater sample sizes such as those in trials by Norman et al (19), Lewis et al (102), and Surkan et al. (18). However this method may have provided a less accurate assessment of the effect of exercise on depression itself (as not all mothers indicated a risk of depression).

The risk of bias attached to these trials has not improved substantially over time, with a lack of blinded outcome assessment (12, 16, 18, 103) and a lack of intention to treat analyses persisting (12, 16, 18, 19, 102, 103). A lack of objective outcome measures is also still apparent, with only one trial using such a measure (the Actigraph accelerometer) (102). Despite the relationship established between depression and other psychological factors such as anxiety (104), related psychological factors have not yet been widely reported amongst exercise trials in postnatal populations. Many trials have reported results significantly in favour of exercise (11, 15, 18, 19, 80, 102, 103), however, several have also reported no benefit of their intervention above that of their comparator groups (12-14, 16, 17), indicating that substantial uncertainty remains regarding the efficacy of exercise in the treatment of PND. For further details of these trials please see chapter six, section 6.3.

1.5 The use of behavioural change theory in interventions

One important aspect to consider in the design of trials in behavioural medicine is the role of behavioural change theory. It is currently recommended by NICE that relevant theories relating to behavioural change are considered in the planning stage of all lifestyle interventions (105). Behavioural change theories and techniques have been found to improve the effectiveness of behavioural interventions in a range of fields of behavioural medicine, such as addiction (106, 107); including smoking cessation (108) and alcohol consumption reduction (109). In areas such as dietary change and smoking cessation, interventions based on the Transtheoretical Model (110, 111) and Social Cognitive Theory (112, 113) have been found to be effective (114).

More specifically, interventions designed to improve physical activity and diet, when designed around a theory of behavioural change, have been found to be more effective than those without an integrated theoretical basis (115). Interventions based on a combination of the Transtheoretical Model (110, 111) and Social Cognitive Theory (112, 113) have been found to be successful in increasing physical activity levels in non-depressed populations (116).

The exploration of the theoretical basis of interventions has begun to influence the field of exercise and depression, including recent interventions based on the principles of self-determination theory (117). However, the latest systematic review of such interventions did not examine the role of behavioural change techniques (28). The study of behavioural change theory and technique in the field of exercise and PND is even more limited.

Only three of the previous exercise interventions in the field of PND have been based on a theory of behavioural change (14, 18, 102), as author defined. Daley et al. based their intervention around the processes of change from the Transtheoretical Model by Prochaska and Diclemente (111), employing the cognitive behavioural techniques of cognitive reappraisal, consciousness raising, goal setting, self-monitoring and seeking social support to promote a change in exercise behaviour (14). Daley et al. reported a non-significant trend in favour of the intervention (14). Similarly, Lewis et al. (102) utilised motivational strategies such as goal setting, social support and self-efficacy for physical activity from Social Cognitive Theory (112) and the Transtheoretical Model (111). No significant difference was reported in the proportion of mothers with a clinical diagnosis of depression between groups at follow up (102). Surkan et al. based their intervention on a Social-Ecological Framework using techniques designed to increase self-efficacy for activity and healthy eating, development of social networks and utilisation of local resources (18). Surkan reported a decrease of 2.0 points on the Centre for Epidemiologic Studies Depression Scale (CES-D) in the intervention group compared to the control group at follow up, which was significant when adjusted for baseline depressive symptoms, BMI, race/religion and household income (18). A decrease of 2.0 points on the CES-D is thought to be below the level of clinically significant change of 5 CES-D points (118).

1.5.1 The use of behavioural change theory in intervention in this thesis

The very preliminary evidence discussed above provides an initial suggestion that techniques designed to increase self-efficacy and the development of social

support may be of value (18). However, as the trial reporting these findings (18) was conducted after the commencement of this thesis, the intervention of the RCT in this thesis was influenced by the evidence from the broader field of exercise interventions. In light of the previous success of physical activity interventions based on a combination of the Transtheoretical Model (110, 111) and Social Cognitive Theory (112, 113), the RCT in this thesis was designed around both of these theories.

The Transtheoretical Model (TTM) of behavioural change was developed by Prochaska and DiClemente (110, 111). The TTM Model defines the psychological stages that occur while a person is attempting behavioural change. During the five stages of precontemplation, contemplation, action, maintenance and relapse, there are believed to be a range of psychological 'processes of change' that can be supported by interventions. The Transtheoretical Model (110, 111) was felt to be a particularly appropriate basis for an intervention for mothers with PND. One of the principle processes of change within the TTM model is that of self-re-evaluation; the concept that considering how one's current actions compare to the idea one wishes to have of oneself can prompt behavioural change (110, 111). Motherhood is thought to bring abrupt changes in a woman's role and focus which can have a negative effect on her sense of self (119, 120). Depression itself has also been found to affect one's sense of personal identity (121). Supporting mothers in achieving personal exercise goals was intended to positively influence a mother's sense of self by reinforcing feelings of personal achievement and self-efficacy for exercise, which is thought to reduce depression (74).

Social Cognitive Theory holds that the interaction between a person's environment, the people within it and the behaviours of those people will influence the adoption of a new behaviour (112, 113). Learning is believed to take place through the observation of others. It has been found that mothers with PND often isolate themselves socially, for fear of the judgement of society. (122) Consequently, providing mothers with opportunities for observational learning through active demonstration of exercise behaviours and encouragement to seek social support for new activities was integral to the intervention in this RCT. For a further in-depth discussion of the theoretical basis of the intervention of the RCT in this thesis please see chapter 3, sections 3.3.1 and 3.3.2.

1.5.2 Other models of behavioural change

Several other theories of behavioural change have been used in lifestyle research. The Health Belief Model was developed by Hochbaum, Rosenstock and Kegels during the 1970's (123). The theory attempts to explain and predict behaviours by focusing on the attitudes and beliefs of the individual. It is believed that a person will take health related action if it is felt that a negative health condition can be avoided, if there is an expectation that taking the particular health related action will result in the negative health condition being avoided and there is a belief that the recommended health action can be successfully undertaken. Four principal concepts are thought to influence a person's readiness to adopt a health related action; a person's perceived susceptibility to a condition; the perceived severity of the condition and its consequences; the perceived benefits of the health action in relation to the condition and the perceived physical and psychological

barriers to adopting the health action. Many mothers with PND are reluctant to accept that they have the condition (124). During this intervention, time spent dwelling on the condition of PND and emphasising the consequences of the condition for the mother, the bond between mother and child and the development of the child may have served to emphasize the perceived severity of the condition and thereby prompt the mother into action. However, this strategy may have been counterproductive to the mother's mental health and was therefore considered unacceptable.

Self-Determination Theory (SDT) was developed by Deci and Ryan (125). Three central concepts are thought to be necessary for a change of behaviour to occur. A person is felt to need a sense of competence, the ability to perform an action; autonomy, the free choice to perform an action and relatedness, a sense of social connection (125). It is felt that intrinsic motivation, (i.e. motivation that comes from a person's own beliefs and motives) is more likely to result in behavioural change than extrinsic motivation which originates from external factors such as others beliefs or needs (125). This model has been frequently used in exercise related research (117, 126). Elements of this theory can be found in the present RCT in terms of the provision of exercise related information, exercise demonstration and encouragement designed to support a mother's sense of competence. Discussion around what a mother wanted to gain from physical activity in terms of her intrinsic and extrinsic motivations, a core aspect of SDT, was also a feature of this RCT. However, two recent exercise interventions based on this theory did not prove

successful in reducing depression (126, 127), therefore the present intervention was not based on this theory.

The Theory of Planned Behaviour was devised by Ajzen and Fishbein in an attempt to predict deliberate behaviour (128). It is held that behaviour is determined by a person's intention to perform that specific action (a person's intention being a function of their attitude towards the behaviour), their subjective norm and their perceived behavioural control or sense of ability to perform the behaviour (128). A person's subjective norm incorporates their beliefs about how people they care about will view their behaviour (128). While the present intervention does seek to improve on mothers' sense of personal ability to perform exercise by the provision of information, encouragement and personal goal setting, modification of the subjective norm may not be an appropriate subject for such an intervention. Many mothers will not disclose that they have PND to their family members (124), therefore it may not be entirely clear how family members would view a mother exercising to improve the symptoms of PND. Mothers were, however, encouraged to seek out supportive elements in their social network in order to improve the practical and emotional support for their progress from contemplation to action and the maintenance of exercise (111, 129).

1.6 Summary of thesis

The overall aim of this thesis was to explore the effectiveness of exercise as a treatment for PND and mothers' views' of exercise in the treatment of PND. A number of research methodologies were employed to improve the evidence base in this field. Chapter one provides a description of the aetiology, epidemiology,

symptoms, treatment and consequences of PND for a mother and her family. The current evidence base regarding exercise, depression and PND is then discussed including the need for further research. Chapter two contains a description of the pilot testing of an accelerometer (the Actiheart) that was used as an objective measure of exercise in the research presented in chapter three. Chapter three provides a report of an RCT that evaluated an exercise counselling intervention in a clinically depressed postnatal population. Chapter four provides a detailed examination of the recruitment methods used during this RCT.

In chapter five, a description is provided of a qualitative study that explored mothers' beliefs regarding the acceptability of exercise in the treatment of PND and the mechanisms by which it was believed exercise provided psychological benefit. Chapter six reports the findings of a systematic review with meta-analysis of RCTs that investigated the effects of exercise interventions in postnatal populations, with psychological outcomes including depression and self-efficacy for exercise. Finally, in chapter seven, the overall conclusions formed from this body of research; its strengths and limitations; implications for the treatment of postnatal depression and recommendations for future research are discussed.

1.6.1 Research questions and hypotheses

1.6.1.1 Chapter two: Actiheart pilot study

Research question: What is the most effective method of using the Actiheart accelerometer within a female population?

Hypothesis: It was hypothesised that through this pilot work the most effective way of using the Actiheart, regarding both data accuracy and participant acceptability, would be determined.

1.6.1.2 Chapter three: A randomised controlled trial investigating the effectiveness of an exercise intervention in the treatment of PND

Research questions:

1. Is an exercise counselling intervention, in addition to usual care more effective than usual care alone in reducing the symptoms of postnatal depression?
2. Is an exercise counselling intervention, in addition to usual care more effective than usual care alone in improving health and well-being, subjective vitality, health related quality of life, body image, social support, self-efficacy for exercise, social support for exercise and level of exercise?

Hypothesis: It was hypothesised that there would be a significantly greater decrease in depressive symptoms in the exercise counselling intervention compared to the usual care comparator at follow up. It was also hypothesised that there would be significant improvements in the secondary outcomes listed in research question two (above) in the exercise counselling intervention compared to the usual care comparator at follow up.

1.6.1.3 Chapter four: Recruitment to a randomised controlled trial of exercise for PND

Research question: What effect did the various amendments made to the recruitment methods and other trial processes have on recruitment to the RCT?

Hypothesis: It was hypothesised that studying the appropriateness and effectiveness of different recruitment methods would be useful in the development of further research in this field.

1.6.1.4 Chapter five: Mothers' views and experiences of exercise as a treatment for postnatal depression: A qualitative study

Research question: What were mothers' views and experiences of exercise as a treatment for PND and what were mothers' reported beliefs regarding the mechanisms by which exercise may have provided psychological benefit?

Hypothesis: It was hypothesised that an exploration of mothers' views of exercise as a treatment for PND and the relationship between exercise, mood and other psychosocial factors such as self-efficacy and social support, would provide valuable insights as to the potential mechanisms by which exercise may confer psychological benefits for mothers with PND.

1.6.1.5 Chapter six: The effectiveness of exercise in reducing depressive symptoms and other psychological outcomes in postnatal women: a systematic review with meta-analysis

Research question: Does the evidence from the current body of RCTs indicate that exercise or physical activity interventions have a significant effect on psychological outcomes relevant to postnatal women, and in particular depressive symptoms?

Hypothesis: It was hypothesised that collectively, exercise interventions would have a significant effect in reducing depressive symptoms compared to comparators.

1.7 Conducting mixed methods research

As described above, this thesis uses a range of research methods to achieve its aim of exploring both the effectiveness and the experience of exercise as a treatment for postnatal depression. Different research methodologies are more appropriate to answer different types of research question.

The aim of the third chapter of this thesis was to investigate the effectiveness of exercise in the treatment of PND. The most appropriate way of investigating the effectiveness of a treatment in a clinical population is an RCT (130). Participants are randomised, reducing selection bias by distributing characteristics between the groups and balancing the known and unknown confounding factors. (130) A treatment can be compared directly to usual care and differences in effectiveness can be assessed via outcome measures and evaluated statistically (131). Validity is measured by the design of the trial including the method of randomisation, allocation concealment, blinding and analysis (131). Generalisability to the population in question is sought (131). The most methodologically robust way of combining and analysing data from a collection of studies providing evidence relating to one research question is through systematic review with meta-analysis (132). Such reviews enable the verification of individual study data, followed by a standardised analysis of common outcomes. This technique provides the most complete estimation of, for example, the effectiveness of a treatment for a condition (132). A systematic review with meta-analysis was therefore conducted to assess the effectiveness of exercise in the treatment of PND. However, it should be borne in

mind that quantitative methodologies have been criticised for not exploring the social and cultural construction of the outcomes under investigation (133).

The aim of a study may be to explore the human experience of a condition, a treatment, or a process. The purpose of such work may be, for example, to explore the lived experience of a treatment within the context of a person's social reality. To explore such a research question, qualitative methodologies are more appropriate (133). The aim of chapter five of this thesis was to explore mothers' views and experiences of exercise as a treatment for PND; a qualitative methodology was therefore chosen to answer this research question.

1.8 Ontology and epistemology

There are many theoretical lenses through which research can be pursued. These viewpoints reflect an individual's ontological and epistemological standpoints, that is, how one views the nature of the world and reality, and how one believes knowledge is acquired. Two predominant viewpoints are those of positivism and interpretivism, which to some degree represent opposite ends of a spectrum (134). Positivism is a school of thought believed to have originated with Descartes (134). It holds that there is only one objective reality. A hypothesis relating to this reality is posited and tested (134). A positivistic stance in research holds that the validity of a study lies in its generalisability or repeatability, if the same method is used the same 'truth' will be found (135). Positivism lends itself towards the quantitative investigation of clinical questions, such as those of treatment effectiveness, where a single truth or most accurate estimate of effectiveness is required (135). The RCT undertaken in chapter three and the systematic review in chapter six of this thesis

were therefore undertaken with a positivist viewpoint, following predetermined protocols in order to reduce subjectivity.

Qualitative research can be undertaken with a positivist or an interpretivist perspective (135). If undertaken with an outlook of positivism, it is believed that a certain distance must be kept between the researcher and the interviewee during the research process in order to limit the influence of the interviewer on the process (136). Positivism holds that there are natural patterns of cause and effect, the aim of such research is to identify the phenomena present (137). A defined protocol is followed to limit the influence of subjective bias (138). However, it has been suggested that the simplification required in such positivist experimental methods and the use of causal explanations in qualitative research is not useful in the understanding of human experience (135). Positivism has been criticised for applying theories to qualitative work that may be more appropriate to quantitative work (135). Positivism encourages the adoption of quantitative criteria such as the importance of attaining validity, which is adapted to qualitative work through the use of strict, prescriptive methodology (135). Overuse of quantification and hypothesis testing in qualitative research has also been criticized as a reliance on a quantitative security mechanism (139). Within these positivistic structures, an individual's experience of reality through the 'lifeworld' (the world of our everyday experiences) can be lost (139).

Contrasting to the positivist viewpoint is that of Interpretivism. In the interpretivist paradigm, there is not one true reality, reality is subjective and focus is placed on our experience of reality (140). If applied to qualitative research, emphasis

is not placed on maintaining an objective distance between the interviewer and interviewee as they are not considered to be separate, reality is experienced together (140). 'We live as if the world exists apart from us, but we only know it and understand it through our attempts to meaningfully interpret it', and those attempts at interpretation are in turn influenced by our temporal and cultural location' (140). Reality is seen to be co-produced between the interviewer and interviewee (135). The 'validity' of the findings is therefore not judged in terms of their reflection of an absolute reality, but of the reality experienced within a social context (135). However, interpretivism has been criticised for merely representing subjective opinion and therefore being unscientific (135).

I consider the qualitative work in this thesis to have been conducted with an interpretivist approach. In the context of qualitative research, whether there is in fact one true reality seems to be of secondary importance to the fact that we all experience reality filtered through our psychosocial context (140). The aim of chapter six of this thesis was to explore women's views and experiences of exercise as a treatment for PND. Mothers' experiences of exercise were therefore explored in the context of motherhood and PND. Mental health conditions such as PND with a mixed aetiology of family history, biochemical, psychological and psychosocial influences surely lend themselves more to exploration through an interpretivist paradigm. The experience of PND itself and of exercise was unique for every mother, as it was experienced within and influenced by the context of her own life, history and relationships. My own interpretation of the discussions between myself and interviewees was in turn influenced by the psychosocial context of my life. The

qualitative work presented within this thesis was therefore conducted within an interpretivist paradigm.

1.9 History of the doctoral researcher

This section is intended to clarify my professional history, its effect on my work as a researcher and my unique contribution to the studies in this thesis. After graduating from the University of Birmingham with a BMedSc Hons in Psychological Medicine, my first appointment within the University was as a research associate in the school of Sport and Exercise Science. My role was to project manage the EMPOWER Study (126), which evaluated an exercise on prescription programme, aimed at improving the physical and psychological well-being of sedentary people in Birmingham.

Following this post I was employed as a research associate in the Department of Public Health, Epidemiology and Biostatistics at the University of Birmingham. I was a member of the BEACHeS study team, who conducted a controlled trial designed to increase physical activity levels and dietary practices in primary school children (141). I was responsible for organising and conducting outcome follow up within inner-city primary schools. During the process of conducting my doctoral research I was a full time research associate and trial coordinator in the behavioural medicine research team at The University of Birmingham. I project managed the PAM-PerS trial, which evaluated the effectiveness of an exercise intervention as a treatment for postnatal depression. My role in this research is discussed below.

Whilst writing up my PhD, in June 2013, I was employed as a research fellow in the department of Neurotrauma and Neurodegeneration at the University of Birmingham, working within the research and charitable organisation Action on

Postpartum Psychosis (APP). It was my responsibility to manage a series of Lottery funded projects focusing on maternal mental health. These ranged from a peer support initiative for mothers recovering from postpartum psychosis (PP) to the development of informative literature created in collaboration with service users, academics and clinicians from the Universities of Birmingham and Cardiff. I was also responsible for designing the service evaluation of the peer support initiative. At APP it was my responsibility to manage staff and volunteers, providing guidance, reviewing work, running training events, representing APP at conferences including that of the Marcé Society and liaising with other research and charitable organisations.

In 2014, I became a research fellow within the prevention and detection theme of the CLAHRC West Midlands programme. My role includes the development and management of a variety of research projects related to behavioural medicine. I am the principal investigator of a study exploring the current provision of support services to tobacco smoking parents residing with children in paediatric intensive care, from which a smoking cessation intervention will be developed. I am in the process of developing a further trial relating to postnatal depression, this will be an international collaboration with colleagues in Canada.

1.9.1 Potential biases

Over the past decade my training and experience has encompassed a range of predominantly quantitative research methods in various fields of behavioural science. Much of this experience has been seen through a medical perspective, which is likely to have influenced my view of PND as a medical condition. However,

whilst much of my background and training have led me to view perinatal mental health in a medical light, my time at the charity APP reinforced the profound effect of perinatal mental illness on mothers, families and children. This experience may have driven my interest in mothers' experience of exercise and PND within the context of their own lives, including the relationship between exercise, PND and a mother's identity, which has been explored in the qualitative chapter of this thesis (Chapter five). For further consideration of the influence of my experiences on the course of the qualitative study conducted in this thesis, please see chapter five, section 5.1.4)

1.10 My contribution to this body of research

In 2009 I was employed as a research associate trial co-ordinator in Primary Care Clinical Sciences at the University of Birmingham and was offered the opportunity to complete a PhD whilst employed. The RCT presented in this thesis was conceived as part of my supervisor, Dr Amanda Daley's NIHR fellowship. I joined the research team at a point when some of the decisions regarding initial methodology, such as the recruitment procedures, the development of the intervention and the selection of outcomes measures had taken place. It was also pre-specified that there would be a nested qualitative study of some form within the trial, though the methodology for this component of the research had not been developed in detail. My initial role was to create participant literature, train and manage the research staff, recruit GP practices and participants and manage the RCT on a daily basis. I was responsible for the management of the trial and its research team between June 2009 and March 2013. During this time I designed and carried out the qualitative study. Following

this, I independently performed the analysis of the RCT and designed and conducted the systematic review and meta-analysis, with the advice of my supervisors. In the following section, my individual contributions to the research presented in this thesis and the contributions of the other members of the research team are described.

1.10.1 Chapter three: A randomised controlled trial investigating the effectiveness of an exercise intervention in the treatment of PND

Dr Daley was the principal investigator of the PAM-PeRS study, my role was that of the trial co-ordinator. Prior to the commencement of the trial I created participant literature, including the participant screening invitation letter (Appendix Figure 1), participant information sheet (Appendix Figure 2) and looking after yourself leaflet (Appendix Figure 3), which were edited by Dr Daley. In addition I created excel databases for patient tracking and oversaw the creation of the citrix randomisation and data storage database.

Following the creation of the participant literature and its ethical approval for use in this study, I conducted interviews with Dr Daley and Professor Jolly for the position of the physical activity facilitator (PAF). I then assisted with the training of the PAF according to the PAF manual created by Dr Daley. The study was provided with research facilitators from the primary care and mental health research networks to perform the participant screening visits. I created a proforma for and trained the research facilitators in conducting screening visits. In addition I trained the PAF and research facilitators and in dealing with situations involving the self-harm protocol (Appendix Figure 4).

During the recruitment phase of this research, it was my responsibility to coordinate the trial and ensure its adherence to the protocol. Dr Daley was on maternity leave during the initial year of recruitment, from April to November 2010, during which time I took on greater responsibility for steering and overseeing this research. Throughout the recruitment process my responsibilities included contacting, recruiting, training and arranging for the payment of all GP surgeries; liaising with the Child Health System and overseeing their provision of screening lists to GPs and participant information to the study populations. I also attended health visitor cluster meetings with Dr Daley, presented our study, discussed its aim and purpose, fielded queries and encouraged participation. I was in regular contact with the health visitor cluster leads and met with them on several occasions to discuss engagement with the study.

I contacted by telephone all participants who expressed an interest in the study, explaining what participation involved and conducting all second EPDS screening questionnaires via telephone. Research facilitators conducted the screening home visits and randomised the participants using a remote citrix database. The PAF provided the intervention through home visits and phone calls and also conducted some of the follow up visits. I arranged all home visits to participants by the research facilitators and PAF.

If at any point of contact or data collection, a mother expressed thoughts, plans or actions related to self-harm or suicide it was my responsibility to action the self-harm protocol (Appendix Figure 4). This process involved discussing a mother's thoughts with her, determining whether there was any immediate risk of harm to

the mother or child, encouraging her to discuss her thoughts with her GP and gaining her agreement for me to contact her GP regarding our discussion.

During the recruitment phase of the trial, I was part of the study management group making decisions regarding changes to the study protocol in response to the challenging recruitment rate. In response I made alterations to the study processes and the participant literature, in collaboration with Dr Daley. During and after the completion of data collection I conducted data entry. I devised an analysis plan with advice from a departmental statistician. I then conducted the analysis from the raw data extracted from the citrix database. This analysis was conducted entirely separately from the published analysis of the trial. (See Appendix Figure 5.)

1.10.2 Chapter two: Actiheart pilot study

I recruited participants for and conducted the Actiheart pilot trial prior to the use of Actiheart in the main RCT. The choice of the Actiheart as an objective measure of exercise was made by Dr Daley prior to my involvement in the trial. I conducted the pilot testing of the Actiheart to assess the practical implications of using the device, with the aim of establishing the optimum method of usage regarding data accuracy and participant acceptability.

During the main trial I independently prepared all data from the Actiheart devices. I examined each individual recording in numeric and graphic form, searching for inaccuracies affecting the analysis of the data. The preparation of the Actiheart data is described in chapter three, section 3.3.22.3. During this process I was in regular contact with Dr Kate Westgate, a specialist in the analysis of Actiheart data from Cambridge University. Once I had fully prepared the data and informed Dr

Westgate of the outputs required, she processed it through an algorithm designed at Cambridge University, I then performed the quantitative analysis of the data outputs as detailed in section 3.3.22.3.

1.10.3 Chapter four: Recruitment to a randomised controlled trial of exercise for PND

Following the trial, I initiated, developed and composed the recruitment methods chapter to examine the difficulties experienced in recruitment to the RCT. The decisions made regarding the many changes to recruitment and trial methodology were made between myself, my supervisors and our trial management group. A patient representative who had experienced PND provided guidance and reviewed the changes made to the participant literature during the trial. (See chapter four, section 4.3.4 for further details)

1.10.4 Chapter five: Mothers' views and experiences of exercise as a treatment for postnatal depression: A qualitative study

A nested qualitative study to explore mothers' experience of exercise as a treatment for PND was part of the original application for the RCT. The interview schedule was devised in collaboration with Dr Katrina Turner from Bristol University and was influenced by an interview schedule devised for a previous qualitative study nested within a postnatal depression trial for which Dr Turner was an author (26). The interview schedule was adapted to explore the experience of an exercise intervention in mothers with PND (for further details see chapter five, section 5.2.5). I conducted all interviews, coded all transcripts and created a coding framework. The initial transcripts were also read and coded by Dr Turner and discussion held

regarding the coding framework. I uploaded the data to NVIVO and created the matrix, summarizing the data in each code. I then performed the analysis, including comparison within the data by characteristics such as RCT study group and severity of depression.

1.10.5 Chapter six: The effectiveness of exercise in reducing depressive symptoms and other psychological outcomes in postnatal women: a systematic review with meta-analysis

The idea for this review was developed by myself, in conjunction with my supervisors. I determined the methodology, outcomes and analysis plan of the review in discussion with my supervisors. I conducted the searches, read all titles, abstracts, full text, references and bibliographies and assessed eligibility using pre-specified criteria determined in conjunction with my supervisors. My supervisors also reviewed the literature as above to safeguard against missing potentially eligible papers and to allow for discussion of any differing decisions. I extracted the data and assessed studies risk of bias using the Cochrane criteria (142). Risk of bias assessments were, again, also performed by my supervisors to allow for discussion of discrepancies. I contacted authors for clarification/additional information. I performed the main, subgroup and sensitivity analyses and presented the findings.

1.11 Summary

This background section has provided discussion of the previous research and rationale for the research included in this thesis, as well as my professional history and unique contribution to this body of work. In the following chapters, each study will now be discussed individually.

CHAPTER TWO

2. ACTIHEART PILOT STUDY

2.1 Introduction

One of the three principal studies included in this thesis was an RCT designed to investigate whether an exercise counselling intervention could improve the symptoms of postnatal depression. A description of this RCT is provided in chapter three. In order to determine whether the intervention of this RCT was successful in encouraging exercise, a secondary outcome of the trial was the difference in exercise levels between the intervention and comparator groups at follow up. The objective measure selected to record activity in the participants of this trial was the Actiheart accelerometer, the use of which was specified in the funding application for the trial. The present chapter provides a report of the preparatory work undertaken with the Actiheart prior to the RCT. The aim of this work was to determine the most appropriate way of using the Actiheart in a female population, with regard to the acceptability of its use and the accuracy of the data collected. This preparatory work also provided an opportunity for myself and other researchers in the team to familiarise ourselves with the methods of use that were selected.

2.2 Background

A variety of subjective and objective measures of physical activity are commonly used in trials. Recent studies of physical activity and exercise in depressed postnatal populations have used predominantly self-reported questionnaires (13, 14, 18, 19) or exercise diaries (11, 15). Frequently used questionnaires across a range of

populations include the Seven Day Physical Activity Recall Questionnaire (7 day PAR) (143), the International Physical Activity Questionnaire (IPAQ) (144) and the Godin Leisure time Questionnaire (145). Such instruments allow the duration and estimated intensity of exercise to be recorded. Some measures also record the context in which the physical activity took place, such as activity related to work, recreation, housework etc. (145). Self-reported questionnaires have certain advantages, they are quick and convenient as they are completed at a discrete point and do not necessitate wearing a device over a period of time, as is required for objective measurement. Self-reported measures also allow the collection of data from a large number of people at comparatively low cost (146). However, self-reported measures also have significant disadvantages. As the record is subjective, such measures are prone to recall bias (100), although daily exercise diaries may be less affected by recall bias than questionnaires completed on a weekly basis. It has been found that moderate to vigorous physical activity (MVPA) is consistently overestimated on self-reported exercise questionnaires (147, 148). This inaccuracy has been postulated to originate from either an overestimation of overall activity, or a misunderstanding of what constitutes the different intensities of exercise (147). Participants may be categorising light activity as moderate or vigorous activity, this may be due to the examples provided on such questionnaires, for example doubles tennis and digging (144), which not all participants will be able to use as reference activities; or misinterpretation of the physiological markers of moderate exercise which are described, such as an increase in heart rate or sweating (147).

Objective measures of physical activity offer many advantages over subjective methods. Principally, they are not subject to recall bias or misinterpretation of the intensity of exercise by the participant. The decision was taken to measure physical activity using both subjective measures (the IPAQ (144)) and objective measures in this RCT.

2.2.1 Objective physical activity measurement

Devices such as pedometers offer a more consistent record of activity than subjective questionnaires, whilst more advanced accelerometers can provide a more scientific estimation of exercise intensity through acceleration and therefore energy expenditure (149). Accelerometers are particularly effective in free living settings as they record all activity, whether structured leisure time exercise, work or household related activity (149). As the intervention of the RCT in this thesis was designed to encourage exercise participation within daily life, accelerometers were considered the most appropriate method of objective measurement. Of the accelerometers available at the start of this study, the Actiheart device was selected. Actihearts have the advantage of being wearable during sleep and in water, making 24 hour data collection possible (150). At the point of conducting this RCT it was not advisable to wear waist mounted accelerometers such as the Actigraph and ActivPAL during sleep or when in water (151-153). More recently, waterproof wrist worn accelerometers have been developed such as the GENEactive (154), however these were not available during the planning stages of this RCT. Prior to conducting the RCT in this thesis, Actihearts had the unique advantage of recording both accelerometry and heart rate data, which, when combined with the participants BMI, provided a more

accurate estimate of exercise intensity than the accelerometry data provided by waist mounted accelerometers such as the Actigraph and ActivPAL (151, 152, 155). The Actiheart device has been found to have acceptable reliability and validity in adult populations (155) and specifically in female pregnant populations (156). Within the University department there was also prior experience of successful use of the Actiheart in children. For these reasons the Actiheart device was considered the most suitable tool for the objective measurement of exercise in the RCT presented in chapter three.

2.2.2 Study population

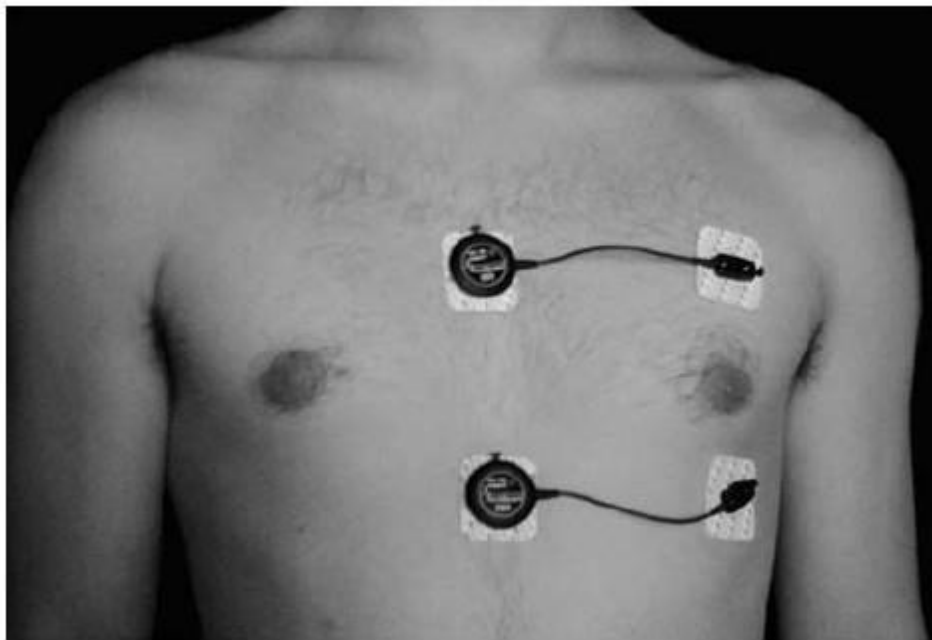
Prior to the commencement of the RCT in this thesis, Actiheart had not been used in any published studies in postnatal populations. The risks, benefits and limitations in this population were therefore unknown and there was no expectation that the validity of the data would be differentially affected by a postnatal population. In view of the lack of indication for differential use in postnatal women, a female population was selected for this preparatory work. In retrospect, use of a female postnatal population would have provided a more appropriate representation of the acceptability of the device to the population of the main RCT.

2.2.3 Actiheart feasibility

It is important to note that some issues with compliance have been reported in research using Actiheart (149). Case reports have provided evidence of skin reactions to elements of the gel and metal components of the adhesive electrodes used to attach Actiheart to the skin (157-160). Actiheart are worn on the chest between vertebra (V)1 and V2 (above the breasts) or V4 and V5 (below the breasts)

(Figure 6) (161), such positions have been reported to be inconvenient in populations of female pregnant women due to enlargement of the breasts and abdominal area (156). This was an indication that the position of the Actiheart could also be problematic in the postnatal population, as enlargement of the breasts and to a lesser extent the abdominal area would still be seen.

Figure 6: Positioning of the Actiheart



At the time the present research was conducted, only ten published studies had used Actihearts as an objective measure of exercise (155, 162-170). Of these ten studies, five had populations of children or adolescents (166-170); of the remaining five whose populations were adult (both male and female) (155, 162-165), only one investigated the acceptability of the device to the participants. Moy et al. reported a mean level of comfort of 7.3 out of a maximum score of 10 (SD 2.4) amongst the 10 men and seven women who wore the device (162). Minor skin reactions to the electrodes were reported by one man and one woman (162). The suitability of

Actiheart within an adult female population was therefore relatively unknown.

Given the reported acceptability issues with wearing the Actiheart and the potential problems specific to perinatal women, it was considered advisable to conduct some initial pilot testing before their use in the RCT reported in this thesis (149).

2.3 Aim

The aim of this pilot study was to assess the feasibility and acceptability of the Actiheart device in measuring physical activity in a female population. Particular reference was made to exploring any practical issues related to wearing the device that would need to be considered prior to the RCT and the quality of data obtained relative to the position of the Actiheart on the chest.

2.3.1 The Actiheart device

Actiheart records heart rate and acceleration and can be calibrated to the individual or to a group. Once the data are combined and cleaned, an advanced algorithm is used to produce the following outputs: Resting Energy Expenditure (REE), Activity Energy Expenditure (AEE), Dietary Induced Thermogenesis (DIT), Total Energy Expenditure ($TEE = REE + AEE + DIT$) and Physical Activity Level ($PAL = TEE / REE$) (150).

These data can also be used to calculate energy expenditure in metabolic equivalent tasks (METs) to give an indication of the intensity of activity. The MET level is the ratio of the energy expenditure during a particular activity compared to that during rest (171).

2.3.2 Actiheart settings

Actiheart can be programmed to record data in a variety of settings. These settings determine the epoch (recording interval) and the maximum potential length of the recording. For recording activity and heart rate, there are short or long term modes. The long term mode was used in the present research as it allows for the recording of data every 15, 30 or 60 seconds, with a maximum recording length of 21 days (the shorter the epoch the shorter the maximum recording length) (161). For recording energy expenditure, Actiheart can either be set up in 'Daily Energy Expenditure' with a fixed 60 second epoch and a maximum recording length of 21 days or 'Advanced Energy Expenditure', which can have an epoch of 15, 30, or 60 seconds and a recording length of 96 hours to 21 days depending on epoch (161). Daily Energy Expenditure is recommended for studies involving free living conditions, as a 60 second epoch is thought to provide sufficiently accurate data while allowing for recording over a significant period of time (161). Actiheart were therefore programmed in the Daily Energy Expenditure setting for this pilot study, as they were in the main RCT.

2.4 Methods

A total of ten women from a department within a University were recruited to the pilot study; none of the participants had previously worn an Actiheart. Each participant was asked to wear the device twice, once above the breast and once below the breast, for two days in each position. If worn above the breast electrodes were fitted between V1 and V2, with the larger sensor placed centrally on the chest and the smaller one to the left. If worn below the breast the electrodes were fitted

at V4 or V5 (161). Prior to fitting the electrodes the skin was prepared by washing the relevant areas with soap and water to clean the skin and remove oils. An abrasive pad was then rubbed on these areas to remove the top layer of skin, improving the electrical contact between skin and electrode (172). The central electrode was fitted first and the Actiheart itself used to position the smaller electrode. The smaller electrode was fitted on the same horizontal plane as the larger one to enable the accurate detection of motion along a vertical axis (161). The electrodes were positioned such that the wire connecting them was not tight, as this could result in sudden pulling of the sensors and subsequent interference in the data recorded.

A multimeter (a device measuring electrical resistance) was used to measure the resistance across the electrodes worn by each participant. The level of resistance gives an indication of the degree of contact between the electrode and the skin and therefore the probability of obtaining high quality data. After each session wearing the Actiheart participants were asked for their feedback on the following issues; how comfortable the Actiheart was to wear and sleep in; the presence of any pain or irritation originating from the electrodes and the visibility of the Actiheart. Participants were also asked for their preference regarding the positioning of the device above or below the breast.

2.4.1 Analysis

The quality of the data was analysed in terms of the percentage of data that were acceptable, lost (not recorded), recovered (erroneous heart rate values are set to 0, heart rate is then estimated from previous heart rate values) and interpolated

(erroneous values still present after recovery are estimated by joining a straight line between adjacent known heart rate values). The proportion of data in each of the above categories was reported for the overall dataset and for data recorded above and below the breast; due to the skewed distribution of the data a Mann Whitney U Test was used to determine whether these proportions were significantly different. Mann Whitney U Tests were also be used to determine whether there was a significant difference in the distribution of resistance across the electrodes fitted above and below the breast.

2.5 Results

Eight participants wore the Actiheart above and below the breast, a further two wore it above the breast only. This provided 10 recordings from above and eight from below the breast. A similar, high proportion of data recorded in both positions was acceptable. A similar proportion of data (18%-22%) was recovered from the two positions, with very little data being interpolated (Table 1). There were no significant differences in the proportions of acceptable, lost, recovered and interpolated data between the two fitted positions of the Actihearts (Table 2). There was no significant difference in the mean resistance across the electrodes when positioned above or below the breast (Table 3).

Table 1: Proportion of acceptable, lost, recovered and interpolated data

	N (%) of data points recorded (n=18)			
Position	Acceptable data	Lost data	Recovered data	Interpolated data
All data	1675.8 (73.5)	113.8 (5.3)	519.1 (20.3)	41.1 (1.8)
Above	1874.3 (72.2)	136.5 (5.47)	608.8 (22.1)	51.9 (1.8)
Below	1427.8 (75.1)	86.0 (5.0)	406.9 (18.2)	27.6 (1.7)

Table 2: Data quality (Mann Whitney U Test)

Data quality	Position	Mean % (SD) of data (n=18)	Significance (two tailed)
Acceptable data	Above	72.2 (27.8)	0.93
	Below	75.1 (20.1)	
Lost data	Above	5.5 (8.2)	0.42
	Below	5.0 (3.8)	
Recovered data	Above	22.1 (22.1)	0.59
	Below	18.2 (17)	
Interpolated data	Above	1.8 (1.9)	0.72
	Below	1.7 (2.3)	

Table 3: Resistance across electrodes (Mann Whitney U Test)

Position	Mean (SD) resistance across electrodes K Ohms	Significance (two tailed)
Above	15.9 (29.8)	0.37
Below	4.8 (7.3)	

ECG: Electrocardiography

2.5.1 Participant feedback

2.5.1.1 *Participant preferences*

Of those who provided feedback after wearing the Actiheart in both positions (n=8), five women expressed a preference for wearing it above the breast and two below; one expressed no preference. Two participants did not wear the Actiheart in both positions as they were unwilling to wear it a second time; one did not wish to use the emery board again to prepare the skin, one experienced a technical fault in the representation of their heart rate data which caused concern and a reluctance to wear the device a second time.

2.5.1.2 *Comfort*

The majority of those wearing the device above the breast reported this to be comfortable (6/10), with a slightly smaller proportion finding wearing the device below the breast comfortable (4/8). Conversely four out of eight women wearing the device below the breast reported this to be uncomfortable, with only one of the ten women who wore it above the breast reporting it to be uncomfortable when initially fitted. Problems reported from wearing the device above the breast included discomfort due to the position of cleavage (1/10) and the electrode to the left of the torso interfering with self-cleaning (1/10). Below the breast, women with abdominal fat reported discomfort due to their abdomen pushing against the device or pushing the device against the underside of the bra (3/8). Similar proportions of women reported the Actiheart to be comfortable above and below the breast during sleep (6/10 above, 5/8 below).

2.5.1.3 *Electrodes*

More women reported that the electrodes were itchy when worn above the breast (7/10) rather than below (3/8). A number of women reported that the electrodes were painful to remove both above (3/10) and below (1/8) the breast, with three out of ten reporting sore skin or red marks after removal from above the breast and three out of eight from below. As a result one woman who wore the device below the breast was unwilling to wear it again.

2.5.1.4 *Practicalities*

When worn above the breast, the Actiheart was often visible or partially visible, with five out of ten women reporting that this bothered them a little. One mother, who was breastfeeding while wearing the Actiheart above the breast, found that her baby pulled at the device, which was uncomfortable. One mother wearing it below also expressed concerns about breastfeeding while wearing the device.

2.6 Discussion

2.6.1 Quality of data

The quality of the data from this pilot was generally good, with a mean of 73.5% of data classed as acceptable and approximately 5% lost. There were no significant differences in quality between data recorded above and below the breast. In view of the proportion of acceptable data obtained in this pilot (72.2% -75.1% depending on position), a cut-off point of 60% acceptable data per reading was decided to be appropriate for the main trial, below which a recording would not be included in the analysis.

2.6.2 Resistance

No significant difference in mean resistance was found between the two positions the Actiheart was fitted in. One moderately high reading of 97.5 K Ohms was recorded above the breast, indicating possible poor fitting of the Actiheart or insufficient skin preparation. If this outlying reading was discounted, the mean resistance levels above the breast of 6.8 (8.4) k Ohms and below the breast of 4.75 (7.3) K Ohms would be considered low enough to provide accurate ECG readings in clinical practice (172, 173). In view of these similar, low levels of resistance it would seem unnecessary to take up time using a multimeter during consultations in the RCT.

2.6.3 Feedback from participants and subsequent modifications made to methods

More participants expressed a preference for wearing the Actiheart above the breast than below. In some women, contact between the central electrode and the skin above the breast was disrupted by the movement and the position of cleavage. This could easily be avoided by placing the electrode slightly higher on the chest. On slim women the position of the left electrode was necessarily nearer the under arm, which had the potential to cause inconvenience, but this issue was less problematic in average or larger sized women.

Two significant problems arose when women wore the electrodes below the breast. Firstly, the central section of the Actiheart often rubbed against the underside of the bra. Secondly, in larger women the movement of fat and the presence of sweat in the abdominal area sometimes caused the electrode to adhere

poorly to the skin, causing a loss of contact between skin and electrode, with two Actihearts becoming detached. These issues might be particularly challenging in postnatal women who are breastfeeding.

Participants experienced itching whilst wearing the electrodes during 10 out of 18 sessions, especially when applied after the skin preparation. In view of the quality of the data (indicating good contact between electrode and skin) and the skin reaction issues, it was decided not to perform skin abrasion prior to applying the Actihearts. Some participants reported that the areas under the electrodes became itchy after a few days of wear. This indicated that if worn for more than two to three days, electrodes may have needed to be replaced. In the main RCT we therefore advised participants to keep the Actiheart on whenever possible but provided spare electrodes in case a change was necessary. Pain when removing the electrodes was experienced by participants after four out of 18 sessions and skin was sometimes red following electrode removal (6/18 sessions). On this basis participants in the RCT were recommend to apply moisturising cream to any sore areas after Actiheart removal.

As a result of this pilot it was clear that an Actiheart, if fitted in either position, had the potential to be inconvenient to a mother if she was breastfeeding during the RCT. If this was raised by a mother, they were advised that wearing something to cover the Actiheart so the baby was not attracted to it (and did not try to pull at it) might be helpful. If this was not possible, women were advised to remove the Actiheart while breastfeeding and replace it afterwards with new electrodes.

2.6.3.1 *Consideration of alternative objective measures*

The use of ActiHearts was specified in the funding application for the main RCT. This decision was based both on the significant advantage in data accuracy afforded by their ability to estimate energy expenditure using accelerometry and heart rate data (155), and their previous successful use in another trial within the department (141). In light of the skin sensitivity issues raised in this preparatory work and the potential for such factors to negatively affect retention to the study, it is possible that other accelerometers may have been more suitable. Waist worn accelerometers such as the Actigraph and ActivPAL (151, 152) may have provided a less accurate assessment of energy expenditure but as they are not attached to the skin using electrodes, they may have been more acceptable to the population. The cost of the ActiHearts prohibited purchasing alternative devices prior to, or during the RCT. An alternative strategy may have been to loan the ActiHearts in order to conduct the pilot test, we would then have been able to reconsider the decision to use them in the main trial after the findings of the pilot.

2.7 **Conclusions**

During this preparatory work, no difference in data quality was found when wearing the ActiHearts above and below the breast. The decision as to where to fit ActiHearts in postnatal women was therefore based on practical factors and the preferences of women themselves. More participants preferred wearing the ActiHeart above the breast than below. Considering the RCT study population of postnatal women, the problems experienced regarding poor adherence of the electrodes below the breast due to abdominal fat and sweat were likely to be the most pertinent issues and not

easily avoidable. Participants of the RCT were therefore advised to wear the Actiheart above the breast unless they expressed concerns about its visibility, in which case they were given the option having it fitted below the breast.

CHAPTER THREE

3. A RANDOMISED CONTROLLED TRIAL TO INVESTIGATE THE EFFECTIVENESS OF AN EXERCISE INTERVENTION IN THE TREATMENT OF POSTNATAL DEPRESSION

3.1 Introduction

In chapter one of this thesis, the academic background of this research was discussed including the definitions, symptomatology, aetiology and epidemiology of postnatal depression. The current evidence base for the use of exercise in the treatment of depression in general adult populations, postnatal populations and postnatal women at risk of depression was described. As previously noted, the most recent systematic review of exercise and PND found that exercise may be an effective treatment for PND (101). However, the evidence base in this field was found to be small, with only five published RCTs (11, 13-15, 80) encompassing a total study population of 238 participants. It was concluded that larger studies with sufficient post-intervention follow up conducted in clinically depressed populations were necessary. From studying the research postdating this review, it became evident that further research of high methodological quality was required. In particular, studies using objective measures of physical activity and a wide range of psychological outcome measures would be beneficial to the evidence in the field of exercise and PND. An RCT was therefore conducted to investigate the effectiveness of exercise as a treatment for PND and is reported in the present chapter.

3.2 Background

There is a substantial body of evidence suggesting the effectiveness of exercise in reducing depressive symptoms in the general population (28). A recent Cochrane review of 35 trials (1356 participants) comparing exercise interventions with control or no treatment groups found a moderate effect size (SMD) for depression of -0.62 (95% CI: -0.81 to -0.42) (28). Exercise is currently also recommended to depressed mothers in the postnatal period by NICE (4) and the American Psychological Association (174). These guidelines are, however, based on a limited number of trials with non-clinical populations (a diagnosis of depression not being required).

Research into the benefits of exercise for depression in the general population has suggested a range of other psychosocial factors that may be beneficially affected by exercise. These factors have been explored as secondary outcomes in this RCT. Discussion around the selection of secondary outcomes is provided below.

3.2.1 Quality of life

A systematic review conducted by Rosenbaum et al. evaluated exercise interventions in populations diagnosed with mental health conditions including depression and schizophrenia (175). Overall, exercise interventions were found to have a significant effect on reducing depression and improving quality of life. Quality of life and well-being outcomes had not been studied in trials of exercise for PND at the time this study was conducted; the potential for exercise to influence these outcomes was therefore explored in this study.

3.2.2 Vitality

Subjective vitality is a measure of a person's feelings of energy and aliveness (176). The research of Ryan and Frederick has explored the nature of subjective vitality and its relationship to psychological well-being and somatic factors such as perceived body functioning (176). Subjective vitality has been found to be associated with self-motivation and maintained weight loss among patients treated for obesity, suggesting it may be a pertinent outcome to consider in a study promoting self-motivation for exercise and long term exercise maintenance (176). Exercise interventions designed to improve depression have also been found to improve vitality (177-179), this outcome was therefore studied in the present RCT.

3.2.3 Body image

Higher levels of depression have been found to be associated with negative aspects of body image such as 'feeling fat', with lower levels of depression being associated with positive aspects of body image such as feelings of attractiveness, strength and fitness (180). The association between depression and body dissatisfaction has been found to be greater in the postnatal period than during pregnancy (180). Body image was therefore felt to be an important outcome to study in a postnatal exercise intervention, which has the potential to alter body shape and therefore affect body image.

3.2.4 Social support and Social support for exercise

Social isolation and a lack of social support are known to be associated with an increased risk of postnatal depression (36). It has been suggested that social support may have an important role in the success of an exercise intervention for postnatal

mothers, in both practical and psychological terms (181). The role of social support has been previously explored within postnatal exercise RCT's. In 2004, Armstrong et al. explored the comparative effects of a group exercise intervention and a group social support intervention (80). Improvements in depression symptoms were reported in both intervention arms compared to the usual care group, with the improvement in the group exercise arm being significantly greater than the social support only arm, suggesting that interventions combining both exercise and the social support provided through a group context may be effective in treating PND (80). However, despite the improvements in depression, the authors reported no significant improvements in social support in either arm; the high baseline levels of social support perhaps creating a ceiling effect (80). The relative role of exercise and social support in postnatal exercise interventions therefore remains unclear. The present study was designed to encourage mothers to improve their use of their social networks and seek support to enable them to exercise; both social support and social support for exercise were therefore considered important outcomes to study in this trial.

3.2.5 Exercise and self-efficacy for exercise

The duration and intensity of exercise performed by mothers in this study was assessed using objective and subjective methods as it was the principal element of the intervention. Self-efficacy for exercise was also assessed. Self-efficacy is defined as the belief in one's ability to perform a specific behaviour, here, exercise (75). It is thought that self-efficacy influences whether a behaviour is likely to be initiated, the degree of effort expended on it, and its long term maintenance if barriers to the

behaviour occur (75). The intervention of the present RCT was designed to support self-efficacy for exercise, initially by providing information and instruction on how to perform exercises chosen by the mother; encouraging the mother to believe that she could successfully exercise and discouraging self-doubt, followed by reviewing and praising achievement and discussion to aid overcoming barriers to exercise. A pilot trial of postnatal exercise by Daley et al. reported a significant improvement in self-efficacy for exercise in the exercise intervention compared to the usual care comparator; no significant difference in depression was reported, however this was a pilot trial not powered to detect a difference in depression (14). Mothers' self-efficacy for exercise was therefore studied as a secondary outcome in this RCT.

3.2.6 Rationale for the present RCT

Due to the potentially harmful effects of taking antidepressants in the postnatal period, especially while breastfeeding (4), there is a reluctance amongst mothers to take them (182). It is also acknowledged that the limited availability of alternative treatments such as psychological therapies presents a significant barrier to their effective usage (4). Exercise, in its simplest forms such as brisk walking is freely available and without the risks attached to antidepressant medication; it may therefore present a feasible alternative to other current treatments for postnatal depression.

3.2.7 Study aim

Prior to this RCT, there was a limited body of evidence relating to the use of exercise as a treatment for PND (11, 13-15, 80). However, a recent systematic review by Daley et al. has suggested that exercise may be an effective intervention for PND

(101). The aim of this RCT was to investigate the effectiveness of an exercise counselling intervention in reducing the symptoms of PND. Due to the lack of evidence regarding exercise in this population, it was felt to be unethical to withhold usual care; therefore exercise was investigated as an adjunctive treatment to usual care. (The contribution of all researchers involved, including my unique contribution to this study are detailed in chapter one, section 1.10.1.)

3.2.7.1 *Research questions*

1. Is an exercise counselling intervention, in addition to usual care more effective than usual care alone in reducing the symptoms of postnatal depression?
2. Is an exercise counselling intervention, in addition to usual care more effective than usual care alone in improving health and well-being, subjective vitality, health related quality of life, body image, social support, self-efficacy for exercise, social support for exercise and level of exercise?

3.2.7.2 *Hypothesis*

It was hypothesised that there would be a significantly greater decrease in depressive symptoms in the exercise counselling intervention compared to the usual care comparator at follow up. It was also hypothesised that there would be significant improvements in the secondary outcomes listed in research question two (above) in the exercise counselling intervention compared to the usual care comparator at follow up.

3.3 **Methods**

This study was a two arm RCT with randomisation to either usual care, or usual care and an exercise counselling intervention. The development of the exercise counselling intervention is discussed below.

3.3.1 **The theoretical framework underpinning the intervention**

As discussed in chapter 1, section 1.5, the use of behavioural change theory in exercise interventions for PND is still at a very early stage and indications of the relative benefits of different models are unclear (14, 18, 102). With only one trial in this field published with an author defined theoretical basis at the start of this thesis (14), the RCT reported in this thesis was based on evidence from the wider field of exercise interventions in non-depressed populations. The finding that interventions influenced by a combination of the Transtheoretical Model (110, 111) and Social Cognitive Theory (112, 113) could be effective in increasing physical activity in populations in developed countries led to the selection of these theories as a basis for the intervention in this RCT (116). A discussion of the integration of these theories into the intervention presented in this chapter is now provided.

3.3.1.1 ***The Transtheoretical Model of change***

The Transtheoretical Model of change developed by Prochaska and DiClemente (110, 111) seeks to define the psychological stages a person progresses through when affecting change. The model was developed through work in the field of smoking cessation. The five stages described in the Transtheoretical Model are: Precontemplation, Contemplation, Action, Maintenance and Relapse. There are 10 processes of change that occur to differing degrees during each of these stages. This

study was constructed to support these processes of change including consciousness-raising, self-re-evaluation and the pursuit of helping relationships (110, 111). It has been found that a person contemplating change may use consciousness-raising to gather information relevant to the change (129). The intervention of this study was designed to support consciousness-raising by the provision of educational materials relating to postnatal exercise and appropriate local exercise opportunities. Education has been found to be one element of successful exercise interventions for PND (15, 19, 102, 103).

The process of self-re-evaluating has been found to take place during successful behavioural change (129). Such self-re-evaluation will involve a person considering how their current behaviour affects their perception of themselves, (110) which may prompt actual changes in behaviour. The process of self-re-evaluation was thought to be particularly relevant to an intervention for mothers with PND, as there are several influences that may have a detrimental effect on a woman's identity at this time. The postnatal period involves major life changes and a mother's sense of personal identity can be affected by this abrupt shift in focus and role (119, 120). Changes in a mother's body image at this time have also been reported to alter a woman's sense of self (9). Suffering depression may also affect a person's sense of their identity (121). The intervention of this study was therefore based on supporting this self-re-evaluation by encouraging mothers to define and successfully achieve their own exercise goals. Belief in one's ability to achieve a desired goal, or self-efficacy is thought to have a positive influence on depression (74). Mothers were also encouraged to consider their social network and seek the

support of helping relationships that could nurture their attempts to become more physically active. Social support is thought to be an important element of psychosocial interventions for perinatal depression (183).

3.3.1.2 *Social Cognitive Theory*

The intervention was also designed with the concepts of Social Cognitive Theory in mind (113). Social Cognitive Theory relates to how individuals acquire and maintain behaviours (113). The theory states that our adoption of a behaviour will be influenced by our environment, the people within our social environment, the behaviours of those people and the way these three factors interact with each other. A key concept in Social Cognitive Theory is that of observational learning; learning by imitating the behaviour of others. For many, childbirth can be an isolating experience, with a loss of contact with friends and colleagues. Mothers with PND may isolate themselves further through fear of the judgement of friends and family (122). Therefore, for both practical and psychological reasons mothers may not feel able to seek out opportunities in which to observe the exercise related behaviour of others in contexts such as the gym or exercise groups. During this intervention, mothers were invited, if they wished, to go for a walk and talk with the Physical activity facilitator. This was designed to provide an example of suitable exercise behaviour which could be imitated and repeated by mothers on future occasions. In addition to modelling this intervention around the principles of the behavioural change theories described above, specific behavioural change techniques were used to encourage adoption of new physical activity behaviours. These behavioural change techniques are discussed below.

3.3.2 Behavioural change techniques within the intervention

The intervention was designed to engage mothers in discussing their current emotional and psychological context and what they would like to achieve from exercise in order to modify their situation. A series of cognitive behavioural change techniques were utilised to facilitate self-modification of exercise behaviours. The following behavioural change techniques have been categorised by Michie and Johnston in their taxonomy of behavioural change techniques to promote change in physical activity and eating behaviours (184). (Appendix Figure 6)

To increase mother's knowledge and understanding of the aim of the intervention, they were initially presented with the potential mood related benefits of exercise for women in the postnatal period and the negative consequences of remaining inactive. Mothers were then encouraged to consider their motivation for exercise. There are many potential physical and psychological barriers to exercise for mothers with PND, mothers were therefore encouraged to consider ways of overcoming these barriers through problem solving. This process was of particular importance in facilitating the initiation of exercise. Restructuring of the participant's physical environment was explored if, for example, they wished to create an exercise environment at home. Mothers were also encouraged to restructure their social environment by seeking social support within their network of family and friends. This support may have involved seeking informal childcare, support from a partner to exercise together, a friend accompanying the mother to the gym or encouragement of exercise from supportive friends or family.

Goal setting was performed at each contact between the participant and PAF. Mothers were encouraged to define their exercise objectives, making them specific, measurable, action-orientated, realistic and timed. The importance of a goal being realistic was stressed in order to avoid the experience of 'false hope syndrome' as described by Polivy and Herman, in which unrealistic expectations result in a loss of control and the eventual failure of the attempted behavioural change (185). Guidance on how to perform exercise behaviours was provided; appropriate duration and intensity were discussed including the indicators of moderate exercise. Demonstration of moderate exercise in the form of a walk with the PAF was provided if desired. The use of graded tasks encouraged progression from the goal of 30 minutes of moderate exercise three times a week in the initial weeks of the intervention, to 30 minutes five times a week in the later stages.

Self-monitoring was encouraged with the provision of exercise diaries relating exercise and mood (Appendix Figure 7), and pedometers. Feedback on exercise behaviours was provided by the PAF. Exercise goals were reviewed including possible reasons for changes that had or had not been successfully made. New goals were set in light of how a mother was progressing. The mood related consequences of the behavioural change were discussed at each meeting between the PAF and mother. Encouragement was provided by the PAF, who was supportive of mothers' attempts to be active, whether goals were achieved or not. Participants were encouraged to self-monitor their own exercise and associated mood related progress using an exercise diary.

In the initial stages of the intervention mothers were provided with two face to face sessions in their home with the PAF. This contact was reduced to two shorter

sessions delivered via phone in the later stages of the intervention, followed by phone contact only if initiated by the participant. Fading of support was used in conjunction with advice on maintenance of exercise behaviours to encourage long term adherence to behavioural change.

3.3.2.2 *Motivational interviewing*

Motivational interviewing (MI) is communication style that was devised for work between health professionals and patient with addiction issues. MI has been defined as ‘A directive, client-centred negotiating style for helping patients explore and resolve ambivalence about health behaviours’ (186). In preparation for delivering the intervention the PAF attended introduction to MI and intermediate MI courses at Sheffield Hallam University delivered by an MI network trainer. It is recognised that the simple provision of information may be premature for those who are not ready to make a decision regarding a new behaviour, perhaps because they are ambivalent about the benefits of the new behaviour. In this intervention, the techniques of MI were used to help mothers to discuss and resolve their views and concerns regarding the benefits and disadvantages of becoming more active, reducing their ambivalence and increasing the likelihood of exercise behaviours being adopted. Motivational interviewing was felt to be an appropriate method of enhancing the effectiveness of communication between the PAF and the participants, particularly in view of the lack of motivation often reported by people with depression (187, 188).

This method of interviewing is also compatible with the theoretical basis of this intervention, the Transtheoretical Model (111), which recognises that people may be at different stages of readiness to alter their behaviours. Mothers in the

present RCT were asked questions such as ‘How important is becoming more active to you?’ and ‘How confident are you that you can become more active?’ in order to gauge their readiness to adopt exercise behaviours. Motivational interviewing provides a range of different communication strategies which are appropriate to people at different stages of readiness to change. Consequently, discussions with mothers who were felt to be in precontemplation began with conversation about their current lifestyle, what a typical day entailed for them, their mental health and any exercise they were currently undertaking. The benefits and disadvantages of exercise and of remaining inactive might be discussed and information provided related to exercise and mood. For those who were in precontemplation who may have been more resistant to change, emphasis was placed on personal choice. For those in the contemplation stage or who were commencing their behavioural change discussion would also focus on what the participant hoped to achieve and why; an exploration of any concerns they had regarding becoming more active; help with decision making and the shared formation of specific exercise plans.

Certain skills were used within all consultations in order to facilitate rapport, including the use of open questions to ensure that the discussion is focused on what is important to the individual mother. Reflective listening was used to indicate the PAFs attention and empathy. Summarising was performed to reflect the PAFs understanding and acceptance of the mothers’ statements and beliefs, whilst the PAF refrained from over representing their own opinions. Affirmation was used to support the mother’s confidence and self-efficacy for decision making. The mother’s self-efficacy for behavioural change was also supported by the PAF assisting them in understanding their own capabilities. Through the use of MI and complementary

communication techniques the focus of the intervention remained on supporting the mother to progress from ambivalence to instigating her own behavioural change (186).

3.3.3 Research design

3.3.3.1 Pilot RCT

Prior to the RCT included in this thesis, a pilot RCT of an exercise intervention for PND was conducted by Dr Daley (14). This pilot was designed to gauge the level of interest from general practices, to inform the sample size of the present RCT and to test procedures for recruitment and intervention delivery.

3.3.3.2 The present RCT

This study was a two arm RCT with individual participant randomisation. Recruitment of women with PND took place in the West Midlands, United Kingdom, between January 2010 and February 2012. The principal Primary Care Trusts (PCTs) involved in recruitment were South Birmingham (SB PCT) and Birmingham East and North (BEN PCT). Sandwell, Dudley, Walsall Teaching and Wolverhampton PCTs also assisted from January 2011 until February 2012. (Primary care trusts were part of the former NHS primary care structure prior to clinical commissioning groups.)

3.3.3.3 The study population and context

Within the population of Birmingham, there were an estimated 19422 births per year in 2009 (189). It is estimated that 10% of mothers experience PND, indicating that 1942 mothers would have been eligible for this study per year. Given mothers known reluctance to disclose PND (124), a conservative estimate of 20% of those eligible responding would provide 388 mothers per year, indicating that the

recruitment target for this RCT of 208 over 2 years was achievable (see chapter three, section 3.3.4 for sample size calculation).

The sociodemographic make up of Birmingham is varied with 46.9% of the population from non-white ethnicities (190). However, it is estimated 85% of the inhabitants of Birmingham speak English as their main language (191), with a further proportion speaking English as a second language. Although these figures indicate that the proportion of Birmingham residents who do not speak any English is relatively small, interpreters were made available for those who felt this would be of benefit to them.

The city of Birmingham has a wide range of geographic areas with different levels of socioeconomic deprivation; however, 47% of the population live in areas in the highest quintile of socioeconomic deprivation in England, as indicated by the index of multiple deprivation (192). A range of levels of socioeconomic deprivation was sought within this RCT by inviting a large number (147) of general practices from across the city and greater West Midlands to take part. As randomisation within this study took place on an individual level and not at GP practice level, differences between the patient groups at different GP practices were unlikely to introduce a significant degree of bias to the results.

It has been estimated that in the UK only 32% of women meet the recommended target of 150 minutes of moderate exercise per week (193). It is known that many women experience a decrease in physical activity after giving birth (194, 195). Consequently, the eligibility criteria of performing less than 150 minutes of moderate activity per week was considered unlikely to substantially reduce the

population of mothers eligible for this study. It was not felt appropriate to recruit mothers already performing more than 150 minutes of moderate exercise per week to this study as they were already achieving the exercise goal of the study, and would be unlikely to receive further physical or psychological benefit.

Between April 2009 and March 2010, the hospital recording the greatest proportion of deliveries in Birmingham, the Birmingham Women's Hospital, recorded rates of 48.3% spontaneous births; 24.5% caesarean sections; 5.4% surgical inductions; 11.1% medical inductions; 2.6% medical and surgical inductions and 8.2% births of unknown delivery type (196). In Birmingham, breastfeeding initiation was 63.7% in 2009 (197). These data indicated that a proportion of mothers would be recovering from caesarean sections and a proportion would be breastfeeding when commencing this study, highlighting the importance of the flexible and personalised design of the exercise intervention.

3.3.3.4 *Postnatal primary health care*

Postnatal care in Birmingham follows the national guidelines for England (198). Care is based on a series of postnatal contacts to check the physical and mental health of the mother and the health and development of the baby (198). These contacts are predominantly delivered by midwives in the immediate postnatal period and up to 10 - 28 days after birth, depending on the needs of the mother and baby (198).

Midwives then hand over main care to health visitors who perform a structured programme of clinic and home visits to mothers up to 5 years after birth (198).

During home visits mothers are offered advice and literature to support sensitive parenting techniques; breastfeeding support; an opportunity to discuss family

interaction with support or referral to counselling offered if needed and assistance with smoking cessation (198). Screening for PND is conducted within 10-14 days of birth and at subsequent contacts (198). The health professional is advised to ask the mother the Whooley questions (22), then conduct the EPDS (23), HADS (56) or PHQ-9 (57) if subsequent assessment is required. If a nurse or health visitor has significant concerns regarding the mother's mental well-being, the mother is referred to the GP for further assessment and possible referral. If inpatient care is required for severe mental illness within 12 months of childbirth, mothers should be admitted to a specialist mother and baby unit (4). Within the city of Birmingham, health professionals can refer mothers to a specialist mother and baby unit for inpatient and outpatient care. Mothers can also access support through the charity ACACIA, which provides a befriending service from mothers who have recovered from PND and access to psychologists through the Improving Access to Psychological Therapies service (IAPT).

3.3.4 Sample size

In order to detect a 1.95 unit difference in EPDS score (effect size = 0.5) at six months post randomisation with 90% power and 5% significance level, a sample size of 166 was required, (83 participants per group). An anticipated dropout rate of 20% at six months post randomisation would necessitate a sample size of 208. Two points on the EPDS scale was considered a moderate change in weighted mean difference (199).

3.3.5 Ethical approval

Ethical and research governance approval were obtained in SB PCT, BEN PCT, Walsall Teaching, Wolverhampton, Sandwell and Dudley PCTs. The University of Birmingham acted as the sponsor for this trial (Appendix Figure 8).

3.3.6 Development of participant literature

The participant screening invitation letters (Appendix Figures 1, 9 and 10), reply forms (Appendix Figures 11 and 12), information sheets (Appendix Figures 2 and 13), screening consent forms (Appendix Figure 14, 15, and 16) and trial consent forms (Appendix Figures 17 and 18) were created by myself and edited by Dr Daley.

Prior to the start of recruitment both the screening consent form and the trial consent form underwent alterations. A statement was added to the first participant screening consent form (Appendix Figure 14) stating that study participation was voluntary and participants could withdraw at any time without their legal rights or medical care being affected. The first screening consent form to be sent to participants was therefore Version two (Appendix Figure 15). A statement was added to the first trial consent form (Appendix Figure 17) giving permission for us to access relevant sections of the medical notes of the child the participant gave birth to prior to taking part in this study. This enabled us to reliably record the age of the baby, and therefore how many days postpartum the mother was when randomised into the study. Version two was therefore the first trial consent form to be used with participants.

After the commencement of randomisation, the language of the participant screening invitation letter (Appendix Figure 1) was made more participant friendly. References to PND and exercise were replaced with references to low mood and physical activity (Appendix Figure 9). At a later point it was further separated into a more succinct participant screening invitation letter (Appendix Figure 10) and a participant screening leaflet (Appendix Figure 19) in response to comments from our steering group and patient public representative. For further details, including the rationale behind this process of literature development see chapter four, sections 4.3.4 and 4.3.9.

3.3.7 Recruitment strategies

Several different strategies were used in this study to maximise recruitment as recommended by Peindel and Wisner (200). This was thought prudent in view of the sensitive and often stigmatising nature of PND and the potential difficulties involved in recruiting depressed mothers with young babies to trials.

3.3.8 Inviting all eligible postnatal women by letter from their GP

The principal recruitment strategy consisted of inviting 147 general practices across Birmingham and the greater West Midlands to take participate, of which 67 agreed. The Child and Families Division of the NHS (CHS) holds confidential records of all children born in the UK. In order to maintain confidentiality, every two weeks the CHS generated lists of recently delivered mothers which were faxed to participating practices. A GP at each practice then screened these patients according to the inclusion and exclusion criteria, removing ineligible patients. The CHS then posted a study information pack containing an invitation letter (Appendix Figure 9) on GP

headed paper and a screening EPDS to eligible women. This information was initially sent to mothers at six-ten weeks postnatal, in view of the peak incidence of PND at six weeks after giving birth (20). After nine months of below expected recruitment this altered to 10-14 weeks postnatal, to allow mothers time to physically recover from giving birth, begin to establish a routine of sleeping and feeding with their baby and therefore be in better position to consider participation in an exercise trial (further details provided in chapter four). A reminder letter and EPDS questionnaire was sent to all non-responders three weeks after the initial letter.

3.3.9 Referrals from health visitors

Health visitors in SB PCT, BEN PCT and Sandwell PCT were asked to identify mothers in their care with babies under six months, who they believed were experiencing PND, either by clinical judgement or as a result of the Whooley Questions (22). When a mother was identified as having low mood or PND, their health visitor was able to refer them into the study after they had been screened against the inclusion and exclusion criteria by their GP. This approach provided the study with a more direct route to potentially depressed mothers. The time a health visitor could take explaining the study to mothers in person may also have been beneficial in recruiting mothers who had previously dismissed the study when they received their study invitation letter from the GP. We were also able to recruit women from practices who were not taking part in routine screening with the CHS, as all health visitors in the participating PCTs were able to make referrals. Health visitor team meetings were attended to discuss the study and encourage health visitors to refer women.

3.3.10 Posters in primary care practices

Participatory primary care practices were asked to display posters containing brief details about the study and the contact details of the research team. All patients enquiring as a result of seeing a poster were screened by a GP against the inclusion and exclusion criteria before being enrolled into the study.

3.3.11 Other recruitment strategies

Additional recruitment strategies included advertisements placed on relevant mother and baby websites and on local radio stations; recruitment at baby immunisation clinics and PND support groups. These strategies are discussed in detail in chapter four, section 4.3.

3.3.12 Inclusion criteria

- A first EPDS score of ≥ 10 when \leq six months postnatal

A threshold score of ≥ 10 was used in the initial screening in order to maximise the likelihood of identifying mothers with PND. It has been estimated that a threshold of ≥ 10 would allow us to identify 90% of patients with PND (23).

- A second EPDS score (two weeks later) ≥ 13

The completion of a second EPDS was intended to reduce the number of mothers with baby blues proceeding to the Clinical Interview Schedule-Revised (CIS-R) (201). The symptoms of baby blues are transient, often resolving by 10-12 days postnatal and are therefore likely to have subsided by the completion of the second EPDS (32, 33). As recommended by Cox et al. a higher EPDS threshold of ≥ 13 , indicating probable depression, was used for eligibility to enter the trial, again reducing the

rate of false positive cases required to complete the clinical interview to diagnose depression (23).

- An ICD-10 diagnosis of depression or mixed anxiety and depression identified by a Clinical Interview Schedule-Revised (CIS-R) (201)

It was considered appropriate to include mothers with diagnoses of depression and mixed anxiety and depression as many people with depression will also suffer comorbid symptoms of anxiety (104).

- Non-pregnant at baseline

As the intervention was exercise based it was not possible to accept pregnant women as their condition might affect the type and intensity of exercise it would be safe for them to undertake.

- Not experiencing psychotic symptoms

Patients experiencing psychotic symptoms require specific medical care, often on an inpatient basis, during which it may not be feasible or appropriate to take part in a trial of regular exercise.

- Not dependent on illicit drugs or alcohol

Mothers dependent on illicit drugs or alcohol require specific medical support that it would not be justifiable to interfere with.

- Not aged under 18 years

In order to guarantee full consent, mothers under the age of 18 were excluded from this study.

- Currently inactive

Mothers not meeting the current public health guidelines for physical activity of at least 150 minutes of moderate intensity physical activity per week were eligible (202).

3.3.13 Exclusion criteria

- Not proficient in English at a level needed to complete research assessments

Birmingham is a multicultural city with 46.9% of the population from non-white ethnicities (190). Unfortunately resources were not available to translate all study literature into all languages spoken in this region. Interpreters were, however, available for participants who were able to complete and return the screening EPDS or expressed an interest in the study and felt an interpreter would benefit them during consultations.

- GP considers patient unsuitable for the trial

On reviewing patient records a GP may have decided that a patient was not suitable for this trial based on medical or personal factors not referred to in the study criteria. This criterion provided a safeguard allowing the final decision regarding eligibility to lie with the GP.

- Women whose babies had died.

3.3.14 The screening procedure

The screening procedure consisted of three stages. The first stage of screening was conducted by the Child Health System (CHS) and GPs at participating GP practices. Secondly, screening was conducted by the research associate of the study team, followed by the final stage of screening during the research facilitators screening

home visit. All screening procedures were granted ethical approval. Further details of the different stages of this screening procedure are provided below, followed by a diagram of the overall screening process (Figure 7).

3.3.14.1 *Stage 1: Screening by the CHS and GPs*

The CHS provided participating GP practices with lists of mothers who had recently given birth. Prior to sending these lists, the CHS removed the names of all mothers under the age of 18 and those whose babies had died. GPs at participating practices then excluded mothers who were currently pregnant, experiencing psychotic symptoms, dependent on illicit drugs or alcohol or whom the GP considered unsuitable for any other reason according to their clinical judgement. Lists of potentially eligible women were then returned to the CHS who posted an invitation letter (Appendix Figure 9), reply form (Appendix Figure 12), first screening EPDS with a question regarding physical activity levels over previous week (Appendix Figure 20), and a screening consent form (Appendix Figure 16) to those women on the lists. Mothers who were recruited from other sources, such as via health visitor referral or posters, were screened by their GP as described above and the above literature was sent by the research associate.

3.3.14.2 *Stage 2: Screening by the research associate*

Mothers interested in participating in the trial then returned the reply form (Appendix Figure 12), their first screening EPDS (Appendix Figure 20) and screening consent form (Appendix Figure 16) to the research associate (myself). If mothers scored ≥ 10 on their first EPDS and had performed less than 150 minutes of moderate activity in the previous week they were contacted and a second EPDS

completed by phone (Appendix Figure 21). Mothers were provided with a verbal explanation of what taking part in the study entailed. If mothers scored ≥ 13 on a second EPDS via phone, they were sent the participant information sheet by the research associate (Appendix Figure 13) and a screening home visit was arranged with a research facilitator to ascertain full eligibility (clinical diagnosis).

3.3.14.3 *Stage 3: Final screening at research facilitator's screening home visit*

3.3.14.3.1 *The research facilitators*

The final stage of the screening process was conducted by research facilitators supplied by the Primary Care and Mental Health Research Networks. The facilitators had a range of backgrounds from nursing to public health to work within the deaf services. All research facilitators conducting home visits were female in view of the sensitive nature of PND and the potential vulnerability of a mother being visited at home, often alone, with her young baby. The screening home visit typically lasted 1.5 hours.

3.3.14.3.2 *The informed consent process*

At the start of the home visit, mothers were provided with an explanation of what participation in the study involved. Mothers then had an opportunity to ask any questions they had regarding any aspect of participation in the study, after which they provided written informed consent to take part in the study. This process involved the participant reading the trial consent form (Appendix Figure 18), placing their initials in the boxes next to the listed aspects of the trial to indicate their consent and providing their signature and the date of signature at the foot of the form. The research facilitator then checked that the form had been completed

correctly and also provided their signature and the date of their signature at the foot of the form. Participants consented to their GP being informed of their participation in the trial and for the sharing of relevant data between the University study team, regulatory authorities and the NHS trust (Appendix Figure 18). The trial consent form was completed prior to the CIS-R diagnostic interview (a questionnaire) as consent had then been provided for the mothers' GP to be informed of her diagnosis, whether she was eligible to take part in the trial or not.

3.3.14.3.3 The CIS-R diagnostic interview

Following the informed consent process at the home visit, the CIS-R diagnostic interview (a computerised questionnaire) was conducted. It was acknowledged that the EPDS was only a screening tool, a continuous scale indicating increasing risk of depression (23) for which there was little consensus regarding use of appropriate thresholds. A diagnostic interview providing an ICD-10 diagnosis was therefore completed by all mothers entering the trial to ensure that all mothers were clinically depressed, providing a coherent clinical population who were likely to respond to a treatment in a similar way.

The CIS-R was developed by Lewis et al. to create a self-completed diagnostic questionnaire that could be used by lay rather than psychiatrically trained individuals (201). Good agreement has been found in testing between psychiatrist and lay interpretations of the CIS-R and no significant bias has been found in lay completion (201). The CIS-R was the gold standard diagnostic tool for depression, providing an ICD-10 diagnosis of depression.

The CIS-R interview took the form of a series of questions presented to the participant on a laptop during the home visit. A series of answers were offered by the programme, from which the participant selected the most appropriate answer for them. The research facilitator did not provide guidance but simply encouraged the participant to select the most appropriate answer for them. At the conclusion of the questions the laptop was handed back to the research facilitator who located and recorded the ICD-10 diagnosis provided by the programme. Women with a diagnosis of a mild, moderate or severe depressive episode or mixed anxiety and depression were eligible to be randomised into the trial. Mothers were informed whether or not they were eligible to take part in the study. All mothers were advised to speak to their GP for advice about how they were feeling.

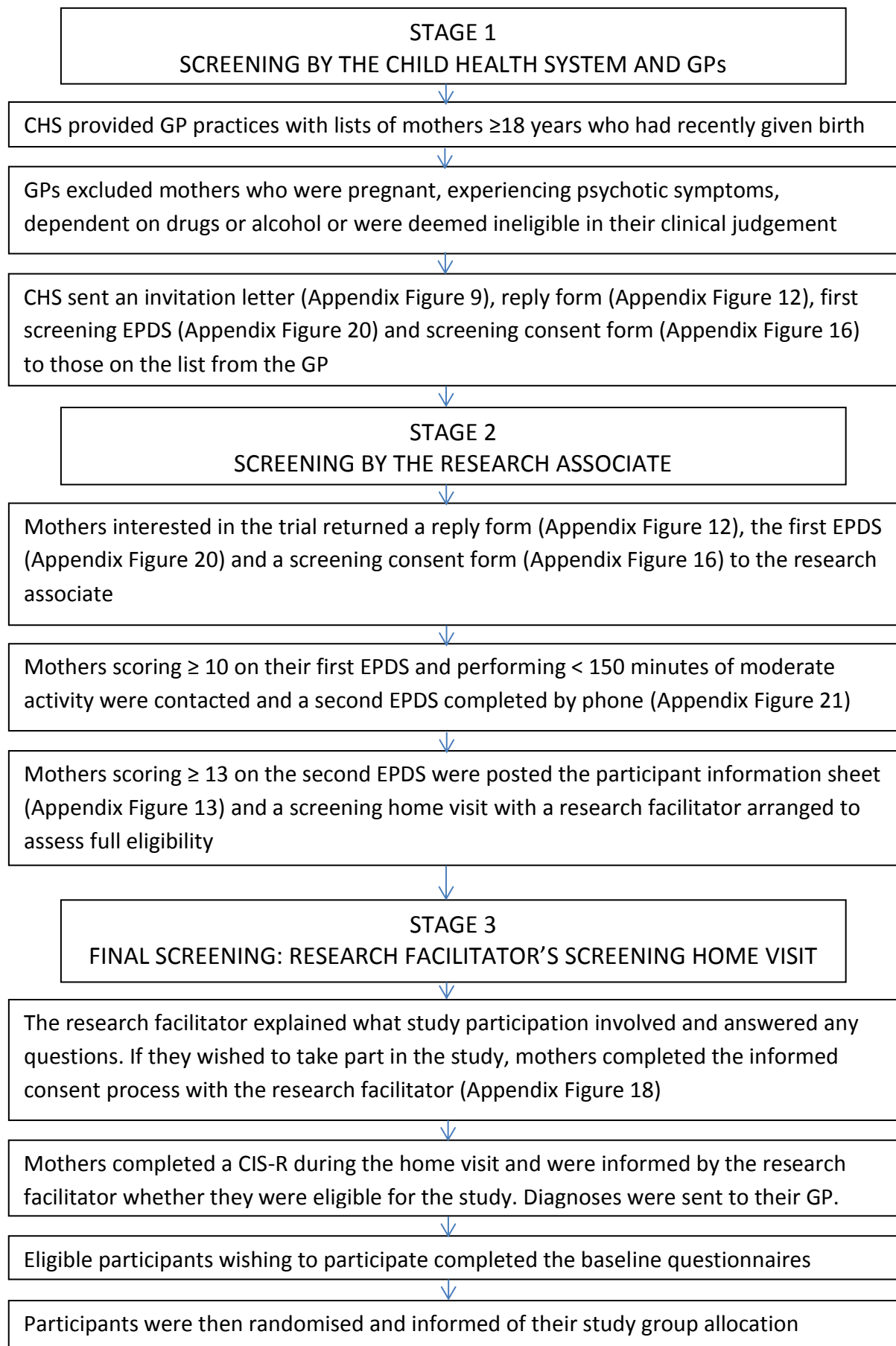
As the research facilitators conducting the CIS-R were not psychiatrically trained, mothers were not informed of their diagnosis at the screening home visit. This prevented the research facilitators from having to provide clinical advice relating to diagnoses of depression and other psychological conditions highlighted by the CIS-R. If mothers wished to discuss the results of the CIS-R, it was explained that as the researchers were not clinically trained, they should speak with their GP. The participant's GP was informed of the exact ICD-10 diagnosis generated by the CIS-R by the research associate (myself) immediately after the home visit.

3.3.14.3.4 Baseline measures and randomisation

During the final part of the screening home visit, eligible mothers who wished to take part in the trial completed the questionnaire pack measuring the primary and secondary outcomes (See section 3.3.15 for further detail on the outcome

measures). Randomisation then took place (Figure 7). (See section 3.3.15.3 for further detail on the randomisation procedure)

Figure 7: The screening procedure



3.3.15 Outcome measures

3.3.15.1 Primary outcome measure

3.3.15.1.1 Depressive symptoms

The EPDS was used to measure the severity of depressive symptoms at baseline, six and twelve months post randomisation. The EPDS was originally developed by Cox et al. in 1987 as a 10 point screening tool for PND in the community (23). It was developed because previous scales such as the Anxiety and Depression Scale (SAD), the General Health Questionnaire and the Beck Depression Inventory, were found to be unreliable in measuring depression in the postnatal period (23). The EPDS was designed to be a self-reported measure and is usually completed in less than five minutes. The authors found the EPDS to have acceptable validity and reliability, with a sensitivity of 86% and a specificity of 78%. Repeated measures analysis was performed against Goldberg's Standardised Psychiatric Interview (SPI) (203).

Mothers who were diagnosed as depressed on the SPI at both points of completion of the EPDS, showed no significant difference between their mean first and second EPDS scores; those who received a diagnosis of depression on their first but not their second EPDS had a significant reduction in score between their first and second score. (EPDS 1: mean score 15.8, EPDS 2: mean score 9.58, $p=0.002$) The EPDS has been used widely and internationally in research since its creation (204).

A range of EPDS cut off points are currently used in postnatal depression research, from ≥ 10 (11), to >10 (15), to ≥ 12 (13, 80), to > 12 (14). No guidance is currently provided to health professionals using the EPDS as a screening tool, however it is recognised that ≥ 10 is frequently used to represent possible depression and > 12 probable depression (4). Within research into the treatment of

PND with psychological and psychosocial treatments, a threshold of an EPDS score > 12 is frequently used as an eligibility criterion to indicate depression (205). In the present RCT a threshold of ≥ 10 was therefore used for initial screening to maximise the likelihood of identifying mothers with possible PND; a threshold of ≥ 10 being estimated to identify 90% of patients with PND (23). A higher threshold of > 12 was used for trial eligibility, as recommended by Cox et al., to reduce the rate of false positive cases who were required to complete the subsequent clinical interview to diagnose depression (23).

3.3.15.1.2 The effects of EPDS usage

It is possible that the completion of the EPDS may identify a risk of depression in women who may not have previously considered the possibility of PND. As this is a screening tool, this indicated risk may or may not represent PND. As a result all mothers completing the EPDS, regardless of their score, were encouraged to speak to their GP or health visitor if they felt they wanted support regarding their low mood. All mothers consented to their EPDS scores being passed on to their GP. This system improved the likelihood of mothers receiving support and treatment for PND if they wished to. The disclosure of thoughts, plans or actions related to self-harm may be distressing for the mother and researcher. A detailed self-harm protocol was devised in collaboration with a clinical psychologist which involved open discussion of the mother's thoughts, encouragement to seek help from a health professional and informing the GP of the mother's thoughts with the mother's full knowledge and consent. For further details see chapter three, section 3.3.16. All researchers

completing the EPDS were also provided with regular clinical supervision by a clinical psychologist.

3.3.15.2 *Secondary outcome measures*

We were primarily interested in the effects of exercise on PND but physical activity has been found to influence other psychological factors which may be beneficial to mothers in the postnatal period. The choice of secondary outcomes was based on the evidence relating to these measures in the fields of exercise, PND and depression, as discussed in detail below.

3.3.15.2.1 *Health and well-being*

The SF-12 Short Form Health Survey (SF-12) was constructed by Ware et al. in 1996 (206). It is based on the physical and mental component summary scores of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). A licence was obtained for the usage of the SF-12. The SF-12 was selected in preference to the SF-36 as it can be completed in less than two minutes making it much more suitable for completion alongside other questionnaires. The SF-12 short form was originally found to have good reliability (physical components: $r^2 = 0.905$, mental components $r^2 = 0.938$; physical components: test retest reliability 0.76, mental components: 0.89). The scale was also found to have adequate relative validity (physical components: median 0.67, mental components: median 0.97) (206). The SF-12 has since been extensively used and validated internationally (207-209).

3.3.15.2.2 *Subjective vitality*

The subjective vitality scale was developed by Ryan and Frederick 1997 (176). The reliability and validity of the scale have been found to be acceptable (210, 211). This

scale was used in preference to other scales such as the four item vitality scale within the SF-36 for two principal reasons. The language of the vitality scale by Ryan and Frederick was considered to be more appropriate to a British audience; phrases within the SF-36 such as 'did you feel full of pep' were considered to be less familiar to those in the UK and therefore might have introduced bias in participants' interpretation. Unlike the SF-36, the vitality scale by Ryan and Frederick did not require licenced software, so was less costly to use.

3.3.15.2.3 Health related quality of life

The EuroQol 5D (EQ-5D) measure was constructed by an international multi-disciplinary group in 1990 (212), whose aim was to develop a short, user friendly self-completed measure of health related quality of life. Its brevity and simplicity made it more suitable than measures such as the 75 item 15-D Health Related Quality of Life questionnaire (15-D) (213), as a measure to be used alongside other questionnaires in this study (214). The EuroQol was designed to assess the five main tenants of health related quality of life; exploring physical functioning via a question on mobility; self-care via a question on washing and dressing; social functioning via a question on usual activities; pain via a question on intensity of pain or discomfort and mental functioning via a question on anxiety and depression (214). This range of factors was considered more suitable than the more detailed questions of the 15-D, which included a section on sexual activity. Factors in the postnatal period may make such a section unsuitable and introduce bias into the results. In 2014 the EQ-5D measure had 107 translations and had been widely used in research (215). The measure achieved good test retest reliability (inter-class coefficient of 0.73) (216) and has been found to have very little responder bias (217). The validity of the scale

has been found to be acceptable through correlations with the SF-36 (218) and the 15 Dimension Health Related Quality of life Scale (213).

3.3.15.2.4 Body image

The MAMA Body Image scale was developed by Kumar et al. to measure changes in a mother's perceptions of her body, somatic symptoms, marital relationship, attitudes to sex and attitudes to her pregnancy and her baby (219). Only the scale relating to body image was used in the present study. The MAMA body image scale has been found to have a test retest reliability of 0.89, acceptable overall validity and to be self-completed by many mothers within 10 minutes (219). This scale was used in preference to other generic body images scales such as the as the Multidimensional Body-Self Relations Questionnaire (220) as it addresses body image related concerns that are specific to the postnatal period.

3.3.15.2.5 Social support

In 2003 Brugha et al. found a lack of social support to be predictive of depression and depressive ideas (221). A recent systematic review of exercise interventions for PND found that when a single study of social support and exercise was removed from the meta-analysis; the effect of the remaining trials on depressive symptoms was no longer significant, highlighting the potential importance of social support in reducing depression (101). In the present study social support was assessed using questions from a longitudinal study of mental health in Britain conducted by the Office for National statistics (222). These questions were selected in preference to other social support questionnaire such as those by Sarason et al., Cohen et al. due to their brevity (223-225). Brevity was felt to be of particular importance in not

discouraging women from participating in this study. A large number of questionnaires and a diagnostic interview needed to be conducted in mothers' homes, with many women looking after a young baby during this process.

3.3.15.2.6 Self-efficacy for exercise

In 1988, Sallis et al. developed a pair of scales to measure self-efficacy for eating and exercise behaviours (226), their work was based on 40 interviews conducted to identify the behavioural and situational components of dietary and exercise change. Questions generated from these interviews were administered to 171 further participants (226). The Self-efficacy and Exercise Habits Survey (SEHS) was used in this study. Sallis et al. found self-efficacy factors to be significantly related to reported exercise behaviours, providing evidence of criterion related validity and reported a test-retest reliability of 0.68 (226). This questionnaire was used within the substantial body of secondary measure questionnaires due to its brevity compared to other measures such as the exercise self-efficacy scale by Bandura, having 12 rather than 18 questions (227).

3.3.15.2.7 Social support and exercise

Sallis et al. also developed a scale designed to measure perceived levels of social support for health-related eating and exercise behaviours (228). The work was based on 40 interviews designed to elicit supportive and non-supportive behaviours, questions from which were again put to 171 participants. Two separate scales were generated relating to family and friends (228). The two scales have been found to have acceptable internal consistency reliabilities: family scale Chronbach's α : 0.90; friends' scale 0.86 and an overall content validity ratio of 0.94 (229). The social

support for exercise scale was selected for this study. There are many validated measures for evaluating social support (223-225), the social support and exercise scale by Sallis et al. was selected as it specifically related to the degree of support within ones social network for exercise, this was felt to be of importance within an exercise intervention for postnatal mothers.

3.3.15.2.8 *Physical activity: The International Physical Activity Questionnaire*

The International Physical Activity Questionnaire - short version (IPAQ) was developed by Craig et al. in 2003 to provide a subjective physical activity measure that could be used in diverse populations and allow for international comparison (144). The IPAQ was designed to be a self-reported measure and has been found to have acceptable validity (test re-test Spearman's reliability coefficient 0.69) and reliability (Spearman's co-efficient comparing the IPAQ long and short versions 0.69 to 0.76) (144). The short version of the questionnaire was selected for this study as it separates physical activity by its intensity, whereas the long version differentiates between different types of physical activity. The purpose of this study was to increase levels of activity of a moderate intensity or above, regardless of the context of the activity. The IPAQ-short form was chosen in preference to other measures such as the 7 Day Physical Activity Questionnaires (7 Day PAR) (230) as overestimation has been found on the moderate category of the 7 Day PAR (231). In the IPAQ, amount of walking, which may be overestimated as moderate activity by other measures, is recorded separately and given a lower MET value when the data is converted into MET Minutes (144).

3.3.15.2.9 *Physical activity: Actiheart accelerometers*

Accelerometers were used as an objective measure of physical activity. An Actiheart is a device attached to the chest via electrodes that records the heart rate and activity level of the wearer every minute. These data, in combination with BMI, can be used to generate a measure of the intensity of the activity undertaken by the wearer. From these data the time a participant was engaged in activity of moderate intensity or greater was calculated. Due to the cost of the device, Actihearts were fitted in a random 60% sample of participants at baseline and follow up. Further detail regarding Actiheart accelerometers has been provided in chapter two.

3.3.15.2.10 *BMI*

Participants' weight and height were collected in order for their BMI to be calculated. BMI was not an outcome measure; it was calculated in order to be combined with accelerometry data, providing a more accurate estimate of the intensity of a participant's exercise and their personal energy expenditure.

3.3.15.2.11 *Exercise diaries*

Intervention participants were encouraged to complete an exercise diary in weeks four, eight, 12, 16 and 20 of the intervention, to maintain a record of the exercise achieved each week and its relationship to their mood (Appendix Figure 7). The exercise diaries were a process measure to investigate whether those in the intervention were increasing their physical activity. They also served as a tool for the behavioural change technique of self-monitoring which was used in the intervention. Exercise diaries were therefore only completed by those in the intervention,

whereas the IPAQ and AH were used as physical activity outcome measures and were therefore completed by intervention and comparator participants.

3.3.15.3 *Randomisation and blinding*

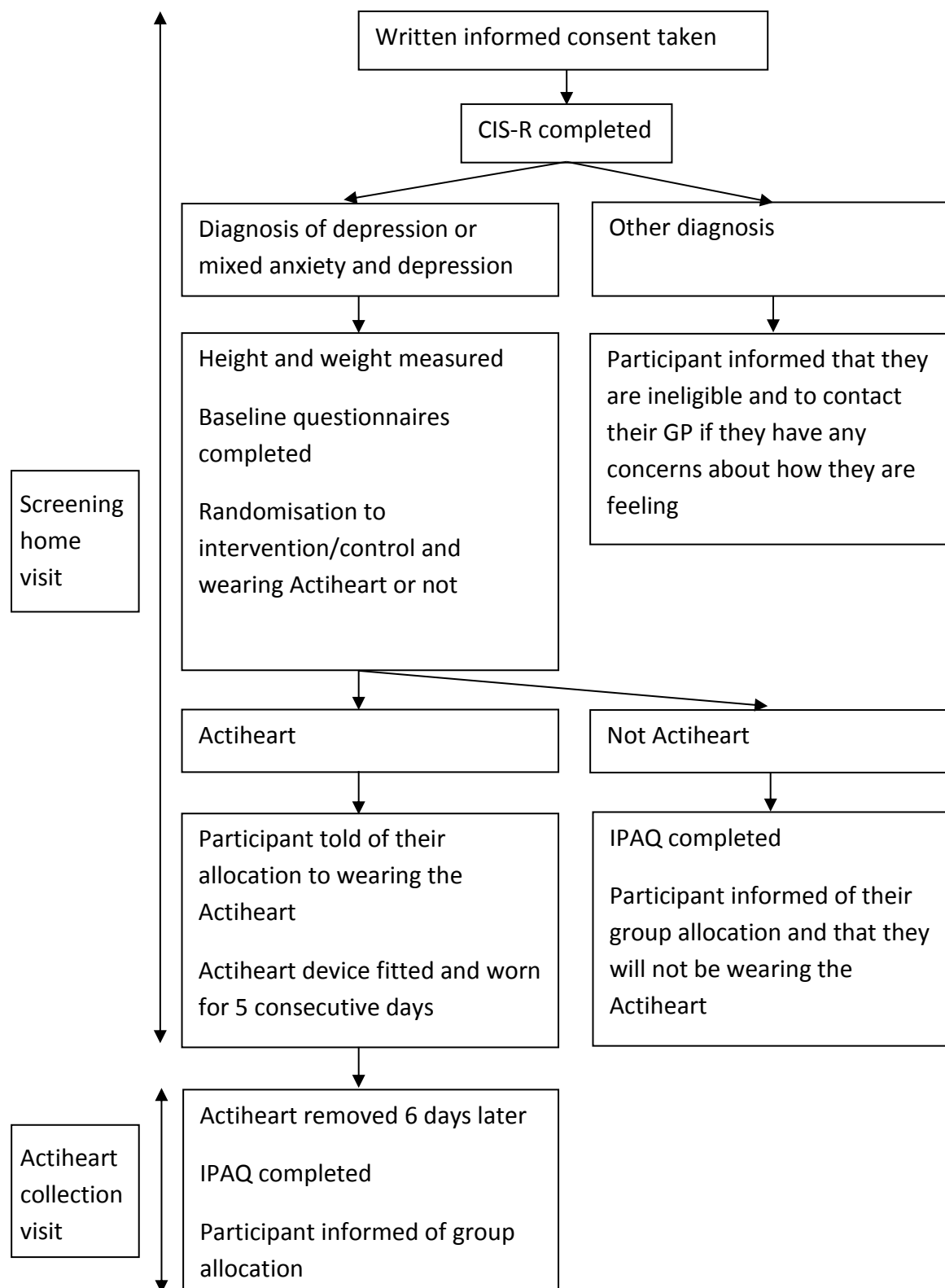
After completion of baseline measures, randomisation was conducted in the participant's home using a remote internet database. This system concealed allocation from the researchers involved in the recruitment process. A computer programme was used to generate an allocation sequence based on random permuted blocks of 10 units. Participants were individually randomised to the trial groups on a 50:50 basis and then separately randomised to wearing an Actiheart accelerometer or not on a 60:40 basis. Randomisation to the intervention and comparator groups was stratified by second EPDS score (13-16 and 17+). The greater proportion allocated to wearing the Actiheart was designed to compensate for any participants declining to wear the device and the possibility of poor quality, unusable data. Participants were initially asked to wear the Actiheart for five days; this was subsequently reduced to three days due to irritation from the electrodes resulting in participants removing the device prematurely. Participants not randomised to wearing the Actiheart were informed of their group allocation after the completion of the baseline questionnaires to avoid influencing their responses (Figure 8).

3.3.15.3.1 *Actiheart collection visit*

If a participant was fitted with an Actiheart the researcher returned six days later to collect it. (This was subsequently decreased to four days). Participants then completed the IPAQ (144). This approach was taken so that the IPAQ data referred to the days on which the Actiheart was worn, allowing for later comparison.

Participants were informed of their group allocation after completion of the IPAQ to prevent knowledge of group allocation influencing participants' responses to questions or their behaviour whilst wearing the Actiheart. The physical activity facilitator (PAF), who delivered the intervention, was not involved in the recruitment or screening processes. Due to the nature of the exercise intervention, participants and researchers were not blinded to group allocation.

Figure 8: Order of randomisation and baseline measures



CIS-R: Clinical Interview Schedule-Revised; IPAQ: International Physical Activity Questionnaire

3.3.16 Self-harm protocol

A self-harm protocol was used to ensure that the relevant health professional was informed of any participants with thoughts, plans or actions relating to self-harm or suicide (Appendix Figure 4). This protocol was devised in consultation with a clinical psychologist and was designed to be actioned on any of the following occasions during the study:

1. An answer of 'Yes, quite often' or 'Sometimes' to the following statement on any EPDS completed: 'The thought of harming myself has occurred to me.'
2. Any reference to thoughts, plans or actions of self-harm or suicide or the phrase 'Patient feels life is not worth living' in the 'Suicide Intent' section of the CIS-R diagnosis.
3. Any mention of thoughts, plans or actions related to self-harm during any contact between researcher and participant, or any concerning behaviour during contact.

The self-harm protocol stated that if any of the above occurred the researcher would contact the participant. The researcher discussed their mood with them to assess the immediate risk of harm; asked whether they had informed their GP about their feelings and encouraged the participant to do so if they had not. The researcher then contacted the relevant GP, informed them of the participant's thoughts or actions and confirmed whether or not the GP was willing for the individual to participate in this study. The researcher also informed another member of the research team as a safeguard to ensure the protocol had been followed. If the participant did not give

permission for the researcher to inform the GP, the decision as to whether to inform the GP lay with a consultant psychologist at the local Mother and Baby Unit.

3.3.17 The comparator group

Participants in the comparator group continued to receive any usual care being provided by their health visitor, GP or secondary care services. In addition, they received a 'Looking after yourself' leaflet which provided lifestyle, dietary and limited exercise information for postnatal mothers and was based on information provided by the NHS (232) (Appendix Figure 3). Participants were offered a consultation with the PAF after completing the trial.

3.3.18 The intervention group

Exercise was being investigated as an adjunctive treatment, therefore participants continued to receive any treatment they were already receiving such as antidepressants, counselling or health visitor listening visits. In addition, intervention participants received individual support to become more active. A female PAF visited participants at one and five weeks post randomisation and provided supportive phone calls at eight/nine weeks and twelve/thirteen weeks post randomisation. The PAF was also available by phone for exercise counselling between these sessions if necessary.

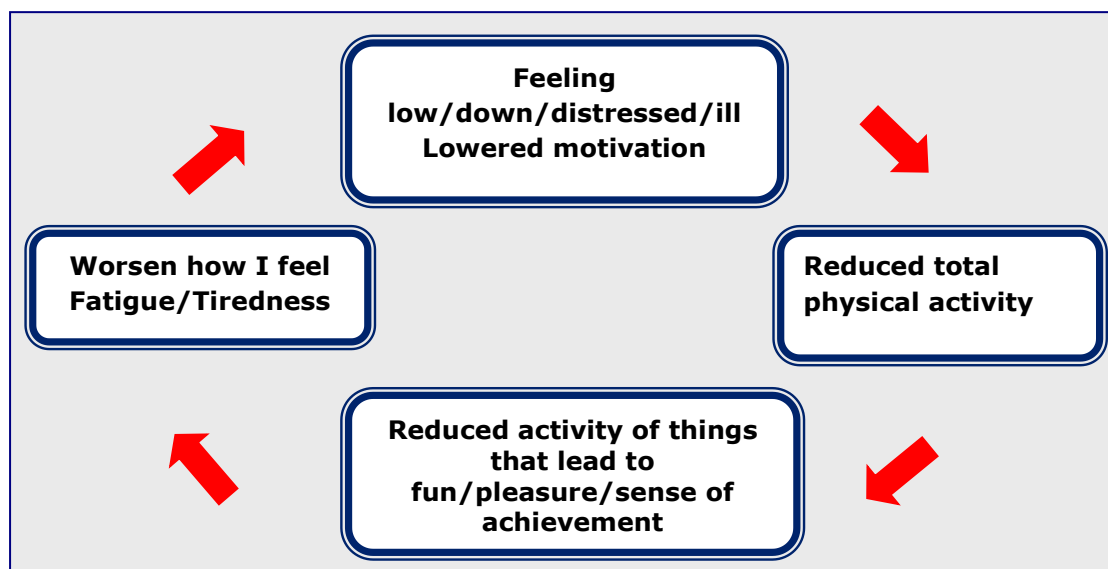
3.3.18.1 *The intervention: consultation one*

The first one hour PAF consultation took place in the participant's home shortly after the collection of baseline data (this was classed as week one of the intervention).

The PAF began by explaining their role and the nature of the contact they would have with the participant. The participant's low mood and symptoms such as

reduced energy, low motivation and disturbed sleep were then discussed in relation to their impact on the participant's daily life and the type and intensity of exercise that might be achievable. The spiral model was used to illustrate how a lack of activity can lead to a worsening of low mood, while activity could help to improve mood and the symptoms of their depression (117) (Figure 9).

Figure 9: The spiral model (117)



The type and duration of any current physical activity or exercise being undertaken by the participant and their attitude towards exercise was discussed with the PAF. Any relevant practical considerations such as breastfeeding, childcare and the support offered by friends and family were also discussed. The PAF aided the participant in finding solutions to any potential barriers to exercise.

The participant's previous levels of exercise were then discussed, including the types of exercise found helpful or enjoyable. The PAF assisted the participant in planning their preferred type, intensity and duration of exercise. Although the

participant led in forming this plan, the PAF guided the participant in making their goals specific, realistic and measurable. The exercise goals were then recorded on a goal setting form to remind the participant of their targets (Appendix Figure 22). Participants were encouraged to complete an exercise diary to maintain a record of the exercise achieved each week and its relationship to their mood (Appendix Figure 7).

As part of the intervention, participants also received a pedometer; a booklet containing information on recommended levels of walking and a 'Looking after yourself' Leaflet for the postnatal period. It was recognised that some mothers might have wished to exercise as part of a group or within gym facilities; therefore participants received a list of local opportunities for exercise suitable for postnatal mothers and a list of local leisure centres.

3.3.18.2 *The intervention: consultation two*

The second hour long home consultation took place in week five of the intervention. As this was the last consultation in person, the PAF encouraged participants to consider how to maintain their exercise independently and become aware of triggers which resulted in decreased exercise so they could mitigate the effects. The main focus of this consultation was on assessing any behavioural change since the previous session. The PAF discussed what exercise the participant was undertaking and how this compared to the goals previously set. If a goal had been achieved there was discussion about any effects on the participant's mood and the benefits and disadvantages of achieving the goal. If a goal had not been achieved, the discussion explored the difficulties experienced and what they could practically do to overcome

them. The participant was then encouraged to set new activity goals for the future. The PAF encouraged the participant to consider whether they needed to make any practical changes or arrange any extra support in order to achieve these goals. The new goals were then recorded on the goal setting form (Appendix Figure 22) for the participant's reference and an exercise diary (Appendix Figure 7) completed for the use of the trial.

3.3.18.3 *The intervention: consultations three and four*

Telephone consultations lasting approximately 15 minutes took place in week eight/nine and week twelve/thirteen of the intervention. These were arranged for a convenient time when the participant was able to discuss their thoughts and progress. The PAF discussed the exercise being undertaken and how this related to their general well-being, as well as their thoughts and emotions specifically surrounding their exercise. Participants' energy levels and potential sense of achievement in completing activities were also explored. Goals from the previous session were reviewed, including discussion of the benefits, disadvantages, barriers to exercise and possible solutions. Goals were set with an emphasis on establishing a routine and strategies for long term maintenance (Appendix Figure 22). An exercise diary was completed (Appendix Figure 7). (Two further exercise diaries were posted to intervention participants at weeks 16 and 20 for return by post.)

3.3.19 Information leaflets

Information leaflets were given to mothers during the first two intervention consultations and posted to participants in weeks 10, 14, 18 and 22 of the intervention. They contained information on incorporating exercise into daily life;

healthy eating; setting specific, realistic, measurable goals; the benefits of exercise; overcoming barriers and ways to improve the quality of exercise. (Appendix Figures 23-28)

3.3.20 Intervention fidelity

To ensure the quality and consistency of the intervention the PAF completed a series of post consultation forms which were reviewed by the principal investigator. The post session summary sheets recorded the main points discussed during the consultation and served as a record of plans made to inform future consultations (Appendix Figures 29 and 30). The contact monitoring form (Appendix Figure 31) was used to record all contacts between PAF and participant, helping to ensure protocol adherence and that all participants received an equal level of support. Reflective worksheets were also completed after every contact between PAF and participant (Appendix Figure 32). These were designed to encourage the PAF to consider how effective they had been at supporting the participant's sense of control, competence and relatedness (Appendix Figure 32). Recordings of the telephone consultations between the PAF and participants were also reviewed by a member of the research team to ensure fidelity to the aims and intended delivery of the intervention.

3.3.21 Follow up

At six and twelve months post randomisation participants completed an identical set of questionnaires to those completed at baseline (apart from a shortened demographics section). Follow up questionnaires were mailed to participants homes for self-completion to minimise influence over participants' responses. At collection visits participants' height and weight were recorded and participants wearing an

Actiheart at baseline were, again, fitted with the device. Participants received a £10 high street voucher at both follow up points to recompense them for their time. It was expected that the maximum effect of the intervention would be found immediately after it concluded at six months post randomisation; exercise participation and its effects decreasing thereafter. Six months post randomisation was therefore chosen as the primary follow up point.

3.3.22 Analysis of quantitative data

3.3.22.1 *Baseline characteristics*

The CONSORT guidance for the conducting of RCTs advises that baseline statistical analyses should not be performed, instead presenting baseline characteristics in descriptive tabular form is recommended (233). Baseline statistical tests are said to be superfluous and potentially misleading as they assess the probability that differences observed in baseline data have occurred by chance, however, any such differences are already known to have occurred by chance as a randomisation process has been followed (233). Baseline data have therefore been presented descriptively and in tabular format in line with the CONSORT recommendations (233).

3.3.22.2 *Primary analysis*

Analysis was conducted in SPSS version 21. Data were analysed on an intention to treat basis. The primary analysis compared the normally distributed mean EPDS scores of the intervention and comparator groups at six and 12 months post randomisation, adjusting for baseline EPDS scores using analysis of covariance. The second EPDS was taken as the baseline data as it was conducted immediately before

randomisation. A comparison of normally distributed means, adjusted for baseline outcome score and baseline EPDS score, was also conducted for all secondary outcomes except physical activity (neither IPAQ nor Actiheart).

3.3.22.3 *Secondary analysis*

A secondary analysis of covariance was conducted for all outcomes (excluding physical activity) adjusting for baseline outcome and the covariates baseline EPDS, age, weight and ethnicity, which were pre-specified in the published study protocol (234). Age was selected as a covariate as it is known to affect the degree of exercise undertaken (235). Weight was investigated as increased weight has been associated with poor body image in the postnatal period and an increased risk of depression (180). Birmingham is a multicultural city with 46.9% of the population from non-white ethnicities (190). Ethnicity was selected as a covariate as there are known to be different levels of acceptability of mental health conditions in different cultures, which may have affected the acceptability of this intervention (236).

The proportion of participants defined by Matthey (237) as improved (a baseline EPDS score > 12 decreasing by ≥ 4 points by follow up but remaining above 12) and recovered (a baseline EPDS score > 12 decreasing by ≥ 4 points to a score of ≤ 12 at follow up) was provided in the intervention and comparator groups at follow up. The difference in the proportion of improved and recovered participants at six and 12 months post randomisation was investigated using a Chi Squared test. Presenting the proportion of improved and recovered participants in this trial was felt to be clinically important. While the difference in mean EPDS scores and the statistical significance of this difference provided an indication of the average effect

of this intervention amongst women, this did not necessarily relate to a clinically significant change in an individual woman (237). Describing the proportion of mothers who would be considered clinically recovered from depression or improved enables health care professionals to consider the potential clinical impact of an intervention (237).

Data from the IPAQ was converted into MET minutes per week (metabolic equivalent tasks). The MET level of an activity is the ratio of the energy expenditure during the activity compared to energy expenditure at rest (171). The IPAQ data were converted into MET minutes/week by multiplication of the number of minutes per week spent at a particular level of activity intensity, by the appropriate MET level. (Minutes of vigorous exercise were multiplied by 8.0, moderate exercise by 4.0 and walking by 3.3 as per the current guidelines for analysis of IPAQ data (238). The analysis of the MET data generated was dependent on its distribution. If the data were found to be skewed, the median (and interquartile range (IQR)) number of minutes of vigorous and moderate exercise; minutes of walking; sitting and the total number of minutes of exercise was calculated for those in the intervention and comparator groups. In order to adjust for baseline values, the change in these variables from baseline to six and 12 months post randomisation was calculated. A Mann Whitney U Test was conducted to determine whether the change in distribution of exercise differed between the groups. If the data were found to be normally distributed, a T-Test was used to assess the difference in the adjusted mean minutes of exercise between the groups at follow up.

Data recordings obtained from Actiheart accelerometers were initially prepared by removal of irrelevant data from prior to and after wearing. Sleeping heart rates were then adjusted to be based only on days where the Actiheart was worn for a full 24 hours. All recordings of less than 24 hours were removed as they were considered to provide an unreliable estimate of daily activity. For recordings with incomplete heart rate data, the heart rate readings were discarded, instead the accelerometry data were multiplied by a scaling factor based on heart rate data from the participant's other recordings, or if no other accurate personal heart rate data were available, an average of the heart rate data from the entire group. Combined heart rate and accelerometry data (or scaled accelerometry data only) were used to estimate daily physical activity energy expenditure (PAEE) within the groups.

The analysis of the exercise data generated was dependant on its distribution. If found to be skewed, the median (IQR) minutes of daily PAEE within the groups at baseline, six and 12 months post randomisation was presented. A Mann Whitney U Test was used to determine whether there was a significant difference between the median of the change in PAEE of the groups between baseline and follow up. If the Actiheart data were found to be normally distributed, the mean (SD) minutes of daily PAEE within the groups at baseline and follow up was calculated. A T-Test was used to determine whether there was a significant difference in the mean PAEE (when adjusted for baseline PAEE) between the groups at follow up. The mean (SD) or median (IQR) minutes of light, moderate and vigorous activity in the groups at baseline and both points of follow up was also be presented, dependent on the distribution of the data.

Exercise diaries were completed at four, eight, twelve, sixteen and twenty weeks post randomisation by intervention participants. If these data were normally distributed, the overall mean (SD) minutes of moderate and vigorous activity and the mean (SD) number of minutes of activity in diaries one to five, was provided. If the data were found to be skewed, medians (IQR) were provided. The most commonly described types of physical activity were reported. Participants' adherence to the intervention has also been described.

3.4 Results

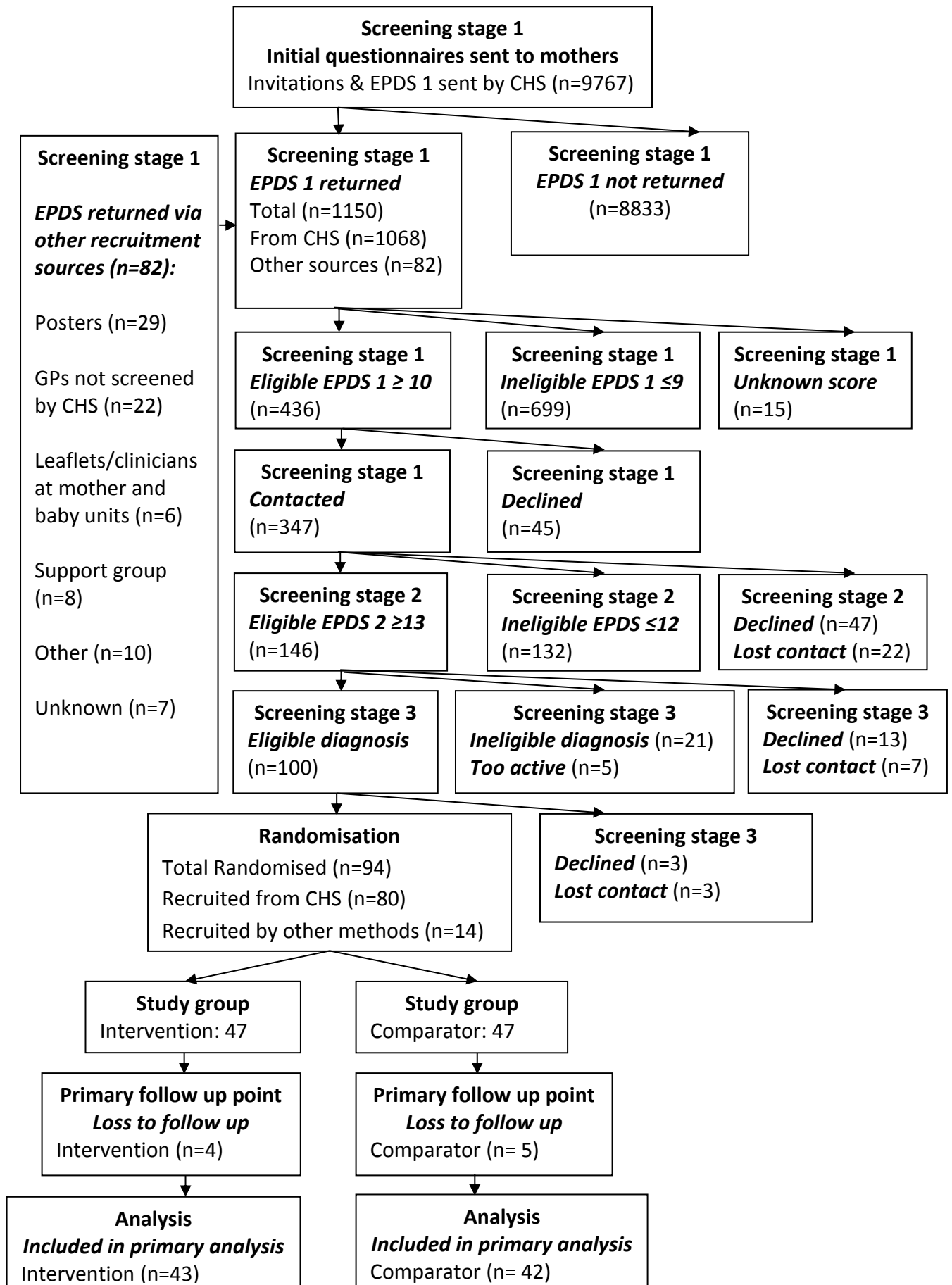
3.4.1 Recruitment

A study information pack was posted to 9767 women, of which 1068 (10.9%) were returned. In addition, 82 women returned their first EPDS questionnaire via the secondary recruitment methods (health visitor referral, seeing posters in practices etc.) Of those returning their first EPDS, 436 (37.9%) scored ≥ 10 . Two weeks later, 146/436 (33.5%) scored ≥ 13 on their second EDPS and were performing < 150 minutes of moderate activity per week. After the screening home visit to assess eligibility via the CIS-R diagnostic interview for depression, 100/146 (68.5%) were fully eligible, of whom 94 were randomised (Figure 10). The characteristics of mothers contacted via the CHS and those randomised were similar in terms of age, deprivation (Index of Multiple Deprivation, IMD) (239) and ethnicity (Appendix Figure 33).

The power calculation to estimate required sample size indicated that 166 participants were required to detect moderate difference of 1.95 points on the EPDS

scale (208 with 20% loss to follow up). Only 94 participants were recruited, with 47 randomised to the intervention and 47 to the comparator group.

Figure 10: Trial flow diagram



3.4.2 Participants' baseline characteristics

The baseline characteristics of randomised participants were generally well balanced between the groups (Tables 4 and 5), however, a greater number of comparator participants were receiving counselling (10/47, 21.3% vs 3/46, 6.5%) and fewer were looking after the home/family (13/47, 28% vs 20/46, 43.5%) than intervention participants. Participants were from a range of ethnic backgrounds, with 62.8% (59/94) of white British origin and 37.2% (35/94) from an ethnic minority background. A large proportion of participants lived within the two highest deprivation quartiles (74/94, 78.7%). The mean EPDS scores were balanced across the groups (Intervention: mean 17.3, SD 3.0, comparator: 17.5, SD 3.7). A substantial proportion of participants reported thoughts of self-harm on the EPDS and CIS-R questionnaires at baseline (32/94, 34.0%). A diagnosis of severe depressive episode was received by 17/94 (18.0%) participants; moderate depressive episode by 50/94 (53.2%) participants; mild depressive episode by 15/94 (16.0%) participants and mixed anxiety and depressive disorder by 12/94 (12.8%) participants. The spread of these diagnoses was balanced across the groups (Appendix Figure 34).

Table 4: Baseline characteristics of randomised participants

Characteristic [range of possible values]	Intervention N (%) (n=47)	Comparator N (%) (n=47)
Age (years) mean (SD)	31.7 (5.3)	29.3 (5.7)
Height (m) mean (SD)	1.6 (0.1)	1.6 (0.1)
Weight (kg) mean (SD)	76.2 (13.3)	76.8 (17.0)
BMI (kg/m ²) mean (SD)	28.8 (5.0)	28.6 (5.8)
Smoker	9/46 (19.6)	9/47 (19.1)
Experiencing long term illness	7/47 (14.9)	7/47 (14.9)
Ethnic origin:		
White	27 (57.4)	32 (68.1)
Mixed	3 (6.4)	2 (4.3)
Indian	3 (6.4)	3 (6.4)
Pakistani	7 (14.9)	5 (10.6)
Bangladeshi	1 (2.1)	0 (0.0)
Black-African	2 (4.3)	1 (2.1)
Black-Caribbean	0 (0.0)	1 (2.1)
Chinese	1 (2.1)	0 (0.0)
Other	3 (6.4)	3 (6.4)
Employment status:		
Paid	17/46 (37.0)	25/47 (53.2)
Self employed	0/46 (0.0)	2/47 (4.3)
Unemployed	7/46 (15.2)	5/47 (10.6)
Student	1/46 (2.2)	2/47 (4.3)
Looking after home/family	20/46 (43.5)	13/47 (27.7)
Sick/disabled	0/46 (0.0)	0/47 (0.0)
Other	1/46 (2.2)	0/47 (0.0)
IMD quartile 1 (least deprived)	3 (6.4)	4 (8.5)
2	7 (14.9)	6 (12.8)
3	13 (27.7)	9 (19.1)
4 (most deprived)	24 (51.1)	28 (59.6)
Years living in area median (IQR)	5.0 (2.0 to 10.8)	4.0 (2.0 to 10.0)
Number of children mean (SD)	2.2 (1.2)	2.2 (1.4)
Number with children aged 2-5 years	25/47 (53.2)	22/47 (46.8)
Number with children aged over 5 yrs	14/47 (29.8)	12/47 (25.5)
Other occupants: Husband	40/45 (88.9)	41/47 (87.2)
Relative	7/30 (23.3)	6/26 (23.1)
Step-children	1/25 (4.0)	2/23 (8.7)

Characteristic [range of possible values]	Intervention N (%) (n=47)	Comparator N (%) (n=47)
Age of baby at randomisation (days) mean (SD)	117.3 (26.5)	121.8 (27.9)
Type of delivery:		
Normal vaginal	27/47 (57.4)	31/46 (67.4)
Instrumental vaginal	6/47 (12.8)	6/46 (13.0)
Elective caesarean	7/47 (14.9)	5/46 (10.9)
Emergency caesarean	7/47 (14.9)	4/46 (8.7)
Currently breastfeeding	16/47 (34.0)	20/46 (43.5)
Have someone you can rely on for practical help at home	35/47 (74.5)	36/46 (78.3)
Have contact with local people with a baby	22/47 (46.8)	27/44 (61.4)
Have someone to talk to if upset or concerned	39/47 (83.0)	35/46 (76.1)
Get as much help as you need from your partner [0-10] mean (SD)	5.4 (3.3)	5.7 (2.7)
EPDS [0-30] mean (SD)	17.3 (3.0)	17.5 (3.7)
EPDS score 13-16	20 (42.6)	20 (42.6)
17+	27 (57.2)	27 (57.4)
Prescribed antidepressants before or during pregnancy	18/39 (46.2)	12/37 (32.4)
Currently at risk of self-harm	14 (29.8)	18 (38.3)
Currently taking antidepressants	10/46 (21.7)	10/47 (21.3)
Currently having counselling/psychological support	3/46 (6.5)	10/47 (21.3)
Currently taking antidepressants plus having counselling/psychological support	1/47 (2.1)	6/47 (12.8)
Exercise pre-pregnancy (hours per week, median (IQR))	0.0 (0.0 to 5.0)	0.0 (0.0 to 4.0)

BMI: Body Mass Index

EPDS: Edinburgh Postnatal Depression Scale

IMD: Index of Multiple Deprivation. This is calculated by combining levels of deprivation in income, employment, health and disability, education, skills and training, barriers to housing and services, crime and living environment (239).

M: metre

Kg: kilogram

IQR: interquartile range

Table 5: Baseline assessments

Assessments [range of possible values]	Intervention Mean (SD) (n=47)	n	Comparator Mean (SD) (n=47)	n
Vitality scale [1-7]	2.8 (0.7)	46	2.8 (0.6)	47
Physical health and well-being (PCS-12) [0-100]	52.7 (7.9)	47	51.0 (9.4)	47
Mental health and well-being (MCS-12) [0-100]	30.8 (7.9)	47	31.2 (7.9)	47
Health related quality of life (EQ-5D) [-0.59 - 1.00]	0.7 (0.2)	47	0.7 (0.2)	46
Body image [10-40]	22.5 (4.4)	44	22.0 (3.9)	41
Social support [8-24]	20.1 (4.0)	47	19.5 (4.4)	47
Social support and exercise				
Family participation [10-50]	15.1 (6.5)	44	14.9 (5.4)	44
Family rewards [3-15]	3.4 (1.2)	45	3.2 (0.8)	45
Friends participation [10-50]	13.0 (5.6)	44	12.8(4.3)	44
Self-efficacy for exercise (SEHS)				
SEHS Sticking to it [8-40]	20.9 (5.9)	37	19.7 (4.8)	40
SEHS Making time for it [4-20]	13.0 (3.4)	35	11.8 (2.8)	36
Assessments	Intervention Median (IQR)	n	Comparator Median (IQR)	n
IPAQ				
Vigorous (MET-mins/wk)	0.0 (0.0 to 0.0)	47	0.0 (0.0 to 0.0)	4
Moderate (MET-mins/wk)	0.0 (0.0 to 360.0)	46	0.0 (0.0 to 0.0)	46
Walking (MET-mins/wk)	495.0 (198.0 to 1386.0)	43	585.8 (99.0 to 1287.0)	44
Total (MET-mins/wk)	918.0 (396.0 to 3108.0)	43	594.0 (99.0 to 1668.0)	43
Sitting (hrs/day)	4.0 (2.3 to 6.0)	32	4.0 (3.0 to 5.0)	28

SEHS: The Self-efficacy and Exercise Habits Survey

PCS-12: Physical Component Summary of the SF-12 Short Form Health Survey

MCS-12: Mental Component Summary of the SF-12 Short Form Health Survey

EQ-5D: The EuroQoL 5D questionnaire

IPAQ: International physical activity questionnaire

MET: Metabolic equivalent task

MET-mins/wk: minutes of activity per week at the specified MET level of intensity

For those assessments where the range has been stated, a higher number represents a greater degree of the outcome.

3.4.3 Participants at follow up

Primary outcome data were provided by 85/94 (90.4%) participants at six months post randomisation and 79/94 (84.0%) at 12 months post randomisation. Those lost to follow up at the primary outcome point (six months) tended to be marginally younger than those who completed follow up, but were similar in terms of their group allocation, mean baseline EPDS score, deprivation quartile (239) and ethnicity (Table 6).

Rates of breastfeeding, thoughts of self-harm, use of antidepressants and counselling at six and 12 months post randomisation are provided in Table 7. Marginally more participants were receiving antidepressants in the comparator group 10/42 (23.8%) than the intervention group 8/42 (19.1%) at six and 12 months post randomisation (comparator: 12/38, 31.6%, intervention: 7/41, 17.1%) (Table 8).

Table 6: Baseline characteristics of those who provided primary outcome data and those lost to follow up

Characteristic	Followed up N (%) (n=85)	Lost to follow up N (%) (n=9)
Randomised to intervention	43 (50.6)	4 (44.4)
Randomised to usual care	42 (49.4)	5 (56.6)
Age (years) mean (SD)	30.8 (5.6)	27.3 (4.3)
EPDS mean (SD)	17.5 (3.4)	17.0 (3.1)
IMD quartile		
1 (least deprived)	7 (8.2)	0.0 (0.0)
2	11 (12.9)	2 (22.2)
3	19 (22.4)	3 (33.3)
4 (most deprived)	48 (56.5)	4 (44.4)
Ethnic origin		
White	52 (61.2)	7 (77.8)
Mixed	5 (5.9)	0.0 (0.0)
Indian	5 (5.9)	1 (11.1)
Pakistani	11 (12.9)	1 (11.1)
Bangladeshi	1 (1.2)	0.0 (0.0)
Black-African	3 (3.5)	0.0 (0.0)
Black-Caribbean	1 (1.2)	0.0 (0.0)
Chinese	1 (1.2)	0.0 (0.0)
Other	6 (7.1)	0.0 (0.0)

IMD: Index of Multiple Deprivation

Table 7: Rates of breastfeeding, antidepressant and counselling use and self-harm ideation at follow up

	Follow up (months)	Intervention N (%)	Comparator N (%)
Breastfeeding	6	8/41 (19.5%)	10/42 (23.8%)
	12	7/41 (17.1%)	6/37 (16.2%)
Reported thoughts of self-harm	6	4/47 (8.5%)	6/47 (12.8%)
	12	2/44 (4.6%)	3/44 (6.8%)
Receiving antidepressants	6	8/42 (19.1%)	10/42 (23.8%)
	12	7/41 (17.1%)	12/38 (31.6%)
Receiving counselling	6	5/42 (11.9%)	9/42 (21.4%)
	12	7/41 (17.1%)	5/38 (13.2%)
Receiving antidepressants and counselling	6	3/42 (7.1%)	4/42 (9.5%)
	12	3/41 (7.3%)	5/38 (13.2%)

3.4.4 Primary outcome

At six months post randomisation, the mean difference in EPDS score between the intervention and comparator groups was 2.04 EPDS points when adjusted for baseline EPDS levels, revealing a greater decrease in mean EPDS levels in the intervention. This difference did not quite reach statistical significance: -2.04 (95% CI: -4.18 to 0.10) $p=0.06$. When adjusted for the pre-specified covariates of baseline EPDS, baseline age, weight and ethnicity the mean difference in EPDS was 2.26 points (95% CI: -4.51 to -0.02, $p=0.048$). At 12 months post randomisation, there was no statistically significant difference in mean EPDS score between the groups, either in the minimally adjusted analysis (-0.55 95% CI: -2.90 to 1.80, $p=0.64$) or the fully adjusted analysis (-1.18, 95% CI: -3.64 to 1.27, 0.34) (Table 9).

3.4.5 Secondary outcomes

There were no significant differences in mean weight, BMI, physical and mental health and well-being, health related quality of life, body image, vitality, social support for exercise and self-efficacy for exercise scores between the groups at six or 12 months post randomisation, through either minimally or fully adjusted analysis (Table 9). Significantly higher mean levels of social support were reported by the intervention than the comparator group at six months post randomisation in both the minimally adjusted (2.11, 95% CI: 0.72 to 3.49, $p=0.003$) and fully adjusted (2.24, 95% CI: 0.83 to 3.65, $p=0.002$) analyses. This difference was no longer statistically significant at 12 months post randomisation: minimally adjusted analysis 1.28 (-0.39 to 2.95), $p=0.13$, fully adjusted analysis 1.49 (-0.22 to 3.20), $p=0.09$ (Table 8).

Table 8: Six and 12 month follow up outcome data

		Intervention		Comparator					
	Follow up	Mean (SD)	N	Mean (SD)	N	Difference in adjusted* means (95% CI)	p value	Difference in adjusted** means (95% CI)	p value
Primary outcome									
EPDS	6	12.51 (5.46)	43	14.67 (4.86)	42	-2.04 (-4.18 to 0.10)	0.06	-2.26 (-4.51 to -0.02)	0.048
	12	12.02 (5.29)	41	12.55 (5.17)	38	-0.55 (-2.90 to 1.80)	0.64	-1.18 (-3.64 to 1.27)	0.34
Secondary outcomes									
Weight (kg)	6	75.06 (13.20)	42	77.36 (17.36)	42	0.38 (-1.91 to 2.67)	0.74	0.79 (-1.57 to 3.15)	0.51
	12	75.40 (16.05)	41	77.11 (18.39)	38	1.16 (-3.52 to 5.85)	0.62	0.56 (-4.38 to 5.49)	0.82
BMI (kg/m ²)	6	28.61 (5.38)	42	28.61 (5.98)	41	0.22 (-0.65 to 1.09)	0.61	0.26 (-0.64 to 1.15)	0.57
	12	28.75 (6.99)	41	28.76 (6.20)	37	0.63 (-1.31 to 2.56)	0.52	0.19 (-1.85 to 2.24)	0.85
Physical health and well-being (PCS-12)	6	51.34 (9.02)	42	51.59 (8.48)	42	-1.11 (-4.45 to 2.24)	0.51	-0.06 (-3.17 to 3.06)	0.97
	12	52.16 (9.16)	40	51.61 (8.57)	38	-0.58 (-3.95 to 2.79)	0.73	-0.41 (-4.01 to 3.19)	0.82
Mental health and well-being (MCS-12)	6	41.45 (9.99)	42	37.90 (10.30)	42	3.38 (-0.91 to 7.67)	0.12	3.46 (-1.11 to 8.01)	0.14
	12	41.60 (12.13)	41	41.02 (12.36)	38	0.65 (-4.96 to 6.25)	0.82	2.26 (-3.65 to 8.17)	0.45

		Intervention		Comparator					
	Follow up	Mean (SD)	N	Mean (SD)	N	Difference in adjusted* means (95% CI)	p value	Difference in adjusted** means (95% CI)	p value
Health related quality of life (EQ-5D)	6	0.78 (0.21)	41	0.72 (0.22)	41	0.07 (-0.02 to 0.15)	0.14	0.07 (-0.02 to 0.16)	0.13
	12	0.81 (0.21)	40	0.78 (0.23)	38	0.05 (-0.05 to 0.15)	0.31	0.06 (-0.04 to 0.16)	0.20
Body image	6	23.73 (5.20)	40	22.53 (4.10)	40	0.53 (-1.09 to 2.14)	0.52	0.60 (-1.07 to 2.28)	0.47
	12	24.43 (5.18)	37	23.94 (4.83)	36	0.63 (-1.31 to 2.56)	0.52	-0.04 (-2.45 to 2.52)	0.98
Vitality	6	3.53 (0.95)	39	3.18 (0.87)	40	0.36 (-0.06 to 0.78)	0.09	0.41 (-0.04 to 0.85)	0.08
	12	3.70 (1.11)	41	3.48 (1.14)	38	0.28 (-0.25 to 0.81)	0.30	0.48 (-0.08 to 1.04)	0.09
Social support	6	20.80 (3.59)	41	18.93 (4.93)	41	2.11 (0.72 to 3.49)	0.003	2.24 (0.83 to 3.65)	0.002
	12	20.80 (3.68)	40	19.73 (5.14)	37	1.28 (-0.39 to 2.95)	0.13	1.49 (-0.22 to 3.20)	0.09
Social support for exercise: Family participation	6	16.87 (7.44)	38	15.48 (6.54)	40	2.23 (-0.95 to 5.41)	0.17	2.00 (-1.42 to 5.41)	0.25
	12	16.88 (7.87)	41	18.67 (9.53)	36	-1.18 (-5.23 to 2.88)	0.57	-0.72 (-5.02 to 3.58)	0.74
Social support for exercise: Family rewards and punishment	6	3.60 (1.68)	40	3.55 (1.30)	40	0.11 (-0.44 to -0.67)	0.69	0.16 (-0.43 to 0.76)	0.59
	12	3.46 (1.47)	41	4.03 (1.65)	38	-0.55 (-1.06 to -0.02)	0.09	-0.34 (-0.99 to 0.31)	0.30

	Intervention		Comparator						
	Follow up	Mean (SD)	N	Mean (SD)	N	Difference in adjusted* means (95% CI)	p value	Difference in adjusted** means (95% CI)	p value
Social support for exercise: Friend participation	6	16.57 (9.08)	37	14.75 (8.11)	40	1.62 (-2.10 to 5.35)	0.39	2.18 (-1.76 to 6.11)	0.27
	12	14.55 (7.13)	38	16.73 (8.36)	37	-2.79 (-6.32 to 0.73)	0.12	-2.23 (-5.92 to 1.56)	0.23
Self-efficacy for exercise SEHS sticking to it	6	22.09 (7.93)	33	20.22 (6.89)	32	2.41 (-1.99 to 6.81)	0.28	3.27 (-1.72 to 8.25)	0.19
	12	23.29 (8.55)	31	22.03 (8.24)	30	0.97 (-3.91 to 5.85)	0.69	1.96 (-3.22 to 7.15)	0.45
Self-efficacy for exercise SEHS making time for it	6	12.21 (4.26)	34	11.07 (3.38)	30	0.27 (-2.04 to 2.58)	0.81	0.91 (-1.53 to 3.36)	0.46
	12	12.81 (3.79)	31	12.15 (4.35)	26	-0.003 (-2.45 to 2.44)	1.00	0.41 (-2.29 to 3.11)	0.76

Follow up: months from point of randomisation

* Adjusted for baseline outcome and baseline EPDS

** Adjusted for baseline outcome and baseline age, weight, ethnicity and EPDS

EPDS: Edinburgh Postnatal Depression Scale

BMI: body mass index

Kg: Kilograms

kg/m²: kilograms per metre squared

PCS-12: Physical Component Summary of the SF-12 Short Form Health Survey

MCS-12: Mental Component Summary of the SF-12 Short Form Health Survey

EQ-5D: EuroQol 5D questionnaire

SEHS: The Self-efficacy and Exercise Habits Survey

3.4.6 Improved and recovered participants

The proportion of mothers who had recovered from PND by six months post randomisation was significantly greater in the intervention than the comparator group. Intervention: 64.5%, comparator: 23.8% (difference: 22.7%, 95% CI: 3.0% to 42.4%, p= 0.027.) This difference was no longer statistically significant at 12 months post randomisation (difference 16.6%, 95% CI: -5.11% to 38.36%, p= 0.114.) There were no significant differences in the proportion of mothers who improved in their depressive symptoms at six or 12 months post randomisation in either group (Table 9).

Table 9: Proportions improved and recovered participants according to the EPDS

Outcome	Intervention	Comparator	Difference (95% CI)	p value
Improved at 6 months post randomisation	6/43 (13.95%)	8/42 (19.05%)	-5.90% (-20.85% to 10.66 %)	0.56
Recovered at 6 months post randomisation	20/43 (46.51%)	10/42 (23.81%)	22.70% (3.00% to 42.40%)	0.03
Improved at 12 months post randomisation	5/41 (12.20%)	5/38 (13.16%)	-0.96% (-15.65% to 13.73 %)	1.00
Recovered at 12 months post randomisation	23/41 (56.10%)	15/38 (39.47%)	16.62% (-5.11% to 38.36%)	0.11

Improved: EPDS score initially above 12, decreased by 4 or more points, still above 12 (237)

Recovered: EPDS score initially over 12, dropped by 4 or more points to 12 or below (237)

3.4.7 Physical activity: the IPAQ

Data provided by the IPAQ were found to be skewed; a Mann Whitney U test was used to test for differences in the distribution of this outcome. The median increase in MET minutes per week (mins/wk) of total exercise between baseline and six months post randomisation was significantly greater in the comparator group than the intervention group. Intervention: median 24.0, IQR: -602.0 to 870.0, comparator: median 655.0, IQR: 39.3 to 1743.0, $p=0.01$. The median change in MET mins/wk of moderate exercise between baseline and 12 months post randomisation differed significantly between groups. Intervention: median 0.0, IQR -300.0 to 0.0, comparator: median 0.0, IQR 0.0 to 160.0, $p=0.045$.

There were no significant differences between the groups in the distribution of the following: the change in total MET minutes of exercise between baseline and 12 months post randomisation; the change in MET minutes of vigorous exercise between baseline and six or baseline and 12 months; the change in MET minutes of moderate exercise between baseline and 6 months, the change in MET minutes of walking between baseline and six or baseline and 12 months and the change in minutes of sitting between baseline and six or baseline and 12 months post randomisation (Table 10).

Table 10: Difference between groups in change in minutes of exercise (IPAQ) from baseline to follow up

Exercise category	Period of change from baseline	Change in minutes of exercise median (IQR)				p value
		Intervention	N	Comparator	N	
IPAQ total (MET mins/wk)	0 to 6 months	24.0 (-602.0 to 870.0)	33	655.0 (39.3 to 1743.0)	40	0.01
	0 to 12 months	-33.0 (-432.0 to 693.0)	37	130.0 (-247.5 to 777.0)	35	0.39
IPAQ vigorous (MET mins/wk)	0 to 6 months	0.0 (0.0 to 660.0)	38	0.0 (0.0 to 720.0)	41	0.59
	0 to 12 months	0.0 (0.0 to 480.0)	41	0.0 (0.0 to 0.0)	37	0.10
IPAQ moderate (MET mins/wk)	0 to 6 months	0.0 (-150.0 to 390.0)	38	0.0 (0.0 to 540.0)	42	0.32
	0 to 12 months	0.0 (-300.0 to 0.0)	40	0.0 (0.0 to 160.0)	37	0.045
IPAQ walking (MET mins/wk)	0 to 6 months	0.0 (-441.4 to 445.5)	34	0.0 (-387.8 to 594.0)	41	0.70
	0 to 12 months	-66.0 (-297.0 to 396.0)	37	0.0 (-412.5 to 396.0)	37	0.54
Sitting (hrs/day)	0 to 6 months	1.0 (-2.38.0 to 3.0)	24	-1.0 (-2.8 to 2.0)	24	0.40
	0 to 12 months	0.0 (-2.4 to 1.6)	24	-0.8 (-2.0 to 2.8)	24	0.94

0 months: baseline

6 months: six months post randomisation

12 months: 12 months post randomisation

IPAQ: International physical activity questionnaire

MET-mins/wk: minutes of activity per week at the specified MET level of intensity

hrs/day: hours per day

3.4.8 Physical activity: exercise diaries

Out of a possible 235 diary entries (47 intervention participants x 5 diaries), 162 were completed (68.9%). At least three diaries were completed by 87.2% (41/47) of intervention participants. In the diaries, participants reported completing a mean of 203.1 (SD 209.4) minutes of combined moderate and vigorous exercise per week. Mean (SD) levels of combined moderate and vigorous exercise per week increased over the course of the intervention from diaries one to five: diary one: 161.1 minutes (165.2), diary two: 217.5 minutes (194.8); diary three: 203.2 minutes (253.9); diary four: 222.5 minutes (217.4); diary five: 245.0 minutes (217.8) (Table 11). The most common types of exercise reported were; brisk walking with the pram, brisk walking without the pram, exercise DVDs, Wii fit workouts, jogging and swimming.

Table 11: Exercise diaries: combined moderate and vigorous physical activity

Exercise diary	N	Mean (SD) minutes of moderate and vigorous exercise
1 (intervention week 4)	41	161.1 (165.2)
2 (intervention week 8)	41	217.5 (194.8)
3 (intervention week 12)	41	203.2 (253.9)
4 (intervention week 16)	23	222.5 (217.4)
5 (intervention week 20)	16	245.0 (217.8)

3.4.9 Physical activity: the Actiheart

Of the 94 participants, 56 were randomised to wearing the Actiheart (29 intervention participants and 27 comparator participants), one of whom refused to wear the device at baseline. Of the 55 participants who wore the device at baseline, 18/55 (32.7%) provided no follow up data; 16 due to experiencing a skin reaction to the electrodes which attached the Actiheart to the skin; one due to providing follow up by post; one due to providing no follow up data. Thirteen participants (13/55, 23.6%) provided data only at baseline and six months post randomisation (10 due to skin sensitivity at six months post randomisation; three due to not completing follow up). Two participants (2/55, 3.6%) provided data only at baseline and 12 months post randomisation due to providing postal follow up data at six months post randomisation. Only 22/55 (40.0%) participants provided Actiheart data at baseline, six and 12 months post randomisation. Issues of skin sensitivity, rashes, soreness and discomfort were not reported to the same degree during the pilot work conducted in a general female population prior to this RCT (chapter two), indicating that skin sensitivity relating to electrodes may particularly affect women in the postnatal period.

A total of 114 recordings from baseline, six and 12 months post randomisation were provided by participants. Of these 86 were greater than 24 hours in duration and therefore usable (Table 12). Of the 86 usable recordings, 51 had accurate heart rate and accelerometry data. For the 35 with accurate accelerometry data but incomplete heart rate data, a scaling factor was applied to

the accelerometry data before physical activity energy expenditure (PAEE) was calculated (Table 13).

Table 12: Usable Actiheart recordings at baseline, six and twelve month follow up

Time point	Number of usable recordings	
	Intervention (n=29)	Comparator (n=27)
Baseline	23	19
6 months post randomisation	13	11
12 months post randomisation	12	8

Table 13: Mean minutes of daily physical activity energy expenditure (PAEE)

Time point	Intervention		Comparator	
	N	Mean (SD)	N	Mean (SD)
Baseline	23	49.8 (20.9)	19	48.2 (22.5)
6 months post randomisation	13	38.2 (17.1)	11	53.9 (27.9)
12 months post randomisation	12	45.2 (18.6)	8	40.2 (9.5)

PAEE: physical activity energy expenditure

As the PAEE data were found to be normally distributed, a T-Test was performed to investigate the difference in change in PAEE from baseline to six months and baseline to 12 months post randomisation between the groups. A significant difference was found between the decrease in PAEE in the intervention group and the increase in the comparator group between baseline and six months post randomisation. There was no significant difference between the groups in the change in PAEE from baseline to 12 months post randomisation (Table 14). The mean (SD) minutes per day spent performing light, moderate and vigorous exercise of the intervention and comparator groups were calculated. Only recordings with accurate accelerometry and heart rate data were used in these calculations in order for the data to be comparable (Table 15).

Table 14: Differences between groups in change in physical activity energy expenditure

Group	N	Mean change in PAEE (SD)	Mean difference in change in PAEE (95% CI)	P value
Intervention Baseline to 6 months post randomisation	13	-5.84 (8.19)	20.51 (5.61, 35.41)	0.009
Comparator Baseline to 6 months post randomisation	11	14.67 (24.40)		
Intervention Baseline to 12 months post randomisation	12	5.20 (14.13)	-5.27 (-17.13, 6.60)	0.360
Comparator Baseline to 12 months post randomisation	8	-0.06 (8.96)		

PAEE: physical activity energy expenditure

Table 15: Daily light, moderate and vigorous activity across groups

			Mean (SD) minutes of activity per day		
Time point	Group	N	light activity	moderate activity	vigorous activity
Baseline	Intervention	12	535.1 (101.9)	101.8 (80.8)	2.7 (2.6)
	Comparator	14	449.7 (151.5)	55.2 (63.5)	2.1 (2.2)
6 months post randomisation	Intervention	8	345.8 (115.5)	13.5 (11.3)	0.0 (0.0)
	Comparator	4	438.6 (134.6)	15.1 (12.4)	1.6 (3.3)
12 months post randomisation	Intervention	8	412.2 (206.1)	40.3 (27.0)	3.7 (9.5)
	Comparator	5	462.1 (152.3)	19.4 (12.2)	0.3 (0.3)

Table 13 contains different numbers of participants to Table 11 and 12 as only recordings with accurate accelerometry and heart rate data were used in these calculations.

3.4.10 Fidelity to delivery of the intervention

The intervention included two home visits and two telephone support calls from the PAF. Delivery of these components was high with 87.2% (41/47) of participants receiving all four contacts; 91.5% (43/47) receiving at least three contacts; 93.6% (44/47) receiving at least two contacts and 97.9% (46/47) receiving at least one contact.

3.5 Discussion

3.5.1 Exercise interventions for PND

This study found that a facilitated exercise intervention in addition to usual care lead to a greater reduction in depressive symptoms than usual care alone, as measured by the EPDS (23). This reduction, although of a moderate magnitude, did not quite reach statistical significance when adjusted for baseline EPDS, but was statistically significant when adjusted for pre-specified covariates. Substantially more mothers who received the intervention were 'recovered' at six months post randomisation than those in the comparator group. These findings suggest that a facilitated exercise intervention may be an effective adjunctive intervention to usual care, providing support for the hypothesis provided in chapter three, section 3.2.7.2. There was no significant difference in depressive symptoms between the groups at 12 months post randomisation. This is perhaps not surprising when the general course of PND is considered. The incidence of PND is thought to peak six weeks after giving birth (20); over the course of the following year a substantial proportion of women will gradually recover (240). This facilitated exercise intervention was found to provide an additional reduction of 2.04 EPDS points compared to usual care alone.

This effect is smaller than that suggested by a recent systematic review of exercise interventions for PND (101). However, this review incorporated a very small evidence base of five studies (n=238) and reported wide confidence intervals, reducing confidence in their findings (101). It is also relevant that none of the included study populations had a clinical diagnosis of depression. The RCT reported here was the first to require a diagnosis of depression prior to randomisation. If only a single EPDS of ≥ 10 had been required in this trial (as in many previous trials), 436 women would have been eligible rather than 100, giving an indication of the difference between this clinical population and the populations of and previous studies.

This RCT found a significantly greater increase in social support scores among women who received the intervention compared to usual care alone. No other significant differences were found in the other secondary outcomes investigated although this study was not powered to detect a significant difference in secondary outcomes, this should be born in mind when considering the conclusions drawn regarding the secondary outcome of social support in section 3.5.3. The findings of this RCT therefore only partially support the hypothesis stated in chapter three, section 3.2.7.2, that significant improvements would be found in the intervention compared to the comparator group in relation to the secondary outcomes studied.

3.5.2 Previous research

The intervention of the present study was based on the provision of individualised exercise counselling. This design generated a reduction of -2.04 (95% CI: -4.18 to 0.10) EPDS points compared to usual care alone. Previously RCTs with similar

intervention models of individual exercise counselling have been conducted by Da Costa et al. (11), Daley et al. (14), Huang et al. (16), Surkan et al. (18) and Lewis et al. (102), however the magnitude of effect found in the present trial was greater than that reported by any of the previous trials. The present trial was not the largest amongst its predecessors, with both Huang and Surkan having larger samples (n=160 and n=679 respectively) and all trials provided personalised exercise counselling via a series of contacts with the study team (11, 14, 16, 18). The present RCT found a significant improvement in self-efficacy for exercise between the groups at follow up. The previous review by Daley et al. provides support for the premise that interventions designed to enhance social support may be more successful in reducing depressive symptoms than those designed to only encourage exercise (101). However it should be noted that significant increases in self-efficacy for exercise were reported in two previous exercise counselling trials (14, 16), neither of which reported significant decreases in depression in the intervention compared to their comparator groups at follow up.

Five trials have previously been published with markedly different exercise interventions to that of the present study. Interventions consisting of pre-specified exercise regimes were used by Armstrong et al. (13), Heh et al. (15), Robichaud et al. (17), Norman et al. (19) and Haruna et al. (12). Interventions based on pre-specified exercise regimes have recorded a range of effects from no significant effects on depressive symptoms (12, 17, 19) to more moderate, significant effects (13, 15). There is currently insufficient evidence to suggest whether pre-specified exercise regimes or exercise counselling interventions (such as the RCT reported here) may be

more successful in reducing postnatal depressive symptoms. Further research directly comparing different intervention types may be useful.

3.5.3 Exercise interventions and social support

As previously noted, this RCT found a significantly greater increase in social support scores in intervention group compared to those who received usual care alone. The intervention was delivered by a PAF who had had four contacts with the participants (two in person and two support phone calls). The consultations were designed to increase participants' motivation for exercise by encouraging them to consider what they wanted to achieve, why and how they might achieve their goals. This process entailed a substantial component of listening to the participant discuss their current mood, their daily life, their hopes and wishes and the barriers they faced to achieve them. It would seem plausible that such an intervention may increase feelings of social support amongst participants. Previous qualitative research has found that in response to feelings of failure and fear of judgement, mothers with PND will often isolate themselves (122). Receiving non-judgemental support that validates their experiences has been found to be beneficial and much valued by mothers (122). Previous research has highlighted the ability of exercise counselling interventions to provide support and reassurance through a 'therapeutic relationship' with the exercise facilitator (241). The reported benefits of social interaction have been further explored in the qualitative chapter of this thesis (chapter five).

3.5.4 The measurement of physical activity

Due to the apparent unacceptability of the Actiheart accelerometer within this population, the objective measure of physical activity provided too little data of an

acceptable quality to be meaningfully interpreted. The self-reported IPAQ physical activity data were skewed with median scores subject to very wide IQRs. The self-reported data did, however, appear to indicate that the comparator group may have achieved more exercise, in particular moderate intensity exercise. It is relevant that the PAF provided the intervention group with a detailed explanation of what constituted the different intensities of exercise. This explanation was not available to those in the comparator group. It is consequently possible that there was differential reporting of intensity and amount of exercise between the groups at follow up. Previous research has highlighted that overestimation of physical activity can be an issue with self-reported measures (148). It is also possible that intervention contamination took place, with the act of taking part in an exercise trial influencing those in the comparator group to increase their exercise levels. Data from the Actihearts appeared to show that those in the usual comparator group performed significantly more overall physical activity than those in the intervention at six months post randomisation, however, at 12 months intervention participants appeared to be performing more overall physical activity than comparator participants (though the difference was not significant). The Actihearts data should be considered compromised with only 22/55 (40%) participants providing data at six and 12 months post randomisation. Of the 86 usable recordings, 35 had accurate accelerometry data but incomplete heart rate data, reducing the accuracy of the PAEE estimates derived.

Despite the equivocal findings suggested by the self-reported and objective measures of physical activity, data from the intervention participants' exercise

diaries did indicate gradual increases in the mean weekly exercise levels over the intervention period. One consequence of the unreliable exercise data is that despite the finding that those in the exercise intervention had a greater reduction in depressive symptoms than those receiving usual care alone, the mechanisms through which this was achieved remain unclear.

3.5.5 Strengths and limitations

3.5.5.1 *Principal strengths*

This RCT is the first in its field to require a clinical diagnosis of depression or mixed anxiety and depression from a gold standard diagnostic interview prior to randomisation. This trial is therefore the largest RCT of exercise in this clinical population to date. Despite not reaching the intended sample size, this trial did find an effect size greater than that on which the power calculation was based. The study also experienced a very high retention rate, with 90.4% (85/94) of participants providing data for the primary outcome. The sample included a substantial proportion of women with moderate and severe depression, including those with thoughts of self-harm. This is important as such women are particularly in need of treatment.

3.5.5.2 *Recruitment difficulties*

This RCT was underpowered, recruiting only 94 participants rather than the 208 (166 with a 20% drop out rate) suggested to be necessary by the sample size calculation. A series of additional recruitment methods were introduced during the trial in order to improve the recruitment rate, the most successful of which included the alteration of the terminology in the participant literature, expansion to further

research sites and the inclusion of mothers with diagnoses of anxiety and depression within the eligibility criteria. For further discussion of the alterations to recruitment methods see chapter four.

Of the 9767 study information packs posted to mothers, only 1150 (11.7%) were returned. It could be presumed that as the study packs were sent to all new mothers, only 7-13% of whom would be likely to have PND (1), a return rate of around 11.7% could be expected for a study described in participant literature as looking at the effects of exercise on mood after giving birth. However, of the 1150 mothers who returned the first EPDS, only 100 received a diagnosis of depression or mixed anxiety and depression. It therefore seems likely that many mothers with depressive symptoms chose not to respond to the study invitation, raising questions about the generalisability of the study findings.

3.5.5.3 Recruitment from different ethnic backgrounds

This study recruited a high proportion of women from ethnic minority backgrounds (37.2%) and from socioeconomically deprived areas (78.7% from the two quartiles of greatest deprivation), who are historically difficult to reach populations in research. However, 46.9% of the population of Birmingham are from ethnic minorities indicating that people from white ethnic backgrounds were still disproportionately recruited to this trial (190); more adaption is clearly needed to make such studies relevant and appropriate to mothers from ethnic minorities.

3.5.5.4 Randomisation

Randomisation to the intervention and comparator groups was stratified by second EPDS score (13-16 and 17+) to ensure a balance of depression severities across the

study groups. Randomisation could have been stratified by other factors such as age, weight and ethnicity, however, based on the existing body of RCTs it was felt that there was insufficient evidence for the effect of these variables on the outcome of exercise trials in depressed mothers. However, as there was some evidence of the influence of these factors on depression and exercise in other depressed populations, they were pre-specified as covariates for the secondary analysis of the RCT (see chapter three, section 3.3.22.3).

3.5.5.5 *Methods of analysis*

An analysis of covariance (ANCOVA, least squares estimation) was conducted for the primary and secondary outcomes, at the primary outcome point of six months post randomisation. This method of analysis was then repeated at 12 months post randomisation. Other more advanced methods could have been used such as a repeated measures analysis of variance (ANOVA) or repeated measures mixed modelling; the simpler ANCOVA approach was chosen primarily for ease of interpretation. A repeated measures ANOVA would have indicated whether there was an overall change in the outcome between baseline and 12 months post randomisation, two additional post-hoc tests would have been required to estimate the difference between study groups at six months and 12 months post randomisation. A disadvantage of the repeated measures ANOVA is that cases are excluded from the analysis where one or more points of follow up data are missing. Alternatively, mixed modelling of repeated measures allows for the inclusion of data where one or more points of follow up are missing, thus maximising the usage of data compared to a repeated measures ANOVA. The analyses of the PAM-PeRS trial undertaken by the trial statistician was ANCOVA (with maximum

likelihood estimation) for the primary point of follow up and repeated measures mixed model analysis utilising all time points for the secondary point of follow up. The results of these different approaches to analysis were similar and did not change the conclusions drawn:

- Difference in adjusted EPDS means at six months (95% CI) p value
(adjusted for baseline EPDS)

ANCOVA (least squares estimation): -2.04 (-4.18 to 0.10) 0.06

ANCOVA (maximum likelihood estimation): -2.04 (-4.11 to 0.03) 0.053

- Difference in adjusted EPDS means at six months (95% CI) p value
(adjusted for baseline EPDS, age, weight and ethnicity)

ANCOVA (least squares estimation): -2.26 (-4.51 to -0.02) 0.048

ANCOVA (maximum likelihood estimation): -2.26 (-4.36 to -0.16) 0.035

- Difference in adjusted EPDS means at 12 months (95% CI) p value
(adjusted for baseline EPDS)

ANCOVA (least squares estimation): -0.55 (-2.90 to 1.80); 0.64

Repeated measures mixed model analysis: -0.95 (-3.16 to 1.25) 0.40

- Difference in adjusted EPDS means at 12 months (95% CI) p value
(adjusted for baseline EPDS, age, weight and ethnicity)

ANCOVA (least squares estimation): -1.18 (-3.64 to 1.27); 0.34

Repeated measures mixed model analysis: -1.39 (-3.69 to 0.92) 0.24

3.5.5.6 *Exercise data*

Perhaps the most significant limitation of this RCT was the lack of reliable exercise data generated by the measures used. This shortfall resulted in a lack of clarity regarding the potential mechanisms through which the intervention caused a reduction in depressive symptoms in this population. In view of the discomfort raised by women wearing the Actiheart during the pilot trial (chapter two, section 2.6.3), other devices such as waist or wrist mounted accelerometers may have proved more acceptable. Though the data they provide may be less accurate due to the lack of heart rate data, their acceptability might have enabled the collection of a greater volume of data, from which evidence based conclusions could have been formed about the levels of exercise within the intervention and comparator arms. This would have enabled greater exploration of the mechanisms behind the effects on depression seen in this RCT.

It is also relevant that this trial recruited currently 'inactive' mothers. This eligibility criterion was based on an assessment of their previous week's activity. It is possible that the previous week may not have been representative of the mothers' overall activity in the postnatal period, introducing the possibility of bias.

3.5.5.7 *The effectiveness exercise*

Greater improvement in depressive symptoms was seen in the intervention than the comparator arm of this RCT, however this difference was only significant when adjusted for pre-specified covariates. In view of the lack of clarity over the level of exercise performed by the participants in this study, it is possible that mothers were not performing the recommended 30 minutes of moderate exercise 3-5 times a

week. It has been found that the mental health benefits of exercise may be related to their intensity (88, 89), therefore placing more emphasis on the moderate nature of exercise may have improved the effectiveness of this intervention. Early indications have also been reported that anaerobic exercise may be of significant benefit to those with depression (28). A combination of aerobic and anaerobic exercise recommendations may therefore also have improved the effectiveness of this RCT. Careful medical advice would have to be sought when advising women in the postnatal period on performing anaerobic exercise in view of the risk of pelvic organ prolapse due to weakening of the pelvic floor muscles. Such exercise may be more appropriate later in the postnatal period.

3.5.6 Clinical implications and further research

This research suggested that exercise may be effective in reducing depressive symptoms in clinically depressed postnatal women, though the mechanisms of the effect are unclear. When conducting further research it is important to note that Actiheart accelerometers, although the gold standard of accuracy in recording physical activity data, may not be the most appropriate device within this population. A possible increase in skin sensitivity after giving birth indicated that wrist or waist mounted accelerometers, though less scientifically advanced, may be more acceptable. If subjective measures such as the IPAQ are to be used, it should be borne in mind that the standard reference activities provided (such as fast bicycling, digging and doubles tennis) may not be entirely appropriate for postnatal women.

Trials designed to explore the relative influence of social support and exercise may also be useful in determining the mechanisms behind exercise interventions. A four arm RCT with three intervention arms; exercise within the home; exercise in a peer group; peer group social meetings and a control group may be an appropriate way of investigating the mechanisms behind exercise interventions. Previous research has focused on interventions of differing format and intensity, from light exercise such as yoga (242); to moderate aerobic exercise sessions (13, 17); to combined cardiovascular and strength exercise sessions (19); to self-determined exercise after exercise counselling (14, 16, 18). Direct comparison between interventions of differing type and intensity would be valuable in determining whether these factors are related to the effectiveness of exercise in reducing depressive symptoms.

In order to assess whether exercise is an effective treatment for PND, it is advisable for future research to be conducted in clinically diagnosed populations. Previous research has broadly been conducted within two different populations; general postnatal populations (12, 18, 19) and populations indicating a risk of depression on a screening questionnaire (11, 13-17). Although such studies provide evidence of the effect of exercise on depressive symptoms, this is distinct from the effectiveness of exercise as a treatment for depression within a clinical population.

3.6 Conclusions

Exercise interventions may be effective in reducing depressive symptoms in those with PND. Such interventions may have the potential to provide a range of benefits in the postnatal period, including improved levels of social support. However, a lack

of certainly should be noted regarding these conclusions as the effect of exercise on depression reported in this RCT was only significant when adjusted for pre-specified covariates and the study was underpowered. Further RCTs with larger populations using acceptable objective measures of exercise, would be useful in determining the effectiveness of exercise interventions with greater certainty.

CHAPTER FOUR

4. RECRUITMENT TO A RANDOMISED CONTROLLED TRIAL OF EXERCISE FOR PND

4.1 Introduction

In chapter three, an RCT of an exercise intervention for PND was reported.

Recruitment of mothers to this trial proved challenging. The power calculation indicated that a sample size of 208 women with PND (166 women with 25% loss to follow up) was required to detect a difference of 1.76 EPDS units (23) between groups at six month follow up (with 80% power and 5% significance) (234). By the conclusion of the two year recruitment period only 94 women had been randomised. In this chapter, the difficulties of recruitment to mental health trials, in particular those with depressed postnatal populations, will be explored. An account of the changes made to the present RCTs recruitment methods and subsequent effects on recruitment rate, will then be discussed.

4.1.1 Recruitment of participants to mental health trials

Randomisation of sufficient participants to a study is vital if reliable conclusions are to be drawn from the data. If the target sample size, based on a power calculation, is not achieved it cannot be concluded with certainty whether or not a statistically significant effect is present. Lower than expected recruitment also raises the possibility that the study population differs systematically from those not recruited. If this is the case, those randomised may respond in a particular way to an intervention, which may not be representative of the population a trial was designed

to study. Such factors can threaten the external validity and generalisability of a trial (243).

Traditionally, recruitment to mental health trials has been found to be challenging. A review of participation in mental health research was conducted by Woodall et al. in 2010 (244). Forty nine studies were included in the review, covering areas such as dementia, schizophrenia, depression and bipolar disorder. Many potential barriers to recruitment were highlighted (244). A lack of acceptance of diagnoses was reported to be a key obstacle to engagement with research (244). This rejection of mental health related diagnoses stemmed from a lack of understanding of such conditions, a denial of the condition on an emotional level and the inhibitory effect of stigma (244). Similarly, the stigma attached to PND, a denial of the condition due to feelings of shame and concern that disclosure may lead to children being taken away, have been reported to discourage mothers from accepting the possibility of having PND and discussing their needs with health professionals (245).

Expanding on their previous research, in 2011 Woodall et al. conducted interviews regarding non-participation in trials with 26 individuals experiencing an episode of psychosis for the first time (246). The authors reported that a patient's conceptualisation of mental illness can differ from that which they feel is being implied by a researcher (246). In particular, some patients reported a belief that due to the many different factors (including social and situational) that were seen to cause symptoms in mental health conditions, scientific research could be of no benefit to them (246). This issue may be especially pertinent in PND, as attributing symptoms such as tiredness and low mood to situational factors, such as exhaustion

after giving birth and looking after a new baby, may deter mothers from believing that they could benefit from medical or scientific intervention.

4.1.2 Recruitment to a postnatal depression trial

Recruitment of women with PND into trials has many potential challenges.

Qualitative research by Whitton et al. into the help-seeking behaviour of depressed women highlighted their reluctance to associate their symptoms with the condition of PND (124). All participants recruited by Whitton et al. completed the CIS-R diagnostic interview, receiving a diagnosis of depression (124). Despite 97% of participants reporting feeling worse than usual, only 32% attributed their symptoms to PND, instead attributing their symptoms to tiredness, problems with a partner, their baby, or other children (124). This study also revealed a great reluctance to discuss such symptoms, especially with health professionals (124). Among the 65% of participants who had spoken to anyone about their symptoms, 54% had spoken to a family or friend; 12% to a health professional and only 4% to their general practitioner (124). This marked reluctance among mothers to accept PND as a medical condition and disclose their symptoms to health professionals, is likely to have resulted in many mothers not responding to invitations to participate in the present RCT. The symptoms of PND, including depressed mood, anxiety and fatigue could also prevent a mother feeling able to take part in a clinical trial involving exercise, especially as motivation among depressed populations is known to be low (187). Physical and practical considerations such as recovery from giving birth and child care needs are also likely to make women averse to taking part in exercise after having a baby.

4.1.3 Ethnicity and the concept of postnatal depression

Birmingham has a multicultural population, in which 46.9% of people are from ethnicities other than white British (190). Cultural norms and beliefs may have had an effect on the acceptability of the present RCT to the population. Recent research by Hanley highlighted the interaction between cultural background and views of PND (236). Ten mothers residing in Wales who were brought up within a Muslim community participated in a focus group. PND was reported to be a concept that the participants were largely unaware of, and did not identify with (236). A medical cause was not described as being sought for symptoms such as an inability to sleep, anxiety and despair; instead a religious significance was often given to them (236). Consequently, religious advice or rituals were sought as a form of treatment (236). A fatalistic view was often conveyed such that anything that befell them was believed to be the will of Allah and it was not felt appropriate to question this (236). The symptoms of depression were also described in a different way; they were not voiced in emotional, but in somatic terms, such as weakness, pain or problems of the heart (236). Participants did not view their health visitor as a person with whom they could discuss emotional issues, not only because their husband would often be present, but also because they saw the role of the health visitor as one of giving practical advice relating to pregnancy and birth (236). Such cultural factors may have impacted on the acceptability of the present RCT to some women from ethnic minority backgrounds.

4.2 **Aims**

4.2.1 **Recruitment to the present RCT**

In light of the difficulties in recruitment to this RCT, two courses of action were undertaken. Firstly, a series of protocol amendments were made to the study processes in order to facilitate participation. The purpose of this chapter is to describe these amendments and explore any effect they may have had on recruitment. In addition, the specific barriers to participating in exercise for depressed mothers were explored during interviews conducted with participants at the end of their involvement with this trial. The findings of these interviews are discussed as part of the qualitative chapter of this thesis (chapter five).

4.3 **Methods**

4.3.1 **Initial recruitment strategy**

4.3.1.1 ***Main recruitment method***

The main method of recruitment to this trial was the mailing of participant invitation letters and screening questionnaires to all mothers from participating GP practices in Birmingham (SB PCT and BEN PCT). Study packs were initially sent to mothers six weeks after giving birth, by the Children and Families Division of the NHS (CHS), on GP practice headed paper (to signify the agreement of the practice).

4.3.1.2 ***Secondary recruitment methods***

In addition, posters and information leaflets were displayed in GP practices.

Meetings were attended with health visitors to provide them with information about the trial and encourage referral of patients. Recruitment also took place via referral

from psychiatrists and posters displayed in the Birmingham Mother and Baby unit. Mother and baby units provide inpatient and outpatient psychiatric care for mothers experiencing a range of postnatal psychiatric illnesses including PND. After several months, however, it became apparent that these methods were not generating a sufficient response from eligible women interested in taking part in the trial.

4.3.2 Changes made to recruitment methods

In response to the lower than predicted recruitment rate, modifications were made to the trial methods. These alterations began with a simplification of the language used in participant literature. Advertisements were also placed on mother and baby websites and via local radio to increase exposure. Additional methods of direct recruitment were explored, including recruitment at baby immunisation clinics, PND support groups and GP practices and mother and baby units in other regions. The procedures of the study were also altered to facilitate recruitment, including an expansion of the eligibility criteria to include diagnoses of mixed anxiety and depression and a later point of contact with the population. In the following section these changes will be discussed in detail, including their impact on recruitment (Figure 11 and Table 16).

4.3.2.1 Ethical approval

Ethical approval, in the form of minor or substantial amendments to the original ethical approval for this RCT, was granted by the National Research Ethics Committee for all the changes reported in this chapter. Ethical and research governance approval were obtained in SB PCT, BEN PCT, Walsall Teaching, Wolverhampton, Sandwell and Dudley PCTs.

Table 16: Recruitment methods

Recruitment method	N (%) participants recruited
Study information mailed by the CHS	80 (85.1)
Posters and leaflets at mother and baby units	4 (4.3)
Posters and leaflets at original GP practices	2 (2.1)
Packs handed out in additional GP practices	2 (2.1)
Referrals from self-screening GP practices	2 (2.1)
Health Visitors	3 (3.2)
ACACIA	1 (1.1)

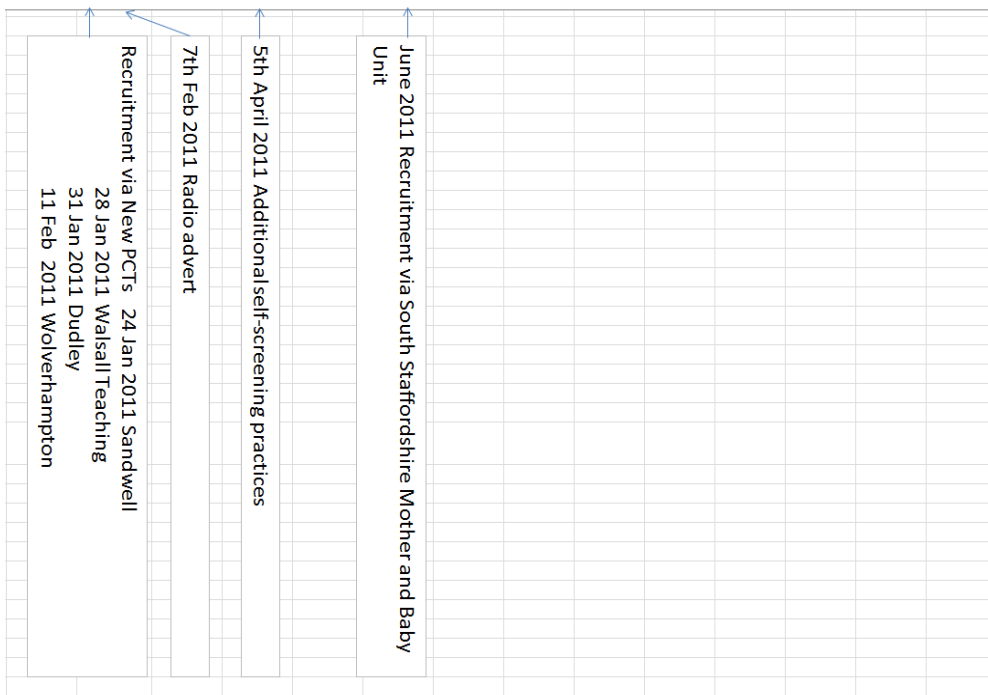
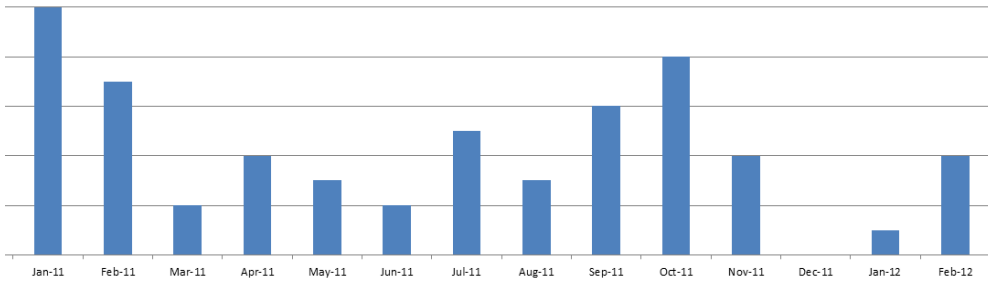
CHS: Children and Families Division of the NHS

Figure 11: Participant recruitment

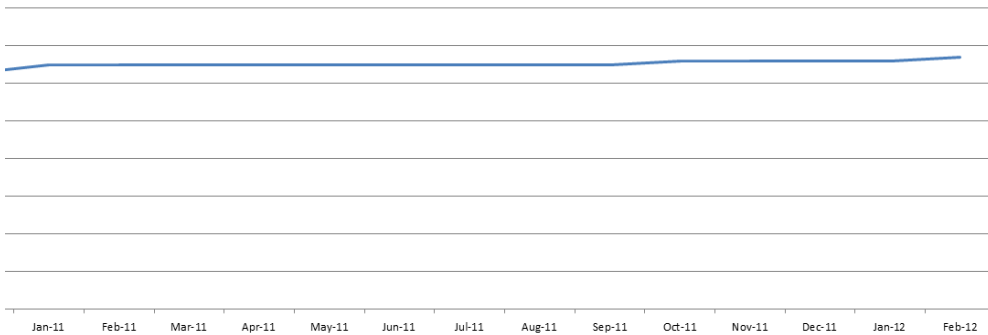


Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11	Oct-11	Nov-11	Dec-11	Jan-12	Feb-12
10	7	2	4	3	2	5	3	6	8	4	0	1	4

Participant recruitment



GP practice recruitment



Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11	Oct-11	Nov-11	Dec-11	Jan-12	Feb-12
65	65	65	65	65	65	65	65	65	66	66	66	66	67

4.3.3 Pilot recruitment phase

Recruitment to the RCT was initially piloted between December 2009 and January 2010 at one general practice. From 1st February 2010 this was increased to three practices with the number gradually increasing from 40 in April 2010 to 65 by January 2011. During this period, the number of questionnaires returned per month increased from one in February 2010 to 33 in April 2010. The first participant was randomised in April 2010.

4.3.4 Alteration to language used in participant literature

In response to the lower than expected rate of recruitment, I suggested that the language of the participant screening invitation letter (Appendix Figure 1) be reviewed by our patient representative. In March 2010 discussion was held with the trial steering group and patient representative regarding possible changes to the invitation letter. In response to the suggestions of the patient representative, the language of the participant screening invitation letter was altered in March 2010 to make it more participant-friendly (Appendix Figure 9). References to 'postnatal depression' were replaced with 'low mood', which was felt to be less off-putting, as many mothers with such symptoms are reluctant to admit they may be experiencing PND (124). The term 'exercise' was replaced with 'physical activity' as 'exercise' was felt to carry connotations of structured activity of a certain intensity, which may have been daunting for women with low mood and a new baby to care for. The intervention was introduced by emphasising the supportive, flexible design of the intervention:

'the physical activity programme will encourage mothers to do whatever type of physical activity they enjoy or prefer doing'

The participant screening consent form (Appendix Figure 15) was also simplified. Questions deemed more relevant to the actual trial consent form were removed (Appendix Figure 16), for example the option to:

'Allow the score from my EPDS questionnaire to be used anonymously for statistical purposes.'

The altered participant screening invitation letter (Appendix Figure 9) and trial consent form (Appendix Figure 16) were first distributed at the beginning of April 2010. There was a substantial increase in the number of participants responding to these letters; 12 participants returned the questionnaire in March 2010, 33 in April and 80 in May, representing an overall increase of 667%. It should be borne in mind that the number of practices taking part in the study also increased during this time, from 29 in March 2010 to 47 in May 2010; an increase of 62%. However, as the increase in returned questionnaires seen over this period (667%) was substantially higher than 62%, the changes made to the literature may have had an additional positive impact.

4.3.5 Baby immunisation clinics

At the suggestion of the trials principal investigator, baby immunisations clinics at 20 of the largest collaborating GP practices were attended between 15th April 2010 and 22nd May 2010. The purpose of this strategy was to increase our contact with potentially eligible mothers. Mothers who had already been screened for eligibility

by their GP were given an information letter, EPDS, reply and consent form. Mothers who had not been screened were given a leaflet containing a brief summary of the study and the contact details of the research team. The response rate from these clinics was, however, very low. Three participants returned questionnaires, two of whom scored below the threshold of ≥ 10 on the EPDS and one who was too active to be eligible.

Baby immunisation clinics may not have been an appropriate environment for discussing this trial. Mothers were anxious as their child was due to receive an injection, there was only a short window of time to discuss the study before their consultation and mothers were often distressed after the consultation by their baby crying. Some mothers did not appear comfortable being approached by a stranger in a comparatively public place to discuss the sensitive topic of PND, perhaps feeling that approaching them suggested, in front of other mothers, that they were experiencing PND. Such factors were highlighted in research conducted by Shakespeare et al. who found that screening women by EPDS in a baby clinic was not acceptable to 54% of their study population with participants describing a feeling of personal intrusion brought about by public discussion of PND (247).

4.3.6 Eligibility criteria

As the trial co-ordinator, I noticed that several mothers with EPDS scores of ≥ 13 were receiving diagnoses of Mixed Anxiety and Depression on the CIS-R interview. Discussion was held with the trial steering group regarding their potential eligibility with a view to increasing the number of potentially eligible mothers. From 21st July 2010 the trial accepted participants with an ICD-10 diagnosis of mixed anxiety and

depression as indicated by the CIS-R clinical interview (201). This was felt to be appropriate as many participants suffering from depression will also have symptoms of anxiety (104). After broadening the eligibility criteria, 11 participants with a diagnosis of mixed anxiety and depression were randomised, representing an overall increase of 13.3% in recruitment (83 to 94 participants).

4.3.7 Point of initial participant contact

Initially, participants received the study information and screening questionnaire six weeks after giving birth. This time point was chosen as the symptoms of PND have been found to peak at around six weeks after giving birth (20). There are, however, practical considerations that may significantly impact on a mother's interest in taking part in an exercise trial at this time. Mothers may still be recovering from childbirth, are likely to be very tired and still establishing a routine of sleeping and feeding with their baby. For these reasons the decision was taken by the principal investigator, after discussion with the trial steering group, to delay the initial screening of mothers until 12 weeks after giving birth. Previous research has found that of a sample of mothers at risk of depression ($EPDS \geq 10$) at two to four weeks postnatal, 41.9% were at risk four to eight weeks postnatal (the original screening point for the present RCT), decreasing to 35.5% at 10-14 weeks postnatal (20). It was therefore felt that delaying screening would not substantially reduce the population of women potentially eligible for this trial and mothers would be in a better position, physically and practically, to consider exercising.

Up to 21st July 2010, screening packs were sent to mothers at six weeks postnatal. In July 2010, 71 EPDS screening packs were returned and four participants

were randomised. From 22nd September 2010, screening packs were sent out at 12 weeks postnatal. In October 2010, 46 packs were returned and three randomised, in November 2010, 75 packs were returned and six randomised and in December 2010, 38 packs were returned and seven randomised. Although the number of participants randomised generally increased after the change in the point of screening, the trend is not distinct, leaving uncertainty regarding the effect of delaying first contact with mothers.

4.3.8 Service support costs for health visitors

Health visitors are in the unique position of regularly visiting women in the postnatal period. As they may come into contact with the estimated 7-13% of women who are depressed postnatally (1) and have the opportunity to talk with them in person, it was felt to be important to involve health visitors in this study. Recruitment via health visitors from PCTs in Birmingham did not, however, prove successful.

Recruitment began in January 2010 and despite regularly attending regional health visitor meetings to encourage their engagement, only three referrals were received by May 2010. Health visitors informed us of the time pressure they were under due to large caseloads. In view of this, the decision was made by the principal investigator, after discussion with the trial steering group and PCT, to compensate health visitors for the extra time taken to introduce their patients to the study. A £25 high street shopping voucher was provided to health visitors for every eligible participant referred. These payments were classed as service support costs by the PCT, however as the payments were made directly to each health visitor and not to

the PCT as a whole, they could be viewed as reimbursement for time given to the trial.

This approach was piloted with one PCT with the view of extending the practice to the other PCT if effective. Health visitors in the PCT receiving service support costs referred 22 women between June and December 2010, leading to three randomisations and an increase of 8.1% in the number of participants recruited (37 to 40). Health visitors who did not receive service support costs referred only two participants during the entire recruitment period, neither of whom was randomised. In October 2010 the decision was taken by the Trust to no longer offer health visitors service support costs for this study. Only two health visitor referrals were received thereafter.

4.3.9 Further alterations to the participant literature

After considering the amount of information and the detailed format of the participant screening invitation letter (Appendix Figure 9), I suggested that a clearer format might improve the appeal of the literature and therefore the receptiveness of mothers to the information presented. In October 2012 discussion was held with the trial steering group and the patient representative regarding possible new formats. Responding to feedback from the patient representative, in November 2010 the participant screening invitation letter (Appendix Figure 9) and reply form (Appendix Figure 11) were altered to make them clearer and more accessible. The invitation letter was substantially reduced in length and was limited to explaining that the GP was inviting all mothers who had recently given birth to take part in the study and describing the aim of the research (Appendix Figure 10). A separate participant

screening leaflet was created with simple bullet points describing what taking part would involve and how to proceed if interested (Appendix Figure 19). The participant reply form (Appendix Figure 11) was also substantially simplified. The section for women declining to take part, their reasons for doing so and their willingness to be interviewed about these reasons was removed. It was felt that making the literature clearer and encouraging those actually interested in taking part to complete the form was more important than discussing participants' reasons for not wanting to take part (especially as none of the participants who completed the decliner section proved to be contactable) (Appendix Figure 12). The new literature was first distributed on 8th November 2010; over the following months (November 2010 to February 2011) the number of participants randomised increased to an average of 6.3 per month. This, although lower than the anticipated 12 participants a month, represented a 110.0% increase on the previous average of three (excluding the pilot period). The proportion of eligible respondents also increased from 23.9% (17/71) to 41.0% (16/39) as only participants interested in taking part were asked to return the questionnaire. This allowed for more efficient use of time as less time was spent processing ineligible participants and decliners.

It should be noted that in addition to the changes in participant literature there was also an increase in the number of GP practices taking part in recruitment (from 56 to 65) which may also have contributed to the increase in recruitment rate observed.

4.3.10 Local support groups and services

ACACIA is an organisation which provides support to mothers and their families affected by pre or postnatal depression in the north Birmingham area (248).

Improving Access to Psychological Therapies (IAPT) is an NHS scheme which aims to increase the availability of psychological therapies to people across England with depression or anxiety disorders. IAPT psychologists have been placed within the ACACIA organisation to support mothers. After discussion with the trial steering group, the principal investigator felt that the involvement of both bodies could be beneficial to recruitment, by allowing greater access to mothers actually suffering from depression. Psychologists and volunteer supporters from ACACIA and IAPT were able to refer participants to the study from 25th November 2010 onwards.

Supporters at ACACIA referred seven mothers to the trial, one of who was randomised. On visiting one of the ACACIA centres it became clear that mothers had children of all ages (making many ineligible as they were more than six months postnatal). Many mothers were also in great distress and discussion of a trial was understandably not their first priority.

4.3.11 Radio advertising

On 7th February 2011, in an attempt to broaden the reach of the study and to provide a reminder to mothers already aware of the study, the principal investigator devised an advertisement for the radio station Heart FM. This is a popular local radio station broadcasting to the West Midlands. Brief details of the study were given including the contact details of the research team. Only one enquiry was received

from this advertisement. The participant was not eligible, as her GP practice was in a PCT not participating in this study.

4.3.12 Internet advertisement

In a further attempt to access the postnatal population, an advertisement created by the principal investigator was placed on the website www.netmums.com (249), a popular organisation providing information on a range of topics relating to pregnancy and parenting. Brief details of the study including contact details were provided. One inquiry was received via netmums, however, the participant became uncontactable.

4.3.13 Additional PCTs

Due to the low number of participants that returned screening information packs (11.7%, 1150 of the 9767 packs posted) I suggested that it may be judicious to increase the accessible population by expanding to additional PCTs. After discussion with the principal investigator and trial steering group and principal additional PCTs were selected for recruitment. GP practices in Sandwell, Dudley, Walsall and Wolverhampton PCTs were provided with packs containing study information and participant enquiry leaflets from January 2011 onwards. See Appendix Figure 35 for a map of the location of the additional PCTs.

Postnatal care for mothers in all West Midlands PCTs followed the national guidelines for postnatal care as described in chapter three, section 3.3.3.4. The proportion of people from an ethnic minority background was slightly lower in the additional PCTs (Sandwell 34.0%; Dudley 11.4%; Walsall 22.9%; Wolverhampton

35.3% (250) compared to Birmingham (46.9%) (190). This may have affected the acceptability of the study as there are known to be different levels of acceptability to conditions such as PND in different cultures (236). The rate of spontaneous births was also greater, and the rate of caesarean sections lower in the new PCTS than across Birmingham (Birmingham Women's Hospital, 48.3% spontaneous births, 24.5% caesarean sections; Sandwell and west Birmingham 71.6% spontaneous births, 9.6% caesarean sections; Walsall 58.5% spontaneous births, 11.1% caesarean section (196). The lower rate of caesarean sections would seem to be conducive to mothers considering an exercise trial, however it should be noted that mothers from the additional PCTs could also elect to be treated at the Birmingham Women's Hospital, therefore the clinical picture may not be as dissimilar between the PCTs as it appears.

Twenty five patient enquiries were received from GP practices in the additional PCTs, two of whom were randomised. Health visitors in Sandwell, Walsall and Wolverhampton PCTs were also encouraged to refer patients. One health visitor referral was received, which did not progress to randomisation. In addition, in April 2011, approval was granted for GP Practices in Dudley PCT to directly screen their own patient list to identify eligible patients. Six referrals were received from three practices in Dudley, two of which were randomised.

4.3.14 Recruitment through additional mother and baby units

In addition to providing inpatient care for mothers with severe postnatal mental illnesses such as postpartum psychosis, mother and baby units also provide outpatient care and group support opportunities for postnatal women with a range

of mental health conditions of varying severities, including postnatal depression. In the local Birmingham mother and baby unit, other trials were known to be recruiting postnatal women at the same time as this study, which seemed to be limiting participation in this particular trial. After discussion between myself and the principal investigator regarding these difficulties, it was decided that recruitment from an additional mother and baby unit might improve access to the substantial number of depressed mothers who access these services. From June 2011 recruitment was extended from the Birmingham mother and baby unit to the mother and baby unit in South Staffordshire. Leaflets and posters were used to advertise the study in the outpatient departments of these hospitals and health professionals were able to refer their outpatients. Four participants were recruited via mother and baby units.

4.4 Discussion

Many of the changes to the recruitment methods described in this chapter were implemented sequentially with very little time between them and occasionally implementation overlapped. It should also be noted that during the recruitment period, the number of participating practices increased, first rapidly, then gradually. The resulting increase in women contacted will have increased the recruitment rate during periods when other changes to the methods were also taking place. Consequently it is very difficult to determine with any certainty what effect, if any, each individual modification had on the recruitment rate. The overall increase in randomised participants seen during the first 15 months of the trial would suggest that some, or a combination of these changes, had a positive influence on recruitment.

4.4.1 Implications for further research

Despite difficulty in separating out the effects of the different changes made to the trial methods, observation of the recruitment statistics would seem to suggest that some methods were more successful than others. Keeping participant literature succinct by providing essential details clearly, omitting unnecessary information and carefully considering the meaning of study terminology to participants, would appear to encourage a response. It should be borne in mind that terms which may be emotive or subject to stigma (such as postnatal depression) may discourage participation in view of the inherent unwillingness of people to associate themselves with such terms (236, 244, 245). Alternative phrases that convey the required meaning, but have fewer negative connotations, such as 'low mood' may improve response rates to mental health trials.

Eligibility criteria have a direct effect on possible sample size. Use of gold standard diagnostic interviews rather than screening questionnaires will substantially decrease the potentially eligible population. If an EPDS cut off of ≥ 10 had been applied to the present trial, 436 of those returning screening questionnaires would have been eligible. Using a diagnostic interview does, however, substantially increase diagnostic accuracy, improving the internal validity of the sample and providing a clinically diagnosed population. Conversely, broadening criteria to encompass relevant diagnoses, such as 'mixed anxiety and depression' in a PND study, will enable an increase in recruitment. Eligible diagnoses should, however, be considered carefully as the study population should be a coherent clinical sample, who are similar enough for meaningful conclusions to be

drawn. The effect of broadening eligibility criteria on the external validity of a trial should therefore be considered carefully.

The current evidence base for the usefulness of payment to health professionals for recruiting to RCTs is limited and equivocal (251). However, service support costs did prove a successful incentive to recruitment amongst health visitors. Nevertheless, a consistent understanding of what constitutes appropriate payment is needed between health care management, health care professionals and researchers if such payments are to be implemented efficiently.

Some methods of encouraging participation appeared particularly ineffective. In baby immunisation clinics, mothers were understandably reluctant to discuss the sensitive topic of postnatal depression in front of their peers. With the process of having their baby immunised forming an additional stressor, this setting appeared to be unsuitable for recruitment. Mother and baby units were also found to yield comparatively few referrals, however this likely to be due, in part, to competing interests from other recruiting studies.

Advertising via local radio and websites relevant to motherhood also proved ineffective in generating direct inquiries, although it is not possible to say whether it may have prompted mothers who had already received the study information to return their questionnaires. However, a recent RCT in a population with depression studied the cost-effectiveness of its various recruitment methods (252). An intensive advertisement campaign was conducted involving local community websites, a specific trial website, Facebook, 12 radio advertisements per day for a month, advertisements on busses, in GP practices, shops, community buildings, sports halls,

colleges, churches, flyers in the street and mental health exhibitions (252). This comprehensive strategy proved very successful, with web advertising and poster distribution proving particularly cost-effective (252). It may be that the degree of advertising used in this RCT was insufficient to generate substantial interest amongst mothers with PND - a very busy population of women lacking in motivation. If advertisement is to be used in future studies, implementing a wide ranging, intensive campaign may prove successful.

4.5 Conclusions

Despite an overall return rate of only 11.5%, the original strategy of mailing study information to all mothers who had recently given birth was still undoubtedly the most successful method of recruitment to the present trial; providing 85.1% (80) of participants. This suggests that maximising the potential study population by applying a screening questionnaire (the EPDS) prior to the diagnostic interview is advisable when recruiting to mental health trials. This method also allowed mothers to receive and consider the study information within the privacy of their own home, which may be a more appropriate setting for studies where a certain stigma may be attached to the condition. Other methods which may prove conducive to recruitment in mental health trials include careful consideration of the likely interpretations of participant literature terminology, the payment of service support costs to health care professionals and improving exposure through intensive advertisement campaigns. Recruitment to trials in mental health may be challenging, but careful study of the effectiveness of the various recruitment methods available in research may help to improve participation.

CHAPTER FIVE

5. MOTHERS' VIEWS AND EXPERIENCES OF EXERCISE AS A TREATMENT FOR POSTNATAL DEPRESSION: A QUALITATIVE STUDY

The purpose of this thesis was to contribute to the body of scientific evidence regarding the effectiveness of exercise as a treatment for postnatal depression. In chapter three, a report is provided of an RCT that investigated the effectiveness of exercise in the treatment of PND. The present chapter describes a qualitative study that was nested within this trial.

5.1 Introduction

5.1.1 Current treatment of PND

PND is commonly treated in a primary care setting, through which the current standard treatments for depression, including antidepressants and psychological therapy, are prescribed (4, 62). There is a known reluctance within the general population to take antidepressant medication; this is even more evident in postnatal populations, where mothers might also be breastfeeding (4, 182). Counselling can be effective but there is often a long waiting list to receive this on the NHS (National Health Service), despite the introduction of the IAPT Programme (Improving Access to Psychological Therapies) (253).

Exercise is recommended by NICE as a treatment for depression within the general population and for mothers with mild or moderate PND (4, 62). Qualitative research has highlighted that exercise is generally found to be an acceptable form of treatment by those who are depressed (187). In 2011, Searle et al. reported the

various biochemical and psychological mechanisms by which depressed people believed exercise may produce a reduction in depression; such as via endorphin release, distraction from thoughts, encouraging a sense of purpose, weight loss and social interaction (187). However, qualitative research has also highlighted the many potential barriers to exercise for those with depression, including lethargy, fatigue and lack of confidence (187), many of which may apply to mothers with PND. In addition, there are psychological, physical and practical factors specific to women in the postnatal period that may affect the feasibility of exercise as a treatment. It should be borne in mind that feelings of shame and fear still prevent mothers from being open with health professionals about depressive symptoms (254). One particular benefit of physical activity is that it can be instigated by the mother herself; it does not necessarily require a disclosure and may therefore be an appealing option, presenting fewer barriers than gaining access to antidepressants or counselling. Mothers' experience of exercise as a treatment for PND has not previously been explored by qualitative methods; the present study was therefore devised to improve the depth of knowledge within this field.

5.1.2 Aim

The aim of the following work was to explore mothers' views and experiences of exercise as a treatment for PND.

5.1.3 Objectives

In order to explore depressed mothers' experiences of this treatment in the postnatal period, the following chapter provides discussion around the following objectives.

- Discussion of mothers' beliefs regarding the acceptability of exercise in the treatment of PND, including the practicalities of motherhood and exercise.
- Description of the reported psychological benefits of exercise and mothers' beliefs around the mechanisms via which these benefits were obtained.
- Discussion of the relationship between motherhood, PND and women's sense of identity and the influence of exercise on this relationship.
- Exploration of mothers' views of exercise within the broader range of treatments currently recommended for PND.

5.1.3.1 Hypothesis

It was hypothesised that an exploration of mothers' views of exercise as a treatment for PND and the relationship between exercise, mood and other psychosocial factors such as self-efficacy and social support, would provide valuable insights as to the potential mechanisms by which exercise may confer psychological benefits for mothers with PND.

5.1.4 Reflexivity

This qualitative study was conducted within an interpretivist paradigm (for further discussion of interpretivism see chapter one, section 1.8) Whilst work conducted with an interpretivist perspective accepts that the reality explored during an interview is a construct of both the interviewer and interviewees previous experiences and views, it is important to acknowledge the influences that may affect my interpretation of this reality (255).

Firstly it is important to be aware of my contribution to this qualitative research. The interview schedule used as a guide for the following interviews was

created by myself and Dr K Turner, a qualitative researcher from the University of Bristol. I conducted the interviews, coded all transcripts and created a coding framework. The first transcript was also read and coded by Dr Turner and discussion held regarding the coding framework. I uploaded the data to NVIVO and created a matrix, summarizing the data in each code. I then performed the analysis, including comparison within the data via characteristics such as intervention/comparator, severity and other demographic characteristics. My substantial involvement in this qualitative research process indicates that the potential biases discussed below may have influenced the research process and the conclusions I have drawn from this data.

I was the co-ordinator of the trial which all of the interviewees had taken part in. I had spoken to every participant at the beginning of the trial and conducted a series of questionnaires with them during their involvement. As much of this contact was by phone, many participants seemed unaware of my previous contact with them or the extent of my role within the trial, however some were aware of my role. Knowledge of my position may have influenced participants' responses, with participants perhaps feeling the need to convey more positive views of exercise as a treatment for PND. My interpretation of participant's responses may also have been affected by the fact that the RCT formed part of my doctoral thesis, if one is invested in a treatment, this could affect ones perception of the positive and negative views communicated by participants. I am an unmarried woman without children and therefore have no personal experience of PND, my lack of experience of the context of my participants experiences may have affected my awareness of the most

pertinent topics to discuss, however, a lack of such experience may also be advantageous in reducing the likelihood of preconceived ideas based on personal experience influencing my interpretation of the discourse.

When working within an interpretivist paradigm it is accepted that the reality experienced is a function of both the interviewer and participant, however methods are recommended to mitigate the effects of the interviewers' subjectivity on their interpretation of the experience (135). One such method is that of triangulation (135). During this study, another researcher read and coded initial transcripts; coding frameworks were then constructed independently. Discussion of interpretation and alteration of the coding framework followed until consensus was reached. The value of this process lies in the exploration of divergent views of the interview discourse, thus reducing the influence of any one researcher over the interpretation process (135).

5.1.5 Qualitative methodology

Qualitative research can be approached through a range of different methodologies. Some of the principal methodological approaches, and their relevance to the present research, are discussed below.

5.1.5.1 Ethnography

The ethnographic method involves becoming immersed within a social context, both observing and to some degree interacting with the participants in order to further understand their behaviour (256). Observation can be supported with field notes and enhanced by interviews and the study of documents. The purpose of ethnography is to describe and interpret the shared patterns of behaviours, beliefs and values

shared by a group (256). Although the observation of a mother within her family unit has the potential to reveal valuable insights about the shared experiences of PND and of exercise as a treatment, the principal focus of this study was the mother and how she viewed her own experiences. In addition, despite the rich behavioural observations that are possible, in the present study, it was not felt to be practical or ethical to observe mothers with PND within their own homes as the act of being observed may place additional strain on a mother who is already psychologically unwell.

5.1.5.2 *Grounded theory*

Sociologists Barney Glasser and Anselm Strauss developed the methodology of grounded theory during the 1960s (257). Grounded theory provided qualitative research with structure and methodological rigour at a time when quantitative methods were felt to be the optimal way of conducting social science research (139). The practical application of grounded theory in qualitative research requires a process of constant comparison (256). Initial interviews are conducted and transcripts analysed through coding. Emerging themes are reviewed and theories relating to the phenomena captured begin to be developed (256). Knowledge of these developing themes and theories then influence the selection of further interviewees, with theoretical sampling being used to help the researcher further develop their theory (139). Throughout the data collection and analysis process, the developing theories are compared to the data and the applicability of the theory considered (139).

Grounded theory was constructed with a positivistic viewpoint, with Strauss and Corbin advising the interviewer to remain an unbiased observer of an objective reality. (For further discussion of positivism see chapter one, section 1.8). This objectivity is enhanced by structured data collection and analysis procedures and verification of findings by comparison to the data (139). However, the work of Guba and Corbin in the 1990s recognised that grounded theory can be used as a methodology, whilst recognising the subjective nature of reality, with the interviewer acknowledging the mutual creation of the reality experienced during the interview process (258). Regardless of the ontological outlook of the researcher, the aim of grounded theory research is to develop a concept or theory that explains the processes or interactions found in the data (256).

The research presented in this chapter could not be said to follow a grounded theory methodology. My inexperience as a qualitative researcher led me away from attempting to guide the research process towards the development of a theory. This study would be better described as a simple piece of descriptive qualitative enquiry, providing an exploration of mothers' views and experiences of exercise in the treatment of PND.

5.1.5.3 *Phenomenology*

An alternative methodology commonly used in qualitative research is that of phenomenology (139). Philosopher Edmund Husserl's theory of philosophical phenomenology (259) lead the way for the development of social phenomenology by social scientist Albert Shutz during the 20th century (260). Social phenomenology draws away from ideas of an objective reality to a subjective reality experienced

through our individual consciousness (139). Our consciousness is not only felt to perceive the world, but to construct our experience of it (139). The focus is placed on the life world as experienced by its members (139). Phenomenological research should be focused on how members of a social world relate to their experiences, how they constitute the objects and events of their reality (139).

When conducting the research presented in this chapter, I did endeavour to allow mothers to explore their experiences of their own reality. I am not skilled or experienced enough in qualitative research to claim that this work was carried out in accordance with phenomenological methodology. The following work was a simple piece of descriptive qualitative research, conducted with an interpretivist viewpoint, in the hope of representing faithfully what women chose to relate of their views and experiences of exercise and PND within their own lives. (For further discussion of interpretivism see chapter one, section 1.8)

5.1.6 Qualitative methods

There are a range of different research methods that can be used to conduct qualitative research, the most commonly used being focus groups and one to one interviews. These methods, and their applicability to the current study, are discussed in the following sections.

5.1.6.1 Focus group interviews

Focus groups are usually comprised of a group of peers, between whom a discussion is guided by a researcher who acts as a moderator. Peers can discuss their opinions, probing the reasons behind their actions and beliefs. This process can elicit a wide range of contrasting beliefs. The data obtained from this method will be a reflection

of the fact that people do not construct their views of reality alone but within a social context (261). However, the practicalities of conducting a focus group with a depressed postnatal population were felt to be prohibitive. Mothers with PND often isolate themselves (122), with low motivation and comorbid anxiety potentially forming barriers to new experiences. Grouping mothers from different areas of the West Midlands together, who may require childcare, was also felt to be a significant barrier to this method.

5.1.6.2 *One to one interviews*

Interviews can be conducted with different degrees of structure. Structured interviews consist of a pre-defined set of research questions that require specific answers (262). The questions are clearly defined to maximise reliability and validity across the data collected. Such interviews are led by the researcher, which can result in missing what is important to the participant (262).

Conversely, unstructured interviews are conducted at most with a brief set of prompts but sometimes with as little as a single open question. The interviewer follows up on points raised by the participant that are felt to be worthy of being explored further (263). Rich data is collected on subjects determined by the participant, however, the data may not be focused on an original series of topics or questions that the interviewer wished to explore. It has been found that when sensitive topics are discussed, interviews can be seen as a cathartic process by the participant (264). With an unstructured format, interviews exploring an emotive topic such as PND may be subject to mothers relating their experience of the

condition in great depth, with the relevance of exercise perhaps being of secondary importance.

Semi-structured interviews are conducted using a list of questions formed around a fairly specific topic, however if a participant raises additional avenues, the interviewer is free to explore them (262). This method allows the process to be guided by the issues the participant feels are important, as long as they are relevant to the original question (262). This research had a specific aim; to explore mothers' views and experiences of exercise as a treatment for PND. This aim required the exploration of mothers' experiences but in relation to a specific treatment. Semi-structured interviews were therefore felt to provide an appropriate level of guidance and flexibility for this particular study. Previous work exploring mothers' experiences of PND (265), mothers experiences of breastfeeding (266) and peoples experiences of physical activity for the treatment of general depression (187, 241) have all used semi-structured interview methods.

5.2 Methods

Interviews were conducted with participants of the RCT reported in chapter three, which was a two arm trial conducted in the UK, investigating the effectiveness of exercise as an adjunctive treatment for PND. Participants in the intervention and comparator groups both had access to usual care whilst participating in the study, including continuing to receive counselling and/or antidepressants at the discretion of their health professionals.

The intervention was delivered by a physical activity facilitator (PAF) and was designed to support mothers to increase their exercise levels. Participants in the

intervention group received two home visits and two phone calls from the PAF over six months, in addition to information leaflets on ways to introduce exercise into daily life including local exercise opportunities.

5.2.1 Sample

All participants in the RCT had an ICD-10 diagnosis of major depression or mixed anxiety and depression (21). Participants were randomised up to six months after giving birth, aged 18 years or more and were not achieving UK government recommendations for activity when recruited (150 minutes moderate exercise per week) (267). Women were ineligible for the trial if they were pregnant, experiencing psychotic symptoms, dependent on illicit drugs or alcohol or had a baby who was not living with them or had died.

5.2.2 Recruitment and sampling

5.2.2.1 Participants

All participants of the RCT were invited to take part in an interview after completing their six month follow up (see chapter three, section 3.3.21 for further details of follow up procedures). Participants were invited for interview between November 2010 and November 2011. Interviews were conducted after the participants' six month follow up for two principal reasons. It was expected that the interview process would be reflective for the participant; conducting the interview after the completion of the trial prevented this reflective process from influencing participants' behaviour prior to collection of the RCT primary outcome data. The aim of this qualitative study was to explore mothers' views and experiences of exercise as a treatment for PND. The point immediately after participation in the exercise trial

was felt to be the optimum time to explore such factors as the effects of the trial might still be present in participants' minds. Recollection of participants' exercise behaviour prior to the trial was also likely to be more accurate at this point than if interviews had been conducted later on.

5.2.2.2 *Sampling technique*

The participants of this qualitative study were purposefully sampled. The aim of purposeful sampling is the selection of 'information rich' cases that enable the exploration of a particular phenomenon (268). A variety of different strategies can be adopted within the purposeful sampling method, dependent on the aim of the research (269). For example, critical case purposeful sampling aims to identify a key example of a phenomena, that is likely to be applicable to other individuals; deviant case sampling seeks to highlight contrasting 'usual' and 'unusual' cases (269). The aim of this descriptive research was to explore mothers' views and experiences of exercise as a treatment for PND. A breadth of experience and viewpoints was therefore sought through the use of criterion sampling (269).

Within this study variation was sought through interviewing participants with a range of experiences and characteristics (criteria). Women were interviewed from both the intervention and comparator groups of the RCT. The majority of interviewees were invited from the intervention arm as it was considered that they would have more experience of performing exercise, having recently completed an exercise intervention. Some participants were, however, invited for interview from the comparator arm; the purpose of this was to explore the exercise experiences of depressed mothers who had not received a trial intervention. Diversity in depression severity was sought by ensuring participants had a range of EPDS scores at baseline

of the RCT and prior to interview. A range of depression severities was felt to be central to a full exploration of depressed mothers' experiences. Variation of depression severity has been purposefully sampled in other qualitative research exploring the use of exercise as a treatment for depression (187).

Maximum variation was also sought in relation to demographic characteristics including age, ethnicity, parity, employment status and socioeconomic deprivation. Such variation has been sought in other qualitative interview studies exploring participants' experiences of other treatments for depression and PND (182, 187, 270). This purposeful sampling process was conducted by recording the characteristics (as described above) of all those agreeing to be interviewed. The variation in characteristics was then studied and participants purposefully selected to ensure variation within these characteristics. See Appendix Figure 36 for an example of the sampling framework and Table 18 for the range of participant characteristics.

5.2.3 Informed consent

Women who agreed to take part in an interview were provided with an information leaflet explaining the interview process and its purpose (Appendix Figure 37).

Mothers were also provided with explanation of the interview process via phone prior to their interview. At the beginning of the interview visit, mothers were given the opportunity to ask any questions they had regarding the interview process.

Participants then provided written informed consent, giving their permission for their data to be used anonymously for the purposes of this study. This process involved the participant reading the consent form (Appendix Figure 38), placing their

initials in the boxes next to the listed aspects of the interview process to indicate their consent and providing their signature and the date of signature at the foot of the form. The interviewer (myself) then checked that the form had been completed correctly and also provided their signature and the date at the foot of the form.

5.2.4 Completion of data collection

Data collection ceased at the point of saturation, at which point no new themes emerged from the interview data. The sample size required to achieve the aim of a qualitative study is influenced by the design and purpose of the study (271). Based upon the conduct of other qualitative work investigating mothers experience of depression and interventions for depression, it was expected that the point of saturation would be reached after the conduction of between 20 and 30 interviews (121, 187).

5.2.5 The development of the interview schedule (Appendix Figures 39 and 40)

The interview schedule was devised in collaboration with Dr K Turner from Bristol University and was based on the interview schedule devised for a previous qualitative study nested within a postnatal depression trial with which she was involved (26). The interview schedule was adapted to explore the experience of an exercise intervention. The schedule was very prescriptive and designed to assess all elements of the exercise intervention process as well as mothers' experiences of exercise and their views of exercise as a treatment for PND. Questions such as those regarding participants' opinion of the screening procedures questionnaires and participant literature of the RCT were useful to my role as a trial coordinator,

considering the merits and areas of improvement of the RCT, however, they were of much less interest in my role as a doctoral researcher exploring mothers' actual lived experience of PND and exercise and the relationship between the two. The schedule was therefore used as a guide and a simple prompt to memory if topics were not brought up by the participant, but the interviews were, in practice, conducted using open questions, allowing the participant to elaborate as they wished. The interviews were therefore predominantly led by the participant, with time being given to the topics they felt were most pertinent. This is reflected in the results, in which preference was given to themes dwelt on by participants, including the relationship of exercise to mood and the relationship between motherhood, PND, exercise identity, rather than mothers' comments on the various processes of the intervention structure, which were generally positive and unremarkable. In retrospect it would have been better to reduce the scope of the topic guide, tailoring it to explore mothers' experiences of exercise and PND, rather than attempting to evaluate the study processes at the same time.

5.2.6 The interview process

Interviews were semi-structured and an interview schedule was used to ensure all core points were covered (Appendix Figures 39 and 40). The schedule was designed to elicit the data required to explore mothers' views of exercise as a treatment for PND with the knowledge of the data gathered during previous research in this field. Topics covered included: mothers' current and previous levels of exercise; their expectations of an exercise trial and their experience of it; mothers' motivations and the barriers to exercise; the benefits of exercise; the influence of

social support and mothers' views of exercise as a treatment for PND. All interviews were conducted in participants' homes and took on average between 35 and 45 minutes.

Interviews were audio recorded using an Olympus DS3400 digital voice recorder. Data files were electronically locked to prevent accidental deleting and transferred directly to my computer. The digital files were then downloaded to an area of the university network accessible only by the immediate study team and were then unlocked and deleted from the voice recorder. Data were transcribed verbatim by a professional company who signed a confidentiality agreement to ensure ethical handling of the data and then verified by myself. Data collection and analysis took place concurrently. After the transcription of the first three interviews, the topic guide was reviewed, allowing for modification of the interview topic guide as needed.

5.2.7 Data analysis methodology

5.2.7.1 *Thematic framework analysis*

A thematic framework analysis was selected for this qualitative work (272). Thematic analysis is a method for identifying, analysing and reporting patterns or 'themes' within data (273). Data are coded and themes emerge after the studying of all of the data from across the interviewees related to that code. A thematic analysis is focused on the patterning of meaning across the participants (273). There are, however, many different methods and methodologies through which qualitative data can be analysed.

5.2.7.1.1 *Alternative method of analysis*

One potential alternative method would have been to conduct an interpretive phenomenological analysis (IPA). Whereas a thematic analysis has no pre-specified theoretical background, IPA is based upon phenomenological epistemology (274). The aim of an IPA analysis is to describe and interpret the meaning attached to a particular action or concept by that particular person (274). The focus of the IPA analysis on the unique characteristics of the individual is maintained in the analysis; while a thematic analysis involves the coding of all transcripts, followed by summarizing and the generation of themes for the entire data set; an IPA analysis entails the coding of one transcript followed by the development of themes for that individual transcript (274). IPA allows a depth of exploration relating to an individual's experience of an event and the meanings they attach to it. This is, in some ways, very applicable to the present study, as the mother's experience of postnatal depression, exercise and the meanings she may attach to her experiences are important in understanding her views of exercise. However, while thematic analysis also enables the description and interpretation of the meaning ascribed by a person to their experiences; it is also conducive to the study of patterns of experience and meaning across the data (273). The use of a framework analysis further supported the exploration of how women's experiences and views were affected by their personal characteristics (272). The aim of this study was to explore mothers' views and experiences of exercise as a treatment for PND. Exploring patterns in mothers' experience and views and how these varied according to mothers' characteristics were felt to be important methods in answering this question. A thematic framework analysis was therefore conducted.

5.2.7.2 *The thematic framework analysis process*

Initially, three transcripts were read twice and then coded. In order to improve objectivity the same transcripts were also read and coded by a second researcher. Coding frameworks were developed independently from supervisors and the trial team and also by a second researcher. After discussion, the coding and frameworks were revised, with new codes being added and existing codes being removed or defined more clearly. Discrepancies in coding and frameworks were resolved through discussion, leading to the generation of one coherent coding framework that was applied to further interviews (for an example see Table 17). All transcripts were then uploaded into NVivo version 10 and electronically coded using this coding framework. Themes were identified by studying the coding framework and the relationship between codes. Codes relating to a particular subject were grouped together under common subthemes, a series of subthemes relating to the same concept were then grouped together under overall themes.

Data analysis was conducted based on the framework approach (272). This entailed summarising data relating to specific codes in a matrix. The data from the codes within each theme and subtheme were then described in the results. The framework approach enabled comparisons to be made within and across the data, i.e. to assess what individuals with certain views or characteristics said in relation to certain issues. For example, how those who experienced isolation following birth viewed exercise in the treatment of PND, or how the opinions of those who reported previous depression differed from those who did not.

Table 17: Example section of coding matrix

Code	Description and example	Reference
Barriers to exercise	<p>Things that made it difficult to or prevented the participant from exercising. This includes mood as a barrier.</p> <p>Examples:</p> <ol style="list-style-type: none"> 1. Time pressure: The practicalities of looking after a baby and possibly other children reducing the amount of exercise the mother feels she can manage 2. The daily tasks of looking after children, such as taking them to school, 'my children's routine' 3. Childcare: The need for child care before exercise is possible 4. PND symptoms 'I wasn't able to even contemplate doing any classes or anything like that because I had quite bad anxiety' <p>'When you are feeling low because you are depressed and everyday activities are enough'</p>	<p>003 line 34</p> <p>003 line 405</p> <p>003 line 36</p> <p>003 line 139</p> <p>003 line 125</p>
Incorporating exercise and overcoming barriers	<p>Overcoming barriers: Fitting exercise around family life.</p> <p>Example:</p> <p>Fitting in walks on the way to nursery/ school to drop the kids off: 'park further away and walk'</p>	<p>003 line 170</p>
Motivation to exercise	<p>Participant's reasons for exercising.</p> <p>Examples:</p> <p>The weather: 'If it is a nice day and it is sunny...I sort of get that feeling Oh I want to get all wrapped up warm and go for a walk'</p> <p>'Exercise itself can spur you onto more exercise.'</p>	<p>003 line 415</p> <p>003 line 370</p>
Exercise benefits	<p>Participant's opinion of the benefits of exercise, including mood related benefits.</p> <p>Examples:</p> <p>'I come back reenergised I suppose and able to do my things better'</p> <p>'I have found that on the days when I have been out for a walk, I have slept better'</p> <p>'If and when I found the time to exercise, I do feel better'</p>	<p>003 line 393</p> <p>03 line 397</p> <p>003 line 26</p>
Exercise mechanisms	<p>The ways in which exercise results in benefits to mood etc.</p> <p>Example:</p> <p>'I have felt better, so it's definitely like released endorphins for me'</p>	<p>003 line 29</p>

5.3 Findings

5.3.1 Participant characteristics

Fifty seven participants of the RCT were invited to take part in this qualitative study (Table 18). Thirty two either declined or were unresponsive. Of those who declined to be interviewed, the predominant reason given was a lack of time. Twenty one interviews were conducted between 25th November 2010 and 30th November 2011. After the completion of 18 interviews, no new themes were emerging from the data. To confirm that data saturation had been reached three more interviews were then conducted (271).

Of the 21 participants in this qualitative study, 13 (61.9%) were from the intervention group of the RCT and eight (38.1%) from the comparator. The majority (n=13, 61.9%) of participants were 30 to 39 years old and had between one and five children, 42.9% (n=9) having two children. Twelve (57.1%) were of white ethnicity, nine (42.9%) from ethnic minorities. A large proportion of participants were either looking after their children at home (n=8, 38.1%) or in paid employment (n=10, 47.6%). The majority (n=18, 85.7%) were not participating in any moderate exercise when they began the RCT. Participants had been diagnosed with a mild (19.0%, n=4), moderate (61.9%, n=13) or severe (9.5%, n=2) depressive episode or mixed anxiety and depression (9.5%, n=2) and had a mean (SD) EPDS score of 16.8 (3.4) at baseline and 12.4 (6.7) at six month follow up (immediately prior to their interview). Nine participants (42%) had indicated self-harm or suicidal ideation at some point during the RCT or interview process. At the point of interview, four participants (19.0%) were receiving antidepressants and three (14.3%) were receiving counselling. Of

those interviewed, seven (33.3%) had no previous history of depression or anxiety, thirteen (61.9%) had experienced previous depression; of which nine episodes were postnatal episodes (42.9%) and three (14.3%) had experienced previous anxiety. The participants who took part in interviews were similar to all RCT participants in the following characteristics: severity of depression; proportion receiving antidepressants or counselling; demographic characteristics including age, parity, employment and levels of activity. However, a slightly greater proportion of those interviewed were from ethnic minority backgrounds (Table 4) and a greater proportion were experiencing thoughts of self-harm than the RCT participants (Table 7).

Table 18: Participant characteristics

Participant characteristic		N (%) (n=21)
RCT group	Intervention group	13 (61.9)
	Comparator group	8 (38.1)
Age	18-29	6 (28.6)
	30-39	13 (61.9)
	40+	2 (9.5)
Ethnicity	White	12 (57.1)
	Black-African	1 (4.8)
	Pakistani	4 (19.0)
	Indian	3 (14.3)
	Mixed	1 (4.8)
Parity	1 child	5 (23.8)
	2 children	9 (42.9)
	3 children	4 (19.0)
	4 children	1 (4.8)
	5 children	2 (9.5)
Employment status	Home	8 (38.1)
	Paid Employment	10 (47.6)
	Unemployed	1 (4.8)
	Self employed	1 (4.8)
	Home and Student	1 (4.8)
Activity at baseline	No moderate activity	18 (85.7)
	< 150 minutes moderate activity/ week	3 (14.3)
	≥ 150 minutes moderate activity/ week	0 (0.0)
CIS-R diagnosis	Mild depressive episode	4 (19.0)
	Moderate depressive episode	13 (61.9)
	Severe depressive episode	2 (9.5)
	Mixed anxiety and depression	2 (9.5)
EPDS at baseline	Range	13-25
	Mean (SD)	16.8 (3.4)
EPDS at 6 months (prior to interview)	Range	4-21
	Mean (SD)	12.4 (6.7)
Self-harm/suicidal ideation at any point during RCT		9 (42.9)
Receiving antidepressants at 6 months		4 (19.0)
Receiving counselling at 6 months		3 (14.3)
Previous depression/anxiety	No previous depression or anxiety	7 (33.3)
	Previous depression	4 (19.0)
	Previous PND	9 (42.9)
	Previous anxiety	3 (14.3)

5.3.2 Themes and subthemes

5.3.2.1 *Emergence of themes and subthemes*

As has been previously discussed in section 5.2.5, the interview schedule used as a guide during this research process was based on a topic guide designed to assess the many elements of an RCT. The guide therefore contained sections with a focus on the evaluation of RCT processes as well as mothers experience of exercise as a treatment for PND. However, the interviews conducted were not bound strictly to the schedule and the interviewer was free to explore the topics more closely related to mothers' views and experience of exercise, whether experienced within the trial or separately within the participant's life. Discussion relating to mothers' views and experiences of exercise was more often prompted by questions in sections of the interview schedule such as mothers' 'Views on exercise as a treatment for PND' 'Exercise undertaken, barriers and support' and 'Other treatment received', than sections such as 'The trial' or 'Experiences of the trial'. However, other sections such as 'Diagnosis' were useful in prompting the exploration of mothers experience of PND, how their experience of the postnatal period affected their sense of identity and subsequently prepared the ground for discussion of how exercise influenced their sense of self during this time.

The main areas of focus during the interviews were mothers' description of their exercise experiences; their motivations to exercise, the barriers they reported and the ways they found to overcome them; the benefits mothers experienced and how they felt these were achieved; mothers' experiences of PND and mothers' views of exercise and other treatments for PND.

The themes that were created from the coded data were a reflection of the questions asked during the interviews and in particular the topics most explored by mothers. Following the coding of data and the creation of themes, the analysis was conducted. An inductive approach was taken to the coding, creation of themes and analysis of this data. An overarching theory of, for example, behavioural change, was not used to guide or influence these processes, the findings of this work and the conclusions drawn from them were grounded in the data (256).

A framework analysis was conducted with the data (272) (section 5.2.7.2). This form of analysis enabled discussion of how the findings within various themes differed by characteristics such as severity of PND and parity; such discussion can be found within results sections relating to the various themes, and within the overall discussion of this chapter.

5.3.2.2 *Summary of themes and subthemes*

The aim of this study was to explore mothers' views and experiences of exercise as a treatment for PND. A series of themes and subthemes exploring different aspects of this aim emerged from the data; the relationship between these categories is illustrated in Figure 12. Mothers' experiences of exercise were first explored through discussion of mothers' reported exercise at the point of interview and any changes compared to exercise prior to having children. Mothers' sources of motivation to exercise were discussed; as were the barriers reported to exercise and how exercise was incorporated into daily life. Exploration of motivation, barriers and successful exercise attempts provided further depth regarding how the process of exercise integrated within the lives of mothers on a physical and psychological level. The

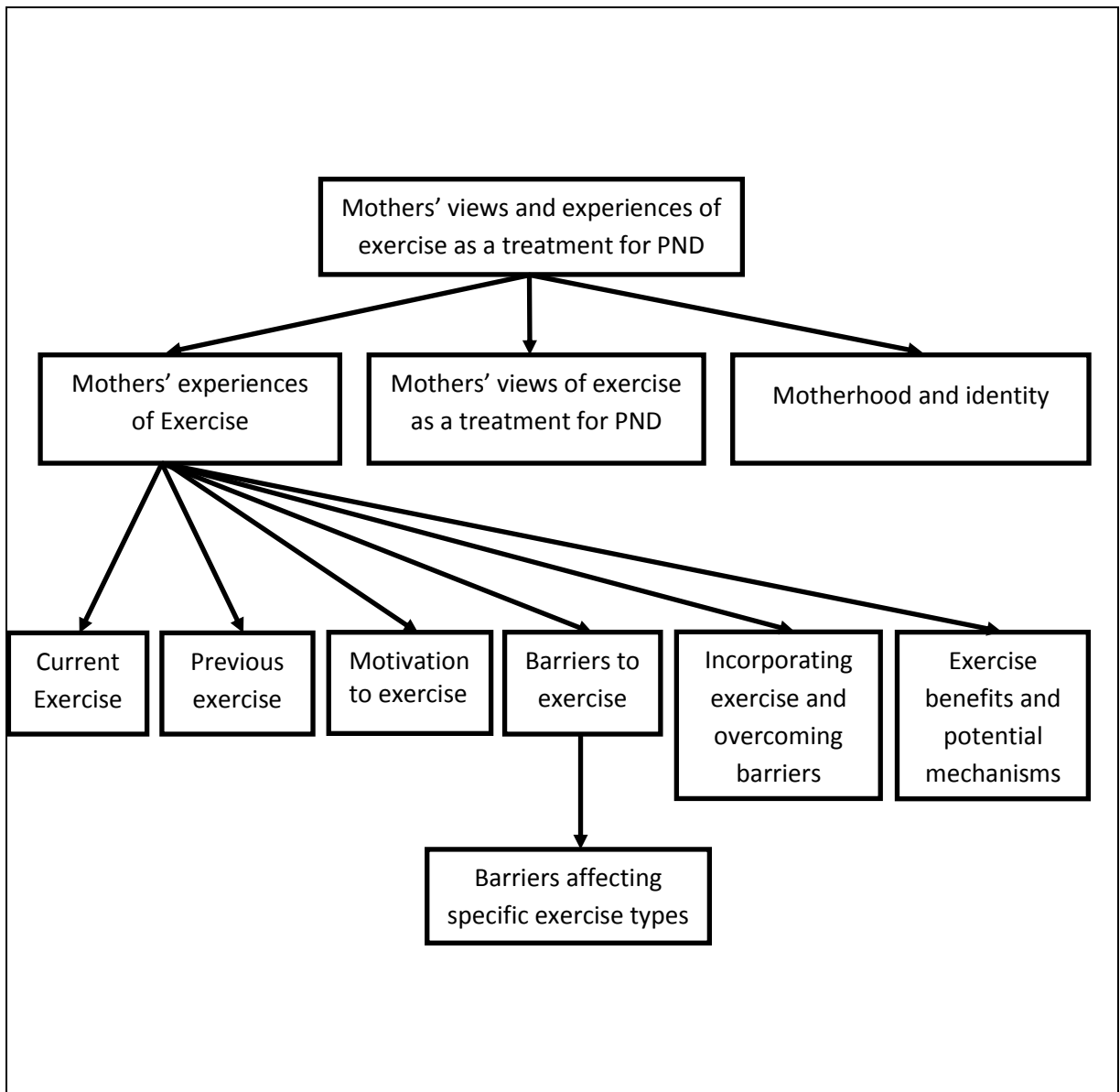
reported benefits of exercise and the postulated mechanisms by which these benefits may have been achieved were then discussed to provide an initial exploration the ability of exercise to influence wellbeing, either through physical or psychological channels. Implied changes in a woman's identity after childbirth were discussed and mothers' beliefs regarding the ability of exercise to influence these effects were described. Finally mothers' stated views of exercise as a treatment for PND, individually and in relation to the broader range of current treatment was explored.

5.3.3 Summary of key findings

This qualitative exploration of depressed mothers' views and experiences of exercise found that despite significant practical, physical and psychological barriers, it is possible for exercise to be successfully incorporated into daily life by women with PND. Mothers reported a loss of personal identity both related to experiencing PND and to their experience of motherhood. For some mothers, exercise was felt to have a positive influence on sense of self by providing an opportunity to focus on themselves and experience a sense of control and achievement of personal goals. A broad range of physical and psychological benefits were reported from exercise: an increased sense of energy to perform the necessities of daily life, improved body image and self-esteem, improved mood and feelings of calmness, reduced isolation and distraction from unwelcome thoughts. A range of views were presented regarding exercise as a treatment for PND, with some mothers believing it to be an important way of improving their mood and others questioning its efficacy for more severe depression. However, a common perspective was that of exercise as a

natural, preferable alternative to antidepressant medication, especially in the treatment of mild to moderate PND.

Figure 12: Overarching question, themes and subthemes



5.3.4 Thematic analysis

5.3.4.1 Current exercise

Mothers most frequently described incorporating exercise in their daily lives through walking, either alone or with the baby in a pram. The expressed purpose of this activity varied from walking for its own sake, to walking for necessity, such as to a child's nursery or the shops. This form of exercise was also described as preferable by those not wishing to join groups, but perhaps appreciating the company of a friend in a similar position. Several mothers reported engaging in more physically demanding forms of exercise such as running, jogging or swimming. Some mothers related that classes aimed at making children active such as 'tumble jungle' provided some activity for them as well. Overall, comparatively few mothers reported going to the gym, but some considered it to be a valuable form of exercise. Some mothers described using home exercise equipment, such as a treadmill or exercise DVD's. Alternatively, many mothers expressed a belief that the activity involved in looking after their children and home provided a substantial amount of exercise.

'My exercise at the moment is from the kitchen, washing and drying, yes I just run around up and down the stairs, I call that exercising at the moment...and then in the morning running around these two.' (ID 263, 34yrs, intervention)

5.3.4.2 Previous exercise

Prior to having their most recent child and more generally prior to having children, women's reported physical activity ranged from very little, to sporadic gym membership, to avid gym attendance. Some women recounted enjoying walking for

leisure or transport, some swimming, others running and some training for marathons. For those who were active, such exercise was often part of a pre motherhood routine with partners or friends.

'I used to do a lot of exercise before I was married, 24 hours, I was exercise mad.' (ID 263, 34yrs, intervention)

5.3.4.3 Motivation to exercise

Mothers described a wide variety of factors that motivated them to become more active. These ranged from knowledge of the physical and psychological benefits of exercise, to views around body image and fitness levels, to the influence of family and friends and their own sense of obligation. Some mothers referred to previous positive experiences of exercise enabling them to more easily envisage the potential benefits, such knowledge was felt to help motivate them through the temporary off-putting effects of exercise.

'I know that once I've done it I feel great so yes I look forward to that ... looking forward to the actual pain and sweat, no, [laughs] (ID 514, 29yrs, comparator)

Many women reported that a desire to experience an expected improvement in energy levels through exercise provided the motivation for beginning. Motivation was described as progressing from tentative thoughts of exercise being useful, to looking forward to the feelings experienced post-exercise and eventually looking forward to the exercise itself.

'those were the two things that motivated me I think. One, that it might help and secondly once I had done it once knowing how I felt afterwards and then it got to the point where I was beginning to look forward to it.' (ID 488, 33yrs, intervention)

Many women described the initial necessity to force themselves to become active as their motivation was severely lacking. Mothers discussed different methods of encouraging themselves, from attempting to be more decisive, to setting targets, to making activity a necessary part of a journey.

'I thought, 'well this afternoon before I pick up the girls I am going to park much further away and go for a walk because that spurs me on a bit but when it is wet and miserable you know I don't want to go.' (ID 3, 39yrs, intervention)

One of the most common themes discussed by mothers was the motivating factor of weight loss and the negative effects of poor self-image on depression.

'at the moment my goal is to try and get myself back into pre-pregnancy shape so I can feel, looking at myself I can feel that I look good and then I will feel good as well' (ID 389, 34yrs, comparator)

However, for some mothers, their post pregnancy fitness levels, which had often decreased during pregnancy, were referred to as being of greater concern than their image. This was particularly evident in those that had good previous fitness levels to compare themselves to.

For some mothers, motivation was considered to stem from a knowledge of their own mood. Some women reflected that they had reached the point where they

had to decide whether they were willing to live with how they felt or make a conscious effort to change it. In these circumstances, if a mother held negative views about traditional treatments for PND, she was more likely to express a desire to try self-help strategies.

'I can't take medication, I am quite sensitive to most things and so for me I think it came to a point where I had to decide what it was that I wanted to do. I could carry on feeling the way I was feeling and doing nothing about it and just accept that that is me, which I didn't like, or I could do something about it and I had nothing to lose.' (ID 488, 33yrs, intervention)

Low or anxious mood states have often been seen as barriers to physical activity. It is noteworthy, however, that the converse was reported by some individuals, for whom a worsening of their mood state was described as a motivator for exercise.

'if I'm low or anxious it is probably to do with me fretting about some really stupid thing like maybe I've eaten a chocolate bar or I think I'm going to put on weight and then I'm going to get ill and I just think stop it and get on with it, and get on with my exercise' (ID 514, 29yrs, comparator)

Support of family members was described as improving a mother's motivation to exercise. A little peer pressure from a friend was also referred to as a significant motivator, with women describing feeling accountable to each other and the need to appear consistent in their efforts to exercise. A sense of obligation or guilt was also described as being a motivator to exercise when there had been financial outlay. A combination of financial guilt and family influence was sometimes described as bringing significant pressure to bear.

'we used to run together and we used to train and when one of us couldn't make it the other would say "did you go? Did you go to the gym?" ...So there was that accountability' (ID 481, 30yrs, comparator)

'I bought the cross trainer. There is no way he is going to let it sit there for much longer because I have paid for it you see now and I can't send it back.'
(ID 488, 33yrs, intervention)

5.3.4.4 Barriers to exercise

Mothers with depression reported a broad spectrum of challenges to initiating exercise, from the physical and practical to the psychological. Mothers reflected on the way depression caused them to isolate themselves not only from activity, but from every part of their lives. The inhibitory effect of anxiety on seeking new opportunities to exercise was also described.

'when I'm feeling low you won't get me out of the house...you won't get me out of my bedroom...I lock myself in my bedroom and just stay there.' (ID 277, 23yrs, intervention)

'I did hit quite a bad low, I wasn't able to even contemplate doing any classes or anything like that because I had quite bad anxiety, so even the thought of going into new places with new people I couldn't face any of that.' (ID 3, 39yrs, intervention)

One reported consequence of acknowledging this frame of mind, was a fear of pushing oneself beyond what one could psychologically cope with. This greatly affected some mother's ability to take on new challenges.

'I knew that with everything I had got going on I wasn't able to put myself under any more pressure with the anxiety.' (ID 3, 39yrs, intervention)

A lack of motivation was a significant barrier to commencing exercise. Even when a positive outcome could be envisaged from exercising, an overwhelming sense of inertia was still sometimes described. Some mothers expressed a need to report what they saw as legitimate reasons for their lack of activity. Despite this, there was recognition that the real cause was a lack of motivation.

'If you are feeling really low, then you just let everything fall on top of you to be honest. It doesn't really make any difference what it is, even if it is something that you enjoy doing, if you are not feeling good you won't do it.'
(ID 389, 34yrs, comparator)

'I was always making a lot of excuses for myself, I don't know why, I think it's just a general mindset when you're not feeling quite well. You just make excuses, like I said, it's too cold... not feeling quite well, he's not feeling quite well...It's always an excuse for lack of motivation' (ID 227, 23yrs, intervention)

A circular problem emerged regarding increasing exercise. Mothers who reported lacking the motivation to begin, described feeling guilty for not exercising and subsequently avoided committing to an exercise plan for fear of the guilt and low mood that would follow if they failed. This self-critical frame of mind also appeared to affect those mothers who had attained a certain level of fitness in the past. Some mothers explained how the activity they were capable of achieving now compared poorly with their previous achievements and they expressed an unwillingness to subject themselves to this comparison.

'the last thing that you really want to do is think about the exercise that you possibly haven't even been doing and that makes you feel even worse.' (ID 3, 39yrs, intervention)

'knowing what I used to be able to do to then only be able to manage ten minutes or something like that would be just too much for me to bear.' (ID 376, 34yrs, intervention)

This same judgemental attitude appeared to be applied by mothers to their own bodies. Many women were very self-conscious and critical of their appearance and felt that people who saw them shared this view.

'I think what is putting me off is I don't particularly like being out running in public, and sort of don't feel that I am fit enough yet to do it outside so I don't really like to be seen.' (ID 376, 34yrs, intervention)

Practical factors formed additional barriers to postnatal exercise. 'Time pressure' was a commonly reported thread through many postnatal women's lives and a significant impediment to exercise. Opportunities for physical activity were often replaced with quicker less energy intensive options, such as travel by car. In some cases, a lack of time seemed to have been used as an 'acceptable answer', when perhaps other factors such as a lack of motivation were the predominant barrier. Some women were aware of this.

'sometimes get sort of side tracked with a time factor, 'haven't got enough time to do it', you know and then if I think 'well actually you have got enough time come on. All you have got to do is go to school twenty minutes earlier and park further away'. You know you can fit that in...I think the motivation, some days can be a little bit lower.' (ID 3, 39yrs, intervention)

Mothers who returned to work after having their child, reported a variety of effects on exercise levels. For some there were fewer opportunities to exercise, for others there were alterations which were not entirely negative, such as the necessity to walk to work. However, when 'time pressure' was a part of life and many tasks seemed vital, exercise was frequently seen to have a lower importance. Priorities sometimes had to operate on a very basic level. If women were able to find some time for themselves, their reported preference was not always to spend it exercising.

'eating and having clean clothes is a higher priority than going for a walk.' (ID 539, 34yrs intervention)

'I think it's because if I've got 20 minutes spare I just prefer to sit on the sofa have a cup of, have a cup of coffee and relax.' (ID 387, 36yrs, comparator)

Situations were often recounted in which the desire to become active was present but the practical window of opportunity was easily lost.

'my husband was at work all day so you know there's no way, there's no-one to leave the baby with or anything like that and he worked long shifts so he didn't get back until eight in the evening by which point any sort of opportunity to really go and do anything in the evening has passed' (ID 46, 35 yrs, comparator)

Some mothers described a lack of encouragement from their families, which could have a profound effect on motivation to exercise.

'I wanted to buy a stepper erm ages and ages...that type of exercise I know is something that I would enjoy doing and I could put it in front of the TV or put my music on or whatever and my husband "what do you want one of them for? You won't use it". And so he discouraged me from getting it and so I didn't.' (ID 488, 33yrs, intervention)

In the immediate postnatal period, the physical recovery from giving birth was the first barrier mothers had to contend with before becoming active. For some mothers the recovery was described as difficult and prohibitive of exercise. The subsequent practicalities of breastfeeding were also reported to interfere with organising activity. The fatigue felt by women with a new born was also raised as a significant barrier to commencing physical activity.

'I had caesarean with all three of them and I was finding it really hard with coping with just the general chores, every day to day ones without doing exercise' (ID 487, intervention)

'I think sometimes you put it down to lack of sleep because if you are tired and as tired as you can be with a...baby, that makes a lot of things insurmountable.' (ID 376, 34yrs, intervention)

Some mothers also described how having a child had restricted their financial means, with equipment such as running machines being beyond their reach.

'I think exercise is probably one of the pursuits of the middle classes unfortunately because you need to have resources.' (ID 151, 37yrs, intervention)

5.3.4.4.1 *Barriers affecting specific exercise types*

Attempts to exercise in many different formats were recounted by mothers, including at the gym, in the home or going for a brisk walk outdoors. These different types of activity were felt to be subject to different kinds of impediments and to different degrees. For some, exercise seen as 'high impact' such as gym-based exercise created a barrier in itself, as a certain amount of unwelcome tiredness was anticipated. For those who wished to begin such exercise, the availability of support from friends and family in providing informal childcare was said to be vital. The alternative option, of taking children to the gym with you, was also described as challenging, as many gym crèches would not take children under a year old. Some mothers argued that there was...

'a lack of resources to help people that don't have family' (ID 539, 34yrs, intervention)

For some mothers, a lack of self-confidence manifested itself in a reported preference for not attending the gym without adult company, but there was often no one to accompany them. Others described a reluctance to 'present' themselves to the world again; this led them away from attending gyms to other more private forms of exercise.

'I don't want to get all dolled up and face the world, it's literally there. [home exercise bike] That helped me actually get going again.' (ID 227, 23yrs, intervention)

Religious beliefs could also make it difficult for some mothers to find an environment they felt comfortable exercising in.

'I was looking for a ladies only so I can take my hijab off, and the other thing erm, I didn't like the camera when they have cameras on, I have to look for a gym where they don't have like camera security, again because I didn't want to have my scarf on.' (ID 409, 32yrs, comparator)

Some mothers discussed choosing activities that seemed more child-friendly such as swimming but even here, practical obstacles were reported.

'if I try to go at the weekend with all three children they won't let you in the pool because I've got three children under eight.' (ID 46, 35 yrs, comparator)

Mothers also described how exercising with children present, while providing enjoyment did not necessarily provide them with a significant level of aerobic activity.

'I love swimming and that, but I can't go proper swimming, I mean I can take her to paddle, but I can't say stay there a minute I'm going to do 30 lengths' (ID 514, 29yrs, comparator)

Walking was reportedly a popular way of introducing physical activity, seeming to circumvent many of the obstacles mothers reported to other kinds of exercise, such

as the monetary requirements, lack of flexibility and childcare requirements of more formal exercise. However, despite its reported popularity, the rewards of walking were not always seen to outweigh the significant effort required to organise it. Some mothers also explained how the aerobic and the social side of walking could be restricted by the presence of children.

'sometimes I feel it's a hassle to take the pushchair and open it up and get everything in the bag and make sure she's ready to go out, the milk is there and just to go for half an hour, and it's not like, I don't enjoy doing that, there's nothing interesting around.' (ID 409, 32yrs, comparator)

'the goals for the walk was I would go for a walk, then have a cup of tea with a friend in the café or whatever and walk home...I couldn't go for a brisk walk with him and then he wouldn't want to sit in a café anyway.' (ID 539, 34yrs, intervention)

For some mothers, walking with friends was seen as preferable; however mothers described feeling self-conscious amongst other women without babies.

'sometimes a friend did accompany me, but it was difficult with the baby because obviously I had to stop and feed and all the rest of it' (ID 76, 44yrs, intervention)

Practical barriers related to outdoor exercise included cold, wet weather and the limiting effect of walking as a form of transport, including the difficulties of carrying the weekly shop over any distance. Time dedicated specifically to walking in desirable surroundings was also said to be hampered by lack of transport. A natural

solution to the numerous practical barriers to outdoor exercise was home-based exercise, however, some women described the monotony of home-based exercise as off-putting. The constant presence of children also made creating a suitable environment for exercise within the home particularly challenging.

'you need to be by yourself and with me I had erm all these children around me 24/7 and I just couldn't do exercise at home ' (ID 487, 41yrs, intervention)

5.3.4.5 Overcoming barriers and incorporating exercise

Some women expressed a view that exercise should be incorporated within daily life and felt that it was desirable to begin gradually. Mothers noted the importance of being aware of their own abilities and not creating high expectations that could be off-putting.

'Exercise is just walking and just in the park, and fresh air...it doesn't matter about your age or what condition you're in...doing a couple of steps, increases to a lot of steps.' (ID 76, 44yrs, intervention)

'you know what you can do and then start to push yourself more and more from that point...if you set the bar too high then you're going to, you're going to be sort of disillusioned from the start' (ID 578, 36yrs, intervention)

Many women reported that physical activity had to be incorporated within both the practical constraints of motherhood, and the constraints of their depression. If mothers were able to be adaptable to their mood, they often described being able to achieve at least some activity.

'I had some days when as I say, just getting up and getting my children to school and looking after [baby] was enough, and you know I really couldn't do any more and on those days I didn't push myself to do anymore. You know erm and then on days when I was feeling a little bit brighter I could achieve more and I was able to, 'right I am going for a walk today' (ID 3, 39yrs, intervention)

Mothers reported various methods of incorporating different types of physical activity into their lives. Walking was by far the most frequently mentioned form of activity, as it could be incorporated into the daily tasks of life, however, many women also recounted introducing walking for recreation.

'when there's nice days like this, just going for a little walk in the park at [name] it's erm, nice, because you just go round the, there's a lake there and there's ducks in there and it's just so nice you know.' (ID 76, 44yrs, intervention)

Parity was a significant influence on the context of walking. Mothers with more than one child more frequently referred to incorporating exercise into daily life and including their children in the activity, such as by walking to school with older children. The lack of crèches available in gyms was understandably described as a greater barrier by those with more than one child, making gyms even less accessible. For mothers with only one child, exercise was more frequently described as separated from daily life and viewed as a break from childcare responsibilities, for example in greater use of the gym. Running was also reported by a significant number of women. Some women explained that they found independence in

running, as it offered exercise by oneself that was accessible from the front door and consequently required minimum child care.

'the only way I've been able to incorporate regular exercise into life is by running because I haven't got to go anywhere, I haven't got to be away from the house for a long period of time...as soon as he gets home from work, I've got my kit on, I'm ready to work and I shoot out the door for twenty minutes'
(ID 151, 37yrs, intervention)

Conversely, many women explained that they felt themselves active in their daily lives. House work and caring for children were said to provide a constant level of activity. Other techniques were also recounted which were intended to improve the exercise content of such activity.

'I would be putting my washing out and I would be marching on the spot, picking up, doing really weird things like that just because I knew, I knew it wasn't going to get my heart racing erm it was just to add to the activity that I was doing' (ID 488, 33yrs, intervention)

Some women discussed how exercise within the home, such as the use of treadmills or cross trainers, had its advantages. The need for childcare was eliminated as well as the financial cost associated with transport and with accessing a gym.

'Yeah, yeah on the running machine I do, yeah... we bought it because I thought if it's there then that excuse sort of falls away...I usually now do it when he's gone to bed, there's no excuse whatsoever because he is in bed. (ID 227, 23yrs, intervention)

Some mothers reported attending exercise sessions outside the home, certain schemes such as the 'Be active' scheme in Birmingham provided free pool use, making such activities more financially accessible. Similarly, groups run by midwives enabled mothers to bring their baby to an exercise class providing what mothers felt to be a suitable environment for them both.

'this swimming thing, which is done by midwives so they're not opposing to you bringing a baby. So that was quite good just knowing that these places exist and that you know, they don't mind you bringing the baby.' (ID 227, 23yrs, intervention)

For some mothers their reported preference was for exercise at a local gym. This structured exercise was again often made possible by relying on informal childcare from family. For some mothers, they envisaged a point in the future when childcare would allow them the freedom to pursue more exercise.

'she might go into nursery for a couple of days and then I'll be freed up to do some sort of more exercise that I want to do.' (ID 76, 44yrs, intervention)

5.3.4.6 Exercise benefits and potential mechanisms

Mothers reported a wide range of physical and psychological benefits from physical activity. The influence of such activity on mood and a mother's sense of identity were also described. Many women explained how tiredness often led to inactivity, which itself led to increased feelings of lethargy. If the motivation could be found to begin exercise, many women reported experiencing an improvement in their energy levels and mood.

'it becomes a vicious circle because you feel tired so you don't want to exercise, so then you feel more tired. Um, it can be quite a downward spiral, and I think it's when you do start to exercise you realise it actually gives you more energy and makes you feel more positive.' (ID 151, 37yrs, intervention)

This increase in feelings of energy and motivation was deemed to be very valuable in enabling mothers to complete the necessary tasks of the day.

'Imagine I've done a full day at work, I've been up since six, I'll either run before we put the girls to bed or I'll run just after...there'll be three evenings where I'm not exercising, I find it really hard to motivate myself then to tackle that second bit of the day, which is dinner, getting stuff ready for tomorrow etc. Whereas if I've done a run I'll just plough through it...and it's fine.' (ID 151, 37yrs, intervention)

Mothers who mentioned low motivation were more likely to report this increase in energy (especially to fulfil domestic chores), than those who reported no motivation problems. Some women believed that this energy boost came from the release of endorphins.

'You spend more energy but you actually feel like you have more energy because you know you've got the endorphins kicking in' (ID 578, 36yrs, intervention)

However, some mothers described the tiredness resulting from exercise as beneficial as it led to improvements in sleep. Some women believed the improvements in their sleeping pattern were related to the intensity of their exercise.

'I've been physically exhausted by the time I have gone to bed. Maybe I have had no other choice but to sleep but it was nice' (ID 488, 33yrs, intervention)

Body image after having a child was discussed by many women. Some mothers reflected that reducing weight led to improved confidence and self-esteem which in turn reduced depressive feelings. Women described two courses of action: a positive cycle of exercise, weight loss and a sense of achievement leading to further exercise or a downward spiral of feeling overweight, sluggish and becoming less active. Weight loss and improving fitness levels also reportedly enabled mothers to be more active with their children, which they took great pleasure in.

'Recently because I started to lose a bit of weight, that encouraged me, I feel lighter and I feel like I enjoy walking faster or running with my daughter when I take her home for the nursery...but whenever I gain more weight I feel more like lazier and I feel difficult to move around, it's like a circle...more weight, you feel more depressed and you're like slower' (ID 409, 32yrs, comparator)

Mothers described feeling a sense of confidence in outdoor activity that they did not always feel in their home. Activity was reported to create a sense of achievement in reaching a simple, clear, attainable goal. Such goals were not always felt to be part of the open ended task of caring for a new-born.

'You have your hands fully anyway, so it's not like you're sitting there bored, but it's a different kind of exercise if you want to say, a different kind of tired. Like when you've done a run and stuff it's like, 'I've achieved something.' At the end of the day with a new-born you're just like dead to the world, you're just done with the world.' (ID 227, 23yrs, intervention)

Mothers with moderate depression were more likely to refer to the ability of exercise to improve self-esteem than those with mild depression. Some mothers reported that this sense of achievement occurred in proportion to the intensity of exercise performed.

'It's just a sense of achievement if you know you've done so much, just pushing that little bit extra and when you come back you feel like you've done something.' (ID 227, 23yrs, intervention)

However, not all mothers related a need to take part in intensive exercise; for some simple practical activity that fitted into the daily routine still gave a sense of pride.

'just like being able to remove my daughter, just like from the nursery without the car, just a matter of 40 minutes really, being able to do that, it's something that really makes me happy.' (ID 409, 32yrs, comparator)

Some mothers described how physical activity in its simplest forms had a traceable effect on their overall mood and the phases of acute depression they experienced. Exercise was also reportedly used preventatively by some mothers, by recognising the early signs of worsening depression and using activity to prevent them developing further.

'I have my down days, of course I do, I can't say to you that I don't, but the thing is I can cope better with them because if I'm feeling really, really low instead of going back to my bed which is what I used to do, I'd try and let her have a nap earlier in the day and try and get out and have a walk.' (ID 76, 44yrs, intervention)

There were many ways in which mothers postulated outdoor activity may create this effect, for example a change of environment acting as a distraction from unwanted thoughts.

'how do you feel when you are doing the walking?' (interviewer)

'Lighter, erm calmer erm there is a world out there and there are other things that are going on that can take my mind off my own stuff, you know. It is kind of distraction I suppose' (ID 3, 39yrs, intervention)

Alternatively, for some, walking outside in a park was said to provide a sense of peacefulness conducive to thinking through problems with a sense of perspective.

'I have conversations in my head and it is a good time for thinking and putting things into perspective. It is breathing the fresh air, looking at the trees and in a certain way I'm content and happy.' (ID 76, 44yrs, intervention)

However, sometimes the sense of freedom and enjoyment experienced outdoors was described as providing an unhelpful contrast with time spent within the home.

'when you come back it's sort of twice as difficult... because my walks were usually on the way to picking my son up from school and we come back and then it is back to that sort of like right get the tea done, get everything sorted, that sorted, homework to look at and it's back to the grind really' (ID 376, 34yrs, intervention)

The apparent propensity of exercise to keep the mind occupied and prevent unwanted, guilt related thoughts had a relaxing effect in some mothers. In contrast, trying to relax in more traditional, inactive, ways was said by some mothers to lead

to more worrying as the mind had time to dwell on the unwelcome thoughts.

'if I say okay sit down and have a cup of tea and relax I am thinking I should do this, should do that, whereas if I am exercising I am doing something else anyway so I am not worrying about the other things' (ID 539,34yrs, intervention)

Another beneficial consequence of the calming effect of exercise raised by some mothers was a feeling of being psychologically more able to cope with caring for their children.

'rather than sort of racing up to the school, racing back again and you know, and also do things like go to the park or something on the way home which we are lucky enough to have and I feel a bit more sort of calmer and able to deal with having both of them for a few hours. (ID 376, 34yrs, intervention)

Mothers with moderate depression were more likely to refer to certain benefits of exercise than those with mild depression. These benefits included receiving a sense of achievement through exercising; feeling calmer or more relaxed and having more energy after exercise, in particular for childcare and household chores.

5.3.4.7 Motherhood and identity

5.3.4.7.1 New identity

Many women referred to a change in or a loss of their identity after having a child.

'obviously I was as new to being a mum as he was to being a person, so I think you just have to find your way of doing it and setting that time aside, because for a while...you do lose yourself a little bit because...once they're here it's like you're just mum.' (ID 227, 23yrs, intervention)

The constant presence of children and the demands of childcare were described by some mothers as having a detrimental effect on their psychological health.

'Maybe it was the depression because I'm always constantly under stress aren't I, I'm always tired, I don't get any time to myself, I don't relax, at nights I'm awake with them, at days I'm with them, you know it's just too much, it would put any human being down' (ID 487, 41yrs, intervention)

5.3.4.7.2 *Exercise as freedom*

Some mothers explained how exercise provided a sense of freedom from their role as a mother and the importance of this. Exercise was described as a rare opportunity to focus on themselves, enabling them to regain a sense of their own identity as separate from being a mother. Some mothers also reflected on the physical loss of control over their own body as they fulfilled the needs of their child before their own; exercise was viewed as helping them to regain a sense of physical autonomy.

'I run out the front door and I could almost do that [hands in the air] because it's like 'yes, I'm away'. There's no-one tugging on my trousers, 'mummy can I have a drink.' It is that real sense of freedom and I think that's so important when you've got little kids because you just don't have that.' (ID 151, 37yrs, intervention)

'it's difficult to find a balance of being mum and that other person as well, because that other person needs to wash her hair and needs to sort of get dressed nicely, eat properly, do a bit of exercise and have a bath to herself...the exercise just makes you feel okay, yes, I'm in control of my body again' (ID 227, 23yrs, intervention)

Many mothers described struggling not to view focusing on themselves as selfish, but the health and psychological benefits of exercise were felt by some to justify this.

'What I am keen to do is start running a bit more again...it is like quite a selfish thing, you go out and I'd be out for an hour and a half or two hours or something and just on my own and I really enjoyed it and it did make me feel healthy, it made me feel good about myself, and it was, you know a great excuse to have you know just a little bit of time off and time away from domestic stuff.' (ID 376, 34yrs, intervention)

The assumption of society that the child would naturally be a mother's first priority left some mothers feeling the need to emphasize that wanting time away from their child was not a reflection of a lack of love for them.

'I was like up with him all night, up with him all day and please god sleep for a bit...I was breastfeeding him as well so I was just like no space for myself and I was like oh my god, don't get me wrong I love my son bits but sometimes you need a little five minutes to yourself.' (ID 729, 24yrs, comparator)

Mothers with more severe depression referred more frequently to the ability of exercise to both provide time away from the 'mother role' and also its ability to help them fulfil the mother role (either through family exercise or through being healthier for their future).

For some, motherhood was seen as an isolating experience. Physical activity was described as one way of regaining a sense of being part of the wider world.

Many women indicated that the need to be constantly within the home was

oppressive and psychologically negative. Simply being outside removed some of their sense of separation, especially for those without the support of a partner.

'It's just nice to be outside as well yeah, see the world around you, there are other people living around, it's not just me (laugh)...That's how I feel sometimes, I feel I am the only one in this world, there is nobody around me because you are always stuck in here with these kids you know, it's just so hard.' (ID 487, 41yrs, intervention)

5.3.4.7.3 *Social interaction and peer support*

Some mothers also reported that group exercise provided the adult social interaction they felt they were lacking. Interaction with those in the same situation was noted to be especially desirable by some mothers. Time spent with those who would empathise with their experiences was felt to be particularly valuable. Mothers with moderate depression discussed the benefits of receiving support from their peers via group activity more frequently than those with mild depression.

[Re mother and baby classes]

'so you get to meet other people in your situation sort of thing, they won't be exactly the same but they're on the same wavelength as you.' (ID 729, 24yrs, comparator)

5.3.4.7.4 *Being a 'good mother'*

Some mothers, who were used to a sense of confidence and competence in their lives, described how the lack of control they experienced while caring for their child affected their sense of self.

'For somebody who's always been very in control, very organised, um, I've always had a really challenging career, this was just something that I'd never experienced before in terms of, um, just feeling utterly out of control and not coping and really being a terrible mother' (ID 151, 37yrs, intervention)

The pressure to be thought a good mother, fully capable of looking after her children, sometimes appeared to originate from external sources and sometimes from a mother herself. For some mothers with PND this pressure seemed to lead to an outward denial of the condition.

'I didn't want to worry my family and have them thinking that there is anything wrong with me or that you know the girls aren't going to be looked after' (ID 578, 36yrs, intervention)

However, some mothers explained that their desire to recover from PND was driven by this need to be better carers for their child. This desire was sufficient to overcome their fear of judgement.

'I needed to get up and do something, the longer I kept myself in the house and kept the kids in the house and didn't go out and doing anything the worse I was making it for all of us... it [exercise] was something that was achievable, it wasn't out of my reach, it was, it was feasible.'

'so you didn't want to just have to wait until you got better, you wanted to do something.' (interviewer)

'No, no, yeah I couldn't afford to, you know two kids that need a mum in decent working order' (ID 578, 36yrs, intervention)

One of the changes in perspective reported after having a child was that of viewing health and exercise from the perspective of needs of the child and family. Some mothers expressed a desire to feel capable of providing positive experiences for their family through exercise. Another powerful driver for exercise was the need to be healthy as your child grows up and beyond to the thought of grandchildren.

'I mean everyone's a little bit vain, but my opinion is I don't care what other people think about me and what I look like and whatever, I don't care but I feel like even more pressure now to be healthy and fit because I want to be here to see her have children do you know what I mean?... it's not just about me now it's about being healthy and having a long life for her.' (ID 514, 29yrs, comparator)

Mothers who reflected most on their loss of identity after birth reported feeling the greatest benefit from exercise that bought them away from the home, by themselves. Mothers who dwelt on their need to bond with or provide positive experiences for their child place more value on activities such as walking with their baby in the pram.

5.3.4.8 Mothers views of exercise as a treatment for PND

There were a range of views as to whether exercise was a potential treatment for postnatal depression, both independently and in addition to other more traditional treatments. Some mothers discussed the inhibiting effect of the stigma attached to PND, which discouraged them from seeking traditional forms of treatment. Some mothers explained that exercise was one method of self-help that did not necessarily require full disclosure.

'initially I did have the concerns that I didn't want anyone to know, I just wanted to erm hide myself away and you know sort of deal with it, but then I realised that I can't do that. I needed to get help and I needed to start to you know, explore avenues that could help me or I could help myself, so I kind of I overcame that a little bit, still had it a bit the stigma and 'what will people think?' But then people don't need to know that I am doing it [exercise] necessarily, it is up to me who I tell and as it turns out now I am much more open about it than I was.' (ID 3, 39yrs, intervention)

Many mothers reported that they found exercise to be an effective treatment for PND. Some explained that it had been an important barrier between themselves and their depression and for some exercise had made their recovery more rapid.

'that's what kept me sane really, putting the children into the pushchair and just going, walking and walking' (ID 151, 37yrs, intervention)

However, some mothers expressed a view that exercise would only be effective if it could be maintained long-term, of which they were doubtful. The barriers of being a depressed new mother were felt by some to render exercise an impractical solution in reality.

'the theory of it is brilliant...But it is just putting it into practice for each individual might not be that easy really.' (ID 3, 39yrs, intervention)

Some mothers explained that they considered exercise to be a preferable first step in managing PND, perhaps negating the need for other forms of treatment.

'I mean I think it's a good idea, I mean I think you should always try more practical things before you resort to drugs in these sort of things.' (ID 46, 35 yrs, comparator)

There was a realisation amongst some that even traditional treatments such as counselling were not a guaranteed cure and looking for ways to improve the situation themselves was also worthwhile.

'even if you get a therapist, even if you get the help that you want specifically, it doesn't mean that they are going to do it for you. You are still going to have to do it yourself, um ... it was just a case of I've got to do something now, make it better, um, rather than look around for someone else to come and do it for me because that person's not going to come.' (ID 227, 23yrs, intervention)

Several mothers expressed a view that exercise and the resulting endorphin release were 'natural' and inherently preferable to antidepressants, which were often seen as a poor artificial solution in the management of PND.

'exercise endorphins, feeling good about yourself, that has to be better than medication, it just has to be... I just can't conceive how it cannot be better than pumping someone full of artificial chemicals that just mess with the brain' (ID 151, 37yrs, intervention)

A view of depression after giving birth as temporary and due to hormonal imbalance was conveyed by some mothers. Antidepressants were seen as the wrong treatment for a temporary condition, a behavioural solution was preferred. Some mothers who

had experience of antidepressants described exercise as a less damaging alternative.

'I felt that the antidepressants were making the situation worse, in the sense that they made me very tired and lethargic and, um, quite disconnected. That was just exacerbating how I was already feeling so ... and I was aware that exercise releases endorphins, which helps with your mental state so it seemed to be, for me, a better alternative to medication' (ID 151, 37yrs, intervention)

Similarly, for those whose previous family history with antidepressants had given them a strong negative impression of them, such medication was described as very undesirable.

'I'm not really a good person with tablets because I've seen my dad and erm, they was addictive... I don't want to be one of them who can take tablets' (ID 210, 26yrs, comparator)

For some mothers with mild depression, a combination of counselling and exercise was described as being the optimum form of management. Antidepressants were felt to be a heavy handed approach, producing unwanted side effects. Medication was often seen as a last resort for those with severe depression.

'the exercise is great, but I also do think the counselling is very important. So some link with, um, counselling support I think would be really ... that would be such a great package of care then, rather than resorting to medication, which I really don't think is helpful for a lot of women, particularly if you've got fairly mild depression...it's a sledgehammer to crack a nut.' (ID 151, 37yrs, intervention)

However, not all women shared a positive view of exercise as a treatment for PND.

Some mothers experiencing very low mood, described such activity as offering only temporary relief from depression.

'The thing with depression it has got a mind of its own, it just doesn't listen to you. No matter how hard you try some days you will still come back after spending the whole day out and the minute you walk through the door you are just like 'here we are again' and it is a constant struggle, a constant battle against it.' (ID 389, 34yrs, comparator)

For some, especially mothers with severe depression, antidepressants were seen as an important component of treatment. However, pharmacological, psychological and self-help strategies were also said to have their place in improving mood.

'I think that it has got to be very tailored to each individual's care plan hasn't it because initially for me the exercise would have probably been enough but when I hit the floor really bad in the summer there is no exercise in the world is going to get me through... it has just been the combination effect of all of it. It has definitely got its place though you know because I think that you can do a lot to help yourself in terms of eating properly and getting out and doing a bit of exercise, doing that walking and trying to find time to relax. So all of that alongside medication and counselling, you know. I don't think either one on its own would have been enough for me.' (ID 3, 39yrs, intervention)

It should be borne in mind that the commonly reported belief that antidepressants were for those with severe depression, appears to have been based on a mothers own perception of the severity of her depression, as this view appeared to be held by mothers with a diagnosis of mild, moderate and severe depression.

5.4 **Discussion**

In the following discussion, the range of practical, physical and mood related barriers to exercise related by women will be discussed, including factors conducive to incorporating exercise into daily life. The loss of personal identity associated with depression and the postnatal period will be discussed and the influence of exercise on a mother's sense of identity. The reported benefits of exercise will be summarised, such as feelings of energy and calmness, improved body image and self-esteem, improved mood, reduced isolation and distraction from unwelcome thoughts. Finally, the range of views reported regarding the acceptability of exercise will be presented, informing the conclusion that many women viewed exercise as a suitable treatment for PND.

5.4.1 **Barriers to exercise**

There were many barriers to mothers including physical activity in their lives. Many were likely to be common to all women in the postnatal period such as recovery from giving birth, the practicalities of childcare, time limitations and financial pressures. In the following section, those factors which may be more unique to mothers with PND have been discussed.

5.4.2 **Co-morbid depression and anxiety**

Several mothers within this study referred to experiencing both depression and anxiety, which have been found to be frequently comorbid in the postnatal period (275). For some mothers within this study, the combination of anxiety and depression created a serious impediment to certain types of exercise. For many,

depression resulted in very low motivation, as it is also known to amongst other depressed populations (188). Anxiety caused self-isolation as the prospect of exploring new environments, opportunities or taking part in group activities was felt to be overwhelming. It is important for health professionals recommending exercise to consider these barriers as well as the physical obstacles to exercise in the postnatal period. However, it should be borne in mind that for some mothers, an awareness of deterioration in their mood or state of anxiety was felt to be a motivator for exercise, with exercise being used to prevent a worsening of mood symptoms. Discussion with the individual patient may reveal whether low mood forms a barrier or a motivator for exercise.

5.4.3 Coping strategies

The language used by many of the mothers in this study revealed a self-critical, self-doubting attitude, both in relation to their physical and their psychological capabilities. Some mothers were very critical of their own appearance whilst exercising in public; others were reluctant to compare themselves to their previous levels of fitness or abilities. Some mothers were frightened to push themselves beyond their psychological limit while suffering PND and were reluctant to commit to exercise for fear of failure and the low mood that would follow. Such thought patterns may be an indication of maladaptive coping strategies such as self-blame and behavioural disengagement; such strategies have been found to be more prevalent amongst depressed populations (276, 277). Recent work by Gourounti et al. has also linked such strategies to an increased risk of depression in the perinatal period (278). Such coping strategies, in women with PND are likely to be a significant

barrier to exercise. Cognitive behavioural therapy (CBT) can support people in progressing to more positive coping strategies such as acceptance of changed circumstances or abilities, positive framing and active coping (279). CBT may therefore be useful for those with PND who are struggling to initiate or maintain exercise.

5.4.4 Successfully incorporating exercise into daily life

For many mothers, taking the view that exercise could be initiated with small steps, incorporated into daily life and increased over time was more successful than assuming that regular gym attendance was the only acceptable method of exercise. This finding is supported by the ‘false hope syndrome’ postulated by Polivy and Herman in which unrealistic expectations are seen to result in the eventual failure of the attempted behavioural change, as initial feelings of control are lost and the behaviour becomes difficult to sustain (185). Being aware of one’s own limitations, both physical and mood-related and not forming unrealistic expectations were found to be beneficial in the present study, in incorporating exercise flexibly into life.

Several practical factors were found to be conducive to exercise. Informal childcare from family and friends was often instrumental in enabling mothers to exercise by themselves. Arrangements such as walking to school, parking further from a destination and walking the remainder, home exercise on a treadmill whilst children were sleeping and running around the block when a partner returned from work all enabled exercise to be achieved within the restrictions of life. For some, exercise was a form of recreation, such as walking in a local park. Mothers with one child were more likely to walk for recreation; those with larger families were more

likely to incorporate exercise into the daily necessities. However, it should be borne in mind that a substantial proportion of women considered themselves sufficiently active in completing childcare and household tasks. It is important to note here that I am an unmarried woman with no children. My lack of experience in these fields of life may have affected my ability to understand the practicalities of exercise with children and therefore my ability to assist women in exploring them.

5.4.5 Motherhood and identity

Some mothers made reference to a shift in their identity after childbirth.

Motherhood has been identified as a time of transition and transformation in women's lives (119). For some mothers in the present study, this was felt as a loss of their personal identity. This lost sense of self has been highlighted by other research conducted in the postnatal period (120). This may be related to the shift of focus from a woman's own needs to those of her child, with the constant presence of children being felt by some to be detrimental to psychological well-being. An altered sense of self may also be related to experiencing depression (121), with some mothers in this study reportedly feeling unable to recognise the person they had become. It was noteworthy that exercise provided a sense of temporary freedom from the mothering role, allowing mothers to focus on themselves and providing a sense of personal achievement. The sense of physical and psychological autonomy that accompanied exercise was felt to support the regaining of their personal identity. However, for many there was a conflict between the desire to prioritise their child and the desire to regain a sense of their own separate identity, this was evident in the struggle not to view exercise as selfish. The presence of such a conflict

has been found in previous research with mothers in the postnatal period (280). However, there was a recognition amongst some mothers in this study that the time spent away from the mothering role facilitated by exercise, actually made them feel more able to fulfil their role as a parent, either through improved mood, energy, ability to engage their family in exercise, or safeguarding their own health for their family's future.

I have not experienced the life changing event of becoming a mother, neither have I experienced depression. My lack of knowledge relating to these processes may have affected my ability to help mothers discuss their experiences. However, a lack of expectation as to mothers' experiences and views may also be useful in preventing me from influencing mothers with my own views, enabling them to speak freely.

5.4.6 The purpose of exercise

The type of activity a mother chooses to engage in may be affected by how childbirth has influenced her sense of identity. Mothers spoke of exercise that took them away from the home without their children, either amongst peaceful surroundings or amongst empathetic peers, as being of greatest benefit in helping them to reconstruct their own identity. However, exercise can also create opportunities for shared positive experiences for mother and child, which can provide a sense of achievement in the mothering role.

5.4.7 Exercise benefits and depression severity

Throughout this research mothers described receiving a range of benefits from exercising and their discussion of the ways in which they believed they obtained these benefits has provided support for the hypothesis stated in chapter five, section 5.1.3.1 that this research could provide valuable insights into the possible mechanisms via which exercise may confer psychological benefits.

One of the principal benefits reported in this study was a feeling of increased energy after exercise. Such effects have been previously reported in postnatal populations (281). In the present study, those with moderate depression referred more frequently to having more energy in general after exercise and more specifically for childcare and chores, than those with mild depression. Mothers experiencing more severe depression may experience a greater corresponding lack of motivation. The contrast between this lack of motivation and the post-exercise energy boost may therefore be more noticeable. Furthermore, anticipation of this post-exercise energy increase and the improved mood that followed, were significant motivating factors for further exercise amongst women of all severities of depression.

5.4.8 Body image and depression

Body image was clearly of great importance to some mothers in this study. Weight gain was felt to be the start of a cycle whereby increased weight led a diminishing of motivation for exercise, which resulted in greater weight gain, which was felt to trigger a deepening of depression. In contrast, weight loss and the accompanying improvements in self-esteem were felt to reduce low mood. In 2010, Azar et al.

conducted a qualitative study exploring the relationship between physical activity and depressive symptoms in young women. In concordance with the present study, the authors also found weight loss and body image to be significant motivating factors for physical activity amongst depressed women (282).

5.4.9 Reduced isolation and negative introspection

There were several further mechanisms by which exercise was felt to have a positive psychological impact. Activity was felt to reduce isolation by improving social interaction. In particular, interaction with other mothers who shared their experiences and thought processes was felt to be valuable. Recent qualitative work by Doran and Hornibrook highlighted that such benefits can be drawn by women from supportive peer interaction in the postnatal period (283). In the present study, a calming, relaxing effect of exercise left women feeling more able to deal with the necessities of childcare. Exercise was also effective in providing a different focus, whether through the activity itself or the surroundings in which it was undertaken, this provided distraction from unwanted thoughts. The ability of exercise to improve mental health by distraction from stressful stimuli was postulated by Bahrke and Morgan in 1978 (284). Some women in the present study shared the view that less aerobically intense forms of exercise still provided psychological benefits related to relaxation, distraction and a sense of calmness that enabled quiet rational thought. It should be borne in mind by health professionals that despite the current emphasis on exercise of moderate intensity, the present study suggests that there may still be psychological benefits to less intensive forms of exercise, for those with PND.

5.4.10 Exercise as a treatment for PND

5.4.10.1 *Social acceptability*

A significant stigma surrounds PND. This frequently results in a reluctance to acknowledge possible symptoms to medical professionals for fear of judgement regarding a woman's capability as a mother (285). The socially acceptable nature of exercise in the postnatal period was seen as an advantage by mothers who were reluctant to seek traditional treatments necessitating disclosure.

5.4.10.2 *The effects of exercise on depression*

As a treatment, many mothers viewed exercise in a positive light. Some mothers found exercise helped prevent low mood and reduced the severity of the periods of low mood experienced. Some also found that engaging in exercise improved the rapidity of their recovery. A recent systematic review of trials testing the effectiveness of physical activity in postnatal depression supported this finding, reporting that exercise had a significant effect in reducing the severity of PND compared to control (101).

5.4.10.3 *Exercise and other current treatments*

A reluctance to take antidepressants for reasons including possible side effects, fears of dependency and the stigma attached to them was found to be prevalent, in agreement with previous research in mothers with PND (182). The significant influence of prior negative personal or family experience with medication on a mother's choice of treatment was also highlighted here, as within previous literature (182). Within this study, exercise and the endorphins believed to be produced, were seen as natural and preferable to more traditional pharmaceutical

treatments. A preference for natural alternative treatments has been reported amongst postnatal women (286). Many women saw exercise as a first step, with medication only for the severely depressed. Just as within the present research, Searle et al. have also found that exercise, as a sole treatment, was not considered suitable for the severely depressed amongst the general population; medication, either on its own or in combination with exercise, was considered preferable (187). However, the present research highlighted that this view was held by those with mild, moderate and severe depression, indicating that a mothers perceived level of depression may be pertinent when considering acceptable treatment in addition to diagnostic category.

5.4.10.4 *Exercise as a treatment for PND: The range of views*

There was feeling amongst some mothers that medication and counselling were not a guaranteed cure for depression, in light of this, exercise was seen as a useful self-help method. However, some mothers viewed exercise as a good idea in theory but not in practice, due to the many physical and practical barriers associated with the postnatal period. Exercise was also seen by a minority of mothers as providing a short term alleviation of low mood, with medication providing constant 'cover', a view that was also found by Searle in 2011 within the general depressed population (187). Some mothers felt that the optimum treatment for PND consisted of exercise in combination with medication and counselling. There was however, a common view that treatment, in whatever form, should be tailored to the needs and preferences of the individual.

5.4.11 The strengths and limitations of this study

This is the first study to explore mothers' views and experiences of exercise as a treatment for postnatal depression, significantly adding to the knowledge base around this treatment. The sample of participants included in this study displayed a good range of demographic characteristics such as age, ethnicity, parity and employment status. This variety improved the depth and the generalizability of these findings. In particular, this study successfully recruited participants from ethnic minority backgrounds, which has previously been found to be challenging in exercise research (287). All interviewees had received an ICD-10 diagnosis of depression or mixed anxiety and depression via the gold standard CIS-R interview rigorously defining this clinical population. Amongst the study participants were mothers with mild, moderate and severe depression and mothers who had indicated thoughts of self-harm or suicide. Exploring the views of depressed mothers with a range of severities and symptoms may be useful to clinicians when considering the feasibility of treatments for a range of patients. All interviews in this study were conducted in participants' homes. This should have provided an environment in which they felt comfortable and therefore facilitated open discussion. This study was conducted with a rigorous qualitative methodology including dual creation of matrices and coding with discussion and comparison between versions, enhancing the reliability of the findings.

Though mothers with a range of depression severities were included in this study, the majority had been diagnosed with moderate (61.9%) or mild (19.0%) depression. Thus, the views and experiences of mothers with severe depression

(9.5%) and mixed anxiety and depression (9.5%) may have been underrepresented; this should be borne in mind when interpreting any conclusions. The participants of this study were recruited from an RCT of exercise for PND. Those participating in such as trial are likely to be receptive to the idea of exercise. The trial itself also under-recruited substantially (94 randomised, initial target n=208). These factors are likely to reduce the generalisability of this study's findings as the population may have been more motivated and held a more positive view of physical activity as a treatment for depression than mothers with PND in general.

The interviews in this study were conducted by a researcher (myself) who also carried out a portion of the follow up of the RCT from which these participants were recruited. It is possible that knowledge of my involvement in the trial may have influenced the answers provided by participants. However, interviews took place after participation in the intervention or comparator group had ceased and were conducted by a researcher who took no part in the delivery of the exercise intervention. It is therefore unlikely that participants would have been concerned about their answers influencing further treatment received through the trial.

5.4.12 Clinical implications

There are evidently many barriers to exercise for women with PND in addition to the physical barriers of recovery from childbirth and the practical barriers of childcare. Anxiety, depression, low motivation, a self-critical attitude and maladaptive coping strategies appear to form significant obstacles, specifically to the initiation, but also to the maintenance of exercise. It may be that CBT could be beneficial for those struggling to initiate exercise.

Viewing exercise as something that can be incorporated in small ways into daily life seemed to be a less off-putting prospect and was more frequently implemented than separating such activity to within a gym. Encouraging practical forms of exercise may therefore be more successful. Benefits such as improved connection to the outside world, a sense of calmness conducive to logical thought and improved mood were reported from even walking at a slow pace. In light of the fact that much of the evidence for activity in depression relates to more aerobic forms of activity, it may be advisable for future research to directly compare different types and intensities of activity, including the presence or absence of children during the activity. A range of factors such as depression severity, social support, self-efficacy for exercise and bonding between mother and child should be studied in order to build a clearer picture of the relative benefits of different activities.

A wide range of other benefits were reported from exercise; improved energy in general and for childcare; improved sleep; improved social interaction; distraction from low mood and worrying thoughts, weight loss and improved body image; a sense of achievement and self-confidence. For clinicians, discussion of such benefits may prove useful when encouraging depressed mothers to begin exercise.

Motherhood involves a profound change in a women's sense of her identity. It seems apparent that a woman's view of exercise and the benefits she may obtain from it are interwoven with the effects of childbirth on her sense of self. Many mothers feel an expectation, but also an innate desire to put the needs of their baby before any priorities of their own. However, it may be psychologically beneficial for a

mother who is depressed and feels a loss of her own identity to take periods of time away from the mothering role to focus on her own health and well-being. Exercise can provide a sense of autonomy, providing temporary freedom from the mothering role. However, mothers may need encouragement not to attach guilt to this choice. Emphasising the importance of a mother's psychological and physical health to the well-being of a child may be a valuable way to remove the barrier of guilt.

There were varying views as to the practicality and usefulness of exercise as a treatment for PND. Its first advantage was its social acceptability and the fact that disclosure of PND was unnecessary. Exercise was clearly felt to improve mood, reduce the severity of low mood and increase the rapidity of recovery in some women. A general reluctance was found to taking antidepressants due to previous negative experiences and a belief that antidepressants were only suitable for severe depression, leading mothers towards behavioural interventions, which were felt to be natural and appropriate for PND. However, antidepressants were felt, by some, to provide more constant protection from severe depression than the temporary effects of the endorphins induced by exercise. Practical barriers, as well as low motivation were felt by some to make exercise impractical; however, in great contrast to other traditional forms of treatment for PND, very few disadvantages were mentioned in relation to exercise. It was clear that for many women, exercise was considered a suitable and desirable treatment for PND, either individually or in combination with other treatments.

5.5 Conclusions

For mothers with depression in the postnatal period, it is possible for exercise to be successfully integrated into daily life, despite significant physical, practical and psychological barriers. A range of potential psychological and physical benefits were reported throughout this study. Exercise also provided a rare opportunity for mothers in the postnatal period to focus on themselves and regain a sense of personal identity. Exercise was commonly seen as a natural, preferable alternative to antidepressants, and a suitable treatment for mothers with mild to moderate PND.

CHAPTER SIX

6. THE EFFECTIVENESS OF EXERCISE IN REDUCING DEPRESSIVE SYMPTOMS AND OTHER PSYCHOLOGICAL OUTCOMES IN POSTNATAL WOMEN: A SYSTEMATIC REVIEW WITH META-ANALYSIS

This thesis has presented an investigation of the effectiveness of an exercise intervention in the treatment of PND and a qualitative exploration of this treatment. In order to provide the most accurate estimate of the effectiveness of exercise as a treatment for PND, it is necessary to combine the current evidence base and assess its quality. A systematic review with meta-analysis of published trials examining the effect of exercise on PND was therefore conducted and is presented in this chapter. For my contribution to this systematic review and the contributions of others, please see chapter one, section 1.10.5.

6.1 Introduction

6.1.1 Postnatal depression and postnatal maternal anxiety

Postnatal psychological morbidity is a significant global issue. PND is highly prevalent, affecting 7 - 13% of women in the year after giving birth (1) and postnatal maternal anxiety (PMA) is thought to affect 11 - 18% of women (275, 288). PND and PMA are often co-morbid (289) and mothers may suffer depressed mood, anxiety, fatigue, feelings of worthlessness and guilt. In some women, PND can lead to thoughts of self-harm or harm of the child (2). Both PND and PMA have also been found to have negative effects on the social and cognitive development of the child (47, 290).

6.1.2 Current treatment for PND and PMA

Current treatments for PND and PMA include antidepressants and psychological therapies such as cognitive behavioural therapy (CBT) (4, 62, 91). There are acknowledged risks of taking antidepressants in the postnatal period, especially during breastfeeding (4) and a subsequent reluctance amongst mothers to take them (182). CBT can be effective, however, there is often a long waiting list for such interventions via the National Health Service (NHS) in the UK (253).

6.1.3 Exercise as a treatment

Current international guidance recommends exercise in the treatment of PND (4, 174). This guidance, however, was based on evidence from a limited number of trials, none of which included postnatal women with a confirmed diagnosis of depression. High quality evidence was therefore lacking at the time these recommendations were published. A recent Cochrane Library systematic review found a moderate effect of exercise in reducing depressive symptoms in the general population compared with no treatment or a control intervention (SMD: -0.62, 95% CI: -0.81 to -0.42) (28). However, a moderate level of heterogeneity was found indicating this result may not be stable (28). In meta-analysis, physical activity has been found to yield a similar effect size to other current treatments for depression; a recent review found no significant difference between the effectiveness of exercise and psychological therapies (SMD: -0.03, 95% CI: -0.32 to 0.26) or between exercise and pharmacotherapies (SMD: -0.11, 95% CI: -0.34 to 0.12) (28). Exercise has also been found to be potentially effective in treating other psychological outcomes, including anxiety (291, 292).

Having a baby is a significant, life changing transition, which involves abrupt changes in circulating hormones, sleep deprivation and adjustment to a new role. During this time women may be at particular risk of psychological morbidity, including depression (293). A systematic review conducted by Daley et al. in 2009 provided some support for exercise as an adjunctive treatment for PND, however, this review included a small number of participants (n=238) from only five trials of average quality (101). Physical activity may, however, be a particularly appropriate form of treatment for depression in the postnatal period, as it offers the additional benefits of improved physical fitness and weight loss at a time when women are more vulnerable to decreased physical activity and postnatal weight retention (194, 195).

6.1.4 Exercise and other psychological factors

6.1.4.1 *Self-efficacy for exercise*

Self-efficacy refers to one's belief in one's ability to perform a specific behaviour, here, exercise (75). Self-efficacy is thought to influence the likelihood of a behaviour being initiated and the long term maintenance of that behaviour if barriers occur (75). Improvements in self-efficacy for exercise may therefore be an important mechanism encouraging the successful incorporation of exercise into daily life. Previous postnatal exercise trials have reported significant improvements in self-efficacy for exercise (14); this outcome was therefore considered pertinent to this review.

6.1.4.2 *Quality of life*

A systematic review conducted by Rosenbaum et al. recently evaluated exercise interventions in populations diagnosed with mental health conditions including depression (175). Overall, exercise interventions were found to have a significant effect on reducing depression and improving quality of life (175). The potential of exercise interventions to influence quality of life in the postnatal period was therefore investigated in this review.

6.1.4.3 *Mother and infant bonding and child development*

In 2010, Field et al. conducted a comprehensive review of studies exploring the interactions between depressed mothers and their infants (45). Depression was found to be associated with altered behavioural patterns, with depressed mothers being less sensitively engaged with their child and displaying more hostile irritable behaviour (45). The altered interaction between mother and child has been postulated to affect the child's social and cognitive development, with physiological changes in the brain as well as behavioural patterns such as less developed cognitive-linguistic functioning and difficult behaviours being noted amongst children of depressed mothers (48, 53). The profound effects of PND on the bonding between mother and child and the potential long term effects on child development indicate the importance of determining whether the effects of exercise on the mothers' depression can also be protective against the long term effects of PND on the child.

6.1.2 Aim

The aim of this review is to synthesise the evidence regarding the effects of physical activity on psychological outcomes relevant to postnatal women. The specific question of whether physical activity is an effective treatment in women at risk of PND will also be addressed.

6.1.2.1 Hypothesis

It was hypothesised that collectively, exercise interventions would have a significant effect in reducing depressive symptoms compared to comparators.

6.2 Methods

6.2.1 Trial identification

The following bibliographic databases were searched electronically for eligible trials: MEDLINE, EMBASE, the Cochrane Library, Psych Lit and SportDiscus. Clinical Trials.gov. The Cochrane Library guidance for the conducting of systematic reviews of interventions currently recommends that the largest bibliographic databases of medical information, MEDLINE and EMBASE and The Cochrane Library, be searched as part of all systematic reviews (142). In addition to these, Psych Lit and SportDiscus were searched, respectively, for their coverage of psychological conditions such as depression and exercise related material. The World Health Organisation (WHO) International Clinical Trials Registry Platform was searched for trials in progress. Searches for grey literature were conducted in <http://opengrey.eu/> and <http://oaister.worldcat.org>.

Searches for the following terms were conducted as text words and MeSH terms where applicable: exercise, physical activity, postpartum, postnatal, mother, birth, perinatal, depression, anxiety, self-efficacy, quality of life, mother and infant bonding and child development (Appendix Figure 41). The searches were unrestricted by date or language and were undertaken up to August 2014. The bibliographies of eligible articles and reviews were searched for additional trials. Authors were contacted if clarification regarding their research was required. In order to enhance objectivity, two researchers reviewed all titles and abstracts independently; then studied full text articles for eligibility. Any discrepancies as to different researchers' eligibility selections were discussed and a consensus reached.

6.2.2 Trial eligibility

In order to maximise the number of studies included in this review, RCTs, quasi randomised trials and controlled trials with concurrent comparators were included. Trials with interventions designed to increase aerobic exercise and comparators involving no care or any type of usual care were eligible. Trials comparing two types of exercise were excluded. Aerobic exercise was defined as activity causing increased heart rate, respiratory rate and sweating. Trials in which participants in both the intervention and control groups also received current standard treatments for PND, including antidepressants and psychotherapy were included. Trials involving co-interventions such as exercise and social support were also included. Trials with a population of mothers less than 1 year postnatal, measuring any of the following outcomes were included; depression, anxiety, quality of life, mother and infant

bonding, child social development and self-efficacy for physical activity or exercise (defined as a person's confidence in their ability to perform exercise) (294).

6.2.3 Quality assessment

The Cochrane Collaboration's tool for assessing risk of bias was applied to all trials by myself and also independently by a second researcher (142). Discrepancies were discussed and a consensus reached. The blinding of personnel and participants to group allocation was not assessed due to the impracticalities of such blinding in physical activity trials. The blinding of outcome assessors was evaluated.

6.2.4 Data extraction

The following data were recorded for all eligible trials: trial design and location; inclusion/exclusion criteria; population characteristics (age; exercise status; population at risk of depression or general population); number of participants; recruitment procedures; details of the intervention and comparator arms; length of follow up; measures of adherence to the intervention and outcomes. Data were extracted independently from supervisors and also by another researcher, using a standardised extraction form. The reviewers were not blinded to trial authors, institution, or publication journal. Any discrepancies were compared with the original data. Authors were contacted if clarification was needed.

6.2.5 Data analysis

It is accepted that scoring above a certain threshold on a depression screening questionnaire (e.g. the EPDS) is an indication of depressive symptoms or a risk of depression, rather than a diagnosis of PND. For the purposes of this review and in

the interest of brevity, populations indicating a risk of postnatal depression on such screening questionnaires or in the clinical judgement of a health professional were referred to as 'depressed' postnatal populations.

Meta-analyses were conducted using Review Manager 5.1.7 (295). All RCTs or quasi RCTs were included in meta-analyses. Sensitivity analysis was then conducted including and excluding quasi RCTs for the main outcome. Controlled trials with concurrent comparators were reported descriptively. A standardised mean difference (SMD) was calculated for all continuous outcomes reported in more than one trial. If more than one measure for an outcome was reported, the primary outcome was used. When a trial had more than one point of follow up, the final point of follow up was used. A weighted mean difference (WMD) was calculated for all continuous outcomes assessed using the same measure. Where the standard deviation (SD) of the difference in score was not reported this was calculated. A correlation of 0.6 was used in the assumptions to estimate SD differences. A fixed effect meta-analysis was undertaken in the absence of heterogeneity, if statistical heterogeneity or heterogeneity within the design of the trials was found, a random effects model was used. The I^2 statistic was used to assess statistical heterogeneity, with $I^2 > 50\%$ considered important. I^2 refers to the percentage of total variation across the included studies that is due to heterogeneity rather than chance (296).

In order to maximise the available data included in the primary analysis, an initial pooled SMD was calculated with all trials regardless of the population recruited or the type of exercise intervention tested. Subgroup analyses were performed in populations of 'depressed' postnatal women and general postnatal populations and in trials with exercise only interventions and those with co-

interventions. A trial was defined as having a co-intervention when it included distinct components designed to influence factors other than exercise, such as diet or social support. For outcomes where there was insufficient data for meta-analysis, the results have been presented descriptively.

6.3 Results

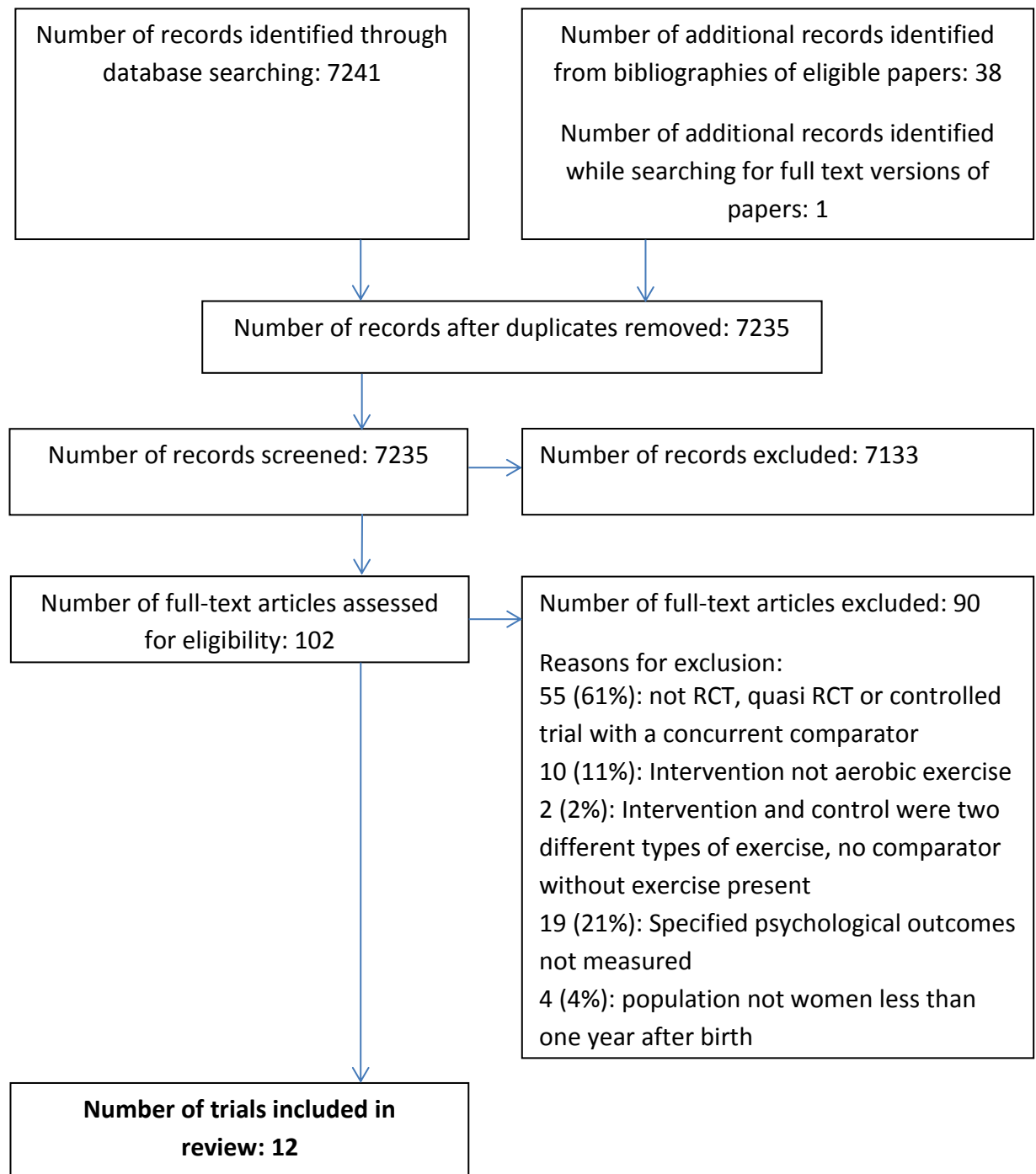
6.3.1 Trial selection

Of the 7235 records initially identified after the removal of duplicates, 7133 were excluded after reading their title and abstracts. A further 90 full text records were excluded based on the eligibility criteria described earlier. Twelve trials were included in the descriptive synthesis (Table 19) and meta-analysis (Figure 13).

6.3.2 Trials in progress

Two on-going trials that potentially fulfilled the eligibility criteria for this review were found in national clinical trials registries (NCT02147626, NCT01883479). These trials will be considered for inclusion in any future updates of this review.

Figure 13: PRISMA flow chart



6.3.3 Trial characteristics

Trials referring to both exercise and physical activity were located during this review. In view of the fact that only two out of 12 trials referred to physical activity (16, 102), when groups of trials are referred to collectively, the term exercise will be used.

All included trials had been peer reviewed and published (11, 13-19, 102, 103, 297). Ten trials were RCTs (11-14, 16-19, 102, 103), one was a controlled trial with a concurrent comparator (297) and one a quasi RCT (15). Collectively the trials included a total population of 1586 eligible participants, with 1176 of those participants being included in the primary meta-analyses (as they provided follow up data on the primary outcome or imputation was performed). Six trials recruited participants at risk of depression at baseline (11, 13-17), of these, four trials used an eligibility criteria that required participants to score above a particular threshold on the EPDS questionnaire (11, 13-15). (These thresholds ranged from ≥ 10 to >12 on the EPDS, Table 20). Despite not reporting the use of a baseline depression threshold criteria, two trials reported mean baseline depression scores which indicated their populations were depressed (mean baseline EPDS scores of between 18.9 and 19.8 (17) and mean baseline BDI scores of between 15.8 and 16.9 (16). These trials were therefore considered to have 'depressed' populations. Six trials recruited general postnatal populations (12, 18, 19, 102, 103, 297). (Table 19)

6.3.3.1 *Participants' history of depression and current treatment*

None of the included trials reported whether participants had experienced prior episodes of PND, one reported that 82.2% of the study population had a history of depression (at any stage of their lives) (102). Two trials reported that around 50.0% (13, 14) and one that 29.0% (102) of participants were taking antidepressants at

baseline; two excluded mothers taking antidepressants (17, 102). One trial reported that around 40.0% of participants (14) and another that a limited number of participants (13) were receiving counselling at baseline. The remainder provided no information on antidepressant or psychological therapy use. (Table 19)

6.3.3.2 *Exercise criteria*

Nine trials did not specify criteria for exercise levels at baseline (12, 13, 15-19, 103, 297), two required participants to be inactive at baseline, defined as less than 30 minutes of exercise three times a week (11, 14) and required participants to be low active at baseline, defined as 90 minutes or less of exercise a week (102). (Table 19)

6.3.3.3 *Intervention characteristics*

Seven trials included interventions that were designed to increase exercise levels (11, 12, 14, 15, 17, 102, 103); two aimed to increase exercise, improve diet and encourage a healthy lifestyle (16, 18); one was intended to increase exercise, improve nutrition and coping skills (297); one was designed to increase exercise and provide social support (13) and one trial aimed to increase exercise and provide education on postnatal issues (19).

Four trials involved supervised group exercise sessions (12, 13, 19, 103); two involved predominantly home-based set exercise programs (15, 17) and six involved tailored exercise counselling intended to encourage independent exercise (11, 14, 16, 18, 102, 297). Comparator groups included usual care only (11, 14, 297); unreported content (12); maintenance of usual activities (17); usual care plus leaflets and discussions with nurses on topics unrelated to exercise (16); usual care as part of the American WIC program (The Special Supplemental Nutrition Program for

Women, Infants and Children involving nutritional assessment, education and food vouchers) (18); unspecified phone support (13) phone support related to stress management, sleep and nutrition (102); daily exercise records and a booklet on PND (15); education on unrelated topics (19, 103) and a booklet of the intervention exercises and details of local gyms (19). The length of interventions varied, ranging from four weeks to twelve months. (Table 19)

6.3.3.4 *Theoretical basis of the interventions*

Three trials reported the theoretical basis of their interventions. Daley et al. based their intervention around the Transtheoretical Model by Prochaska and Diclemente (111) employing the cognitive behavioural techniques of cognitive reappraisal, consciousness raising, goal setting, self-monitoring and seeking social support to promote a change in exercise behaviour (298). Similarly, Lewis et al. reported utilising motivational strategies such as goal setting, social support and self-efficacy for physical activity from Social Cognitive Theory (112) and the Transtheoretical Model (111). Surkan et al. based their intervention on a Social-Ecological Framework (299) using techniques designed to increase self-efficacy for exercise and healthy eating, development of social networks and utilisation of local resources (18).

6.3.3.5 *Recruitment methods*

A range of recruitment methods were used, including maternity wards in secondary care (11, 12, 16, 17, 19, 103), public health centres (12, 297), family practitioners (13, 14, 102), psychiatrists (13, 14), health visitors (14), midwives and nurses (13, 14), PND support groups (14) and self-referral via advertising (14, 15, 18, 102) (Table 19).

6.3.3.6 Outcome measures

A range of outcomes were measured. Depression was measured by 11 of the 12 trials (11, 13-19). Nine trials (11-14, 17, 19, 102, 103) that measured depression used the EPDS (23), one trial (16) used the Beck Depression Inventory (BDI) (300) and one trial (18) used the Centre for Epidemiologic Studies Depression Scale (CES-D) (301). Of the nine trials that used the EPDS, one (13) also used the Depression Anxiety Stress Scale (DASS) (302); one (11) also used the Hamilton Rating Scale for Depression (HAM-D) (303) and one (102) also used the Patient Health Questionnaire-9 (PHQ-9) (57). One study that used the EPDS (102) also used the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I) (304) to assess the proportion of clinically depressed women in the groups at follow up. (Table 19)

Self-efficacy for exercise was measured in three trials (14, 16, 297) (Table 22). One trial (14) used the Self-efficacy scale by Marcus et al. (305); one trial (297) used the Exercise Self-efficacy Scale by Bandura et al. (113) and one trial (16) used the Self-Rated Abilities for Health Practices Scale (306) (Table 23). Quality of life was reported by one trial (12) using the Short Form Health Survey-36 v2 (SF-36v2) (307) (Table 22). No trials reported data on anxiety, mother and infant bonding or child social development.

6.3.4 Adherence

Eight trials reported adherence to interventions (Table 19). Of those interventions consisting of exercise classes, two reported that a mean of 23.7/36 (65.8%) (13) and 44/50 (88.0%) (12) classes were attended and another reported that 26/27 (96.3%) participants were adherent to classes (as defined by the author)

(17). A study that included group education sessions reported a weekly group attendance rate of 75-80% (297). One trial whose intervention consisted of set, predominantly home-based exercises reported that 32/40 (80%) intervention participants took part in the exercise sessions (15). One trial providing phone based physical activity counselling reported that 44/61 (72%) of participants completed all 11 sessions (102). Two further exercise counselling trials reported that 35/46 (76.1%) (11) and 10/11 (90.9%) participants who returned exercise diaries (14) achieved the intervention's exercise goals.

Table 19: Trial characteristics

Trial, design	Inclusion/ Exclusion Criteria	Population characteristics	Recruitment procedures	Intervention (Int) Comparator (Comp)	Adherence to intervention	Depression outcomes	Depression results
Armstrong 2003 (13) Queensland Australia RCT	Inclusions: 6 weeks - 12 months postnatal; EPDS \geq 12 Exclusions: conditions preventing regular aerobic exercise.	n=20; Majority 21 - 30yrs Depressed population: baseline mean EPDS: int:17.40 (SD 4.65), Comp: 18.40 (SD 4.77).	1. Referred by nurse, social worker, counsellor, GP, psychiatrist 2. Advert	Int: Exercise program 12 weeks Three 30-40 minute group pram walks a week of moderated intensity Exercise diary Tea gathering once a week (with children) Comp: Phone support at 6 weeks post randomisation	Mean 23.7 out of 36 sessions attended (65.8%). Mean 68% intensity of age predicted heart rate. (Aim: 60-75%)	EPDS and DASS Pretest, 6 weeks, 12 weeks post baseline	Multi intervention group depression improved significantly compared to control
Da Costa 2009 (11) Montreal Canada RCT	Inclusions: 4-38 weeks postnatal EPDS \geq 10 Inactive (\leq 30 mins 3 times a week); English or French speaking. Exclusions: current alcohol or substance abuse obstetric or concomitant diseases	n=88; Mean age: Int: 34.3 (SD 3.4), Comp: 32.7 (SD 4.8) Sedentary population Depressed population: Baseline mean EPDS: Int: 13.6 (SD 3.6), Comp: 13.6 (SD 3.9)	1.obstetric/ gynaecology offices 2. Media adverts, pamphlets and flyers	Int: Exercise counselling 12 weeks Aim: 60-120 mins of aerobic exercise a week 4 meetings with an exercise psychologist at baseline (12 weeks postnatal) and weeks 1, 3, and 7 Heart rate monitors Exercise logs Comp: 'usual care'	Adherence to the aerobic component of \geq 60mins a wk: 76.1% (35/46) Mean 124 (SD 96.3)mins a wk Strength aims achieved by 52.4%. Mean 4/4 exercise psychologist sessions attended	EPDS and 17 item HAM-D 3 months post baseline and 6 months post baseline	No significant change in EPDS from baseline to follow up. Decrease was significant for those with baseline EPDS \geq 13.

Trial, design	Inclusion/ Exclusion Criteria	Population characteristics	Recruitment procedures	Intervention (Int) Comparator (Comp)	Adherence to intervention	Depression outcomes	Depression results
Daley 2008 (14) Birmingham UK RCT	Inclusions: ≥16 yrs old ≤12months postnatal EPDS>12 or clinical judgement Inactive: < 30 mins 3 times/wk for 3mnths English speaking Exclusions: Severe PND (inpatient/psychosis) pregnancy	n=38 Majority 29-31 yrs old Sedentary population Depressed population: Baseline mean EPDS (SD): Int: 17.7 (5.2), Comp: 19.2 (4.7)	1.GPs and health visitors 2.Mother and baby unit 3.Depression support groups	Int: Exercise counselling 12 weeks Aim: 30 mins moderate activity 5 days a week Two 1 hour home consults at weeks 1 and 4 Two 10 min phone calls in weeks 3 and 9 Comp: Usual care Exercise consult at end of trial	10/11 women (90.9%) achieved goal of ≥ 105 mins of exercise a week Mean of 174 mins of exercise per week achieved	EPDS 12 weeks after end of intervention. (24 weeks from baseline)	No significant difference in EPDS between groups
deRosset 2013 (297) North Carolina, USA, Controlled trial with a concurrent comparator	Inclusions: >20yrs old /married Limited English proficiency Proficient in spoken Spanish Hispanic Overweight/obese Exclusions: History of heart murmur, congenital heart disease, family history of sudden death, Participation in other weight management programme	n=24 Mean age 29.3 (SD 4.8) General postnatal population: EPDS not measured	Brochures handed out by research assistants at two health centres, phone numbers of interested mothers collected	Int: Group exercise counselling 12 weeks Aim: 30-60 mins physical activity a day One 60 minute group exercise, nutrition and coping skills education session a week. Encouraged to set up buggy walking groups Personal nutrition and exercise goals set each session Comp: Usual care Visit with health care provider at 6 weeks postnatal Offered intervention after trial	Weekly attendance at education sessions: 75-80%	Depression not measured (exercise self-efficacy)	No significant difference in exercise self-efficacy at follow up

Trial, design	Inclusion/ Exclusion Criteria	Population characteristics	Recruitment procedures	Intervention (Int) Comparator (Comp)	Adherence to intervention	Depression outcomes	Depression results
Haruna 2013 (12) Tokyo Japan RCT	Inclusions: > 20 yrs old ≤12months postnatal Exclusions: Medical complications Restricted physical activity Psychiatric disorders	n=110 Mean age 33.8 (SD 3.8) General postnatal population: 16 (5.8%) had baseline EPDS≥9	Volunteers from one hospital and two public health centres	Int: Exercise program 4 weeks Four 90 min group sessions a week consisting of: Exercise: 50-60mins of aerobic bouncing on an exercise ball. Time to interact with peers. Comp: No details provided Offered intervention at end of trial	Intervention: 88% (44/50) class attendance	EPDS Two months post-baseline (which was immediately post intervention and 4 months after birth)	No significant difference in EPDS between groups at follow up
Heh 2008 (15) Taipei Taiwan quasi RCT	Inclusions: 20 - 35yrs old Married First time mothers EPDS > 10 Normal spontaneous delivery of single full term health baby Exclusions: Obstetric complications, Psychiatric history	n=80 Depressed population: Baseline mean EPDS Int: 16.5 (SD 2.6), Comp: 16.3 (SD 3.2).	Letter and screening with EPDS Those >10 invited to take part by phone/mail 6 weeks after birth	Int: Exercise program 3 months Whole body gentle stretching exercises; one 1 hour group session and 2 home sessions a week CD of this exercise to take home Weekly reminder calls Booklet on PND Daily activity record Comp: Daily exercise record Booklet on PND Exercise information post follow up	3 women in experimental group did not carry out the exercises (Declined to take part: Int: 5/40 Comp: 7/40)	EPDS 5 months after birth	Significantly greater decrease in EPDS in the intervention compared to the comparator group at follow up

Trial, design	Inclusion/ Exclusion Criteria	Population characteristics	Recruitment procedures	Intervention (Int) Comparator (Comp)	Adherence to intervention	Depression outcomes	Depression results
Huang 2011 (16) Northern Taiwan RCT	Inclusions: ≥ 18 yrs old; Chinese speaking and reading; Intention to give birth at trial site. Exclusions: Cognitive impairment Psychiatric illness In other trial	n=160(postnatal +control groups) Age: EPP: 30.7 (SD 3.7); Comp: 31.9 (SD 4.9) Depressed population: Baseline mean BDI: Int: 16.9 (SD 6.8), Comp: 15.8 (SD 7.4)	Nurse research assistant at obstetric clinics recruited women before 16 weeks gestation	Int: Exercise counselling Postnatal EPP group: 6 months Three 1:1 counselling sessions on exercise and diet at 24-48hrs postnatal, 6 weeks and 3 months (Pregnant group not included in analysis) Comp: 'Standard care' Discussions with nurses and leaflets on unrelated topics	No adherence details	BDI 6 months after birth	Significant increase in BDI in postnatal EPP intervention compared to comparator
Lewis 2014 (102) Minnesota USA RCT	Inclusions: ≥ 18 yrs old ≤8 weeks postnatal Personal/ maternal history of depression <90mins exercise/wk Exclusions: Current depression Hospitalisation for a psychiatric disorder in the past 6 months Not proficient in English Physical conditions or medications preventing exercise	n=130 Mean age 31.5 (SD 5.0) General postnatal population: EPDS not provided	Adverts in newspapers and online Physician referrals (Physical activity screening prior to giving birth)	Int: Exercise counselling 6 months Aim: 30 mins of moderate to vigorous activity ≥ 5 days a wk 11 telephone consultations Participant chosen activity Physical activity DVD option Literature on physical activity and local opportunities to exercise. Comp: (Wellness/support) Counsellor delivered telephone sessions on stress management, sleep, nutrition.	72% completed all 11 telephone sessions (intervention and comparator)	SCID-1 at 6 months only, PHQ-9 EPDS at 6 months only	No significant difference in proportion in intervention and control depressed at follow up (SCID) Significant decrease in PHQ-9 and EPDS in intervention compared to control

Trial, design	Inclusion/ Exclusion Criteria	Population characteristics	Recruitment procedures	Intervention (Int) Comparator (Comp)	Adherence to intervention	Depression outcomes	Depression results
Norman 2010 (19) Melbourne Australia RCT	<p>Inclusions: 6-10wks postnatal English speaking and writing</p> <p>Exclusions: Psychiatric disorder medicated and managed by a general practitioner or a psychiatrist or if hospitalisation needed</p>	<p>n=161 Mean age Int: 29.3 (SD 4.0), Comp 30.1 (SD 5.3)</p> <p>General postnatal population: Baseline mean EPDS: Int: 8.00 (SD 6.16), Comp: 6.75 (SD 5.44)</p>	Recruitment at discharge from hospital postnatal ward	<p>Int: Exercise program 8 weeks One 1 hour group cardiovascular and strength exercise session a week at hospital facilitated by a physical therapist. One 30 minute educational session a week on postnatal issues Booklet on exercise List of gyms and community facilities</p> <p>Comp: Education only Topics unrelated to diet or physical activity Health care professionals contact details Booklet of exercises from intervention List of gyms and community facilities</p>	No adherence details	EPDS 8 weeks post baseline (end of intervention) 12 weeks post baseline	Significant decrease in EPDS in intervention compared to comparator

Trial, design	Inclusion/ Exclusion Criteria	Population characteristics	Recruitment procedures	Intervention (Int) Comparator (Comp)	Adherence to intervention	Depression outcomes	Depression results
Robichaud 2008 (17) Tennessee USA RCT	Inclusions: 6wks- 1yr postnatal 20-40 yrs old English speaking Physician approval for exercise Exclusions: Taking antidepressants High blood pressure	n=51 Mean age: Int: 31.1, Comp group 30.4; Depressed population: baseline EPDS Int: 19.76 (SD 4.64), Comp: 18.87 (SD 3.22);	Screened by doctor at gynaecology and obstetrics practice. Contact details passed to researchers	Int: Exercise Program 6 weeks Home-based walking programme of 30 mins (2 miles) 3 times a week. One 20-25 min goal setting interview DVD of walking instructions Weekly exercise logs Weekly 'check-up' calls/emails Comp: Maintain usual activity Intervention after trial	96% (26/27) adherence (less than 4 exercise sessions missed)	EPDS 8 weeks post baseline (immediately post intervention)	No significant difference in EPDS between groups
Surkan 2012 (18) Northeast USA RCT	Inclusions: Low income mothers eligible for U.S. Special Supplemental Nutrition Program for Women, Infants and Children (WIC)	n= 679 Mean age 26.7 (SD 5.8) General postnatal population: Baseline CES-D Int: 14.3 (SD 10.7), Comp: 14.0 (SD 11.5)	Via the WIC programme and from community centres	Int: Exercise counselling 12 months Aims: 5 fruit or veg a day red meat \leq 3 times a week 30 mins physical activity 5 times a week 5 home visits on exercise and diet and monthly phone calls on diet and physical activity Usual WIC care: Comp: Usual WIC care: nutrition assessment, education, food vouchers	No adherence details	CES-D Recruited 6 - 20 weeks after birth. Mean follow up period 13.3 months (SD 3.7)	Modest decrease in CES-D in intervention compared to control. Difference was significant in fully adjusted analysis

Trial, design	Inclusion/ Exclusion Criteria	Population characteristics:	Recruitment procedures	Intervention (Int) Comparator (Comp)	Adherence to intervention	Depression outcomes	Depression results
Thiruppathi 2014 (103) Nellore India RCT	Inclusions: Women at point of discharge from a hospital postpartum ward Exclusions: Severe postnatal depression requiring inpatient psychiatric treatment Psychotic symptoms Pregnant	n=45 Mean age: Int: 26.3 (SD 4.0), Comp 25.1 (SD 5.3) General postnatal population: Intervention: baseline EPDS Int: 8.0 (SD 0.8) Comp: EPDS: 7.8 (SD 0.6)	Recruited from a postnatal hospital ward	Int: Exercise program 4 weeks Sessions in hospital; 15 mins of appraisal; 15 minute of activity demonstration; 30 minutes of physical activity (warm up, cardiovascular intervals, toning, pelvic floor exercises, stretching) Written materials (as below) Comparator: health care education program Written materials on nutrition, baby care and posture	No adherence details	EPDS	Significant decrease in intervention group from baseline to follow up. No significant change in comparator group

EPDS: The Edinburgh Postnatal Depression Scale, range 0-30.

BDI: The Beck Depression Inventory, range 0-63.

DASS: The Depression Anxiety Stress Scale, range 0-4.

CES-D: The Centre for Epidemiologic Studies Depression Scale, range 0-60.

HAM-D: The Hamilton Rating Scale for Depression, range 0-66.

PHQ-9: The Patient Health Questionnaire-9, range 0-27.

SCID-1: Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I)

For the above scales, higher numbers represent greater distress.

GP: general practitioner

WIC: Special Supplemental Nutrition Program for Women, Infants and Children

mins: minutes; hrs: hours; wk: week; mths: months; yrs: years

Int: Intervention

Comp: Comparator

6.3.5 Trial quality and publication bias

Using the Cochrane criteria for the assessment of bias, four trials were considered at unclear risk (11, 13, 102, 103) and eight at high risk of bias (12, 14-19, 297). The principal factors introducing a risk of bias were a lack of intention-to-treat analyses (exclusion of drop outs), a lack of clarity on selective outcome reporting (not registering trials or publishing protocol papers), a lack of robust sequence generation and concealment of randomisation procedures and unclear blinding of those conducting outcome assessments and analysis (Table 20). It is difficult to make any conclusions about the possibility of publication bias due to the relatively small number of trials in this review.

6.3.6 Provision of additional data

Three trials provided additional data for their primary outcome. Standard deviations of the published mean EPDS scores were provided by DaCosta et al. (11). Unadjusted versions of the published mean CES-D scores were provided by Surkan et al. (18). Due to the skewed nature of the data, median PHQ-9 scores were published by Lewis et al. (102). After confirmation that the change in PHQ-9 scores from baseline to follow up was normally distributed, unadjusted mean (SD) PHQ-9 scores were provided by the authors.

Table 20: Trial quality

Trial	Sequence generation	Allocation concealment	Blinding of outcome assessor/analysis	Incomplete outcome data	Selective outcome reporting	Overall risk of bias
Armstrong 2003 (13) (Depressed postnatal population)	Unclear:	Unclear: sealed envelope. Unclear if opaque or sequentially numbered	Unclear: Blinding of outcome assessor unclear. Unclear if researchers conducting analysis blinded	Low: All participants included in analysis (n=20).	Unclear: All listed outcomes reported on. Trial not registered on trial registries (proposed outcomes unavailable)	Unclear
Da Costa 2009 (11) (Depressed postnatal population)	Unclear: stratification in blocks of 4-6 based on baseline depression severity. Unclear how sequence generated	Low: Trial personnel blinded at point of allocation	Unclear: One measure of the primary outcome administered by phone by blinded interviewer. One outcome assessed by postal questionnaire. Unclear if researchers conducting analysis blinded	Low: Follow up: 62/88 (70.45%) Missing data balanced across arms. Non completers had similar baseline demographic and clinical characteristics to completers. Analysis intention-to-treat, missing data imputed (n=88).	Unclear: Listed primary outcome measures reported on. Trial registered after its completion NCT00384943	Unclear
Daley 2008 (14) (Depressed postnatal population)	Low: computer-generated random list from independent statistician	Unclear: No details	Unclear: Outcomes assessed by postal questionnaire. Unclear if researchers conducting analysis blinded	High: Follow up: 31/38 (81.6%) Missing data balanced across arms. No data on characteristics of drop outs. Intention-to-treat analysis was performed but drop outs were excluded.	Low: Listed primary outcomes reported on. All primary outcomes listed on the ISRCTN reported in results (ISRCTN75708176)	High

Trial	Sequence generation	Allocation concealment	Blinding of outcome assessor/analysis	Incomplete outcome data	Selective outcome reporting	Overall risk of bias
deRosset 2013 (297) (General postnatal population)	Unclear: 'The study statistician revealed the randomisation plan' no details of how the randomisation plan was generated	Low: Randomisation only revealed after the conclusion of recruitment and the collection of baseline data	High risk: Women informed of group allocation by letter Outcome assessors blinded at baseline, unclear if blinded at follow up. Unclear if researcher conducting analysis blinded	Unclear: No details provided of the numbers included in the analysis. No details provided of the numbers of drop outs, if any.	Unclear: Listed primary outcome measures reported. Trial not registered on trial registries (proposed outcomes unavailable)	High
Haruna 2013 (12) (General postnatal population)	Low: Permuted block randomisation by researchers not involved in allocation. Block size 4.	Unclear: No details	High: Outcome assessors not blinded. Data analyser not blinded. Data enterer blinded.	High: Follow up: 95/110 (86.4%). Not an intention-to-treat analysis - drop outs excluded. Missing data balanced across arms. No data on characteristics of drop outs.	Unclear: Listed primary outcomes reported. Trial not registered on trial registries (proposed outcomes unavailable)	High
Heh 2008 (15) (Depressed postnatal population)	High: Alternate allocation by delivery date	High: Allocation not concealed	Unclear: Outcome assessor blinded. Unclear if researchers conducting analysis blinded	High: Follow up 63/80 (78.75%). Missing data balanced across arms. Analysis was not intention-to-treat as those lost to follow up excluded from analysis.	Unclear: Listed primary outcomes reported. Trial not registered on trial registries (proposed outcomes unavailable)	High

Trial	Sequence generation	Allocation concealment	Blinding of outcome assessor/analysis	Incomplete outcome data	Selective outcome reporting	Overall risk of bias
Huang 2011 (16) (Depressed postnatal population)	Low: a randomised table used by the researcher	High: Randomised list visible to researcher	Unclear: Outcome assessment blinded but unclear if researchers conducting analysis blinded	High: Follow up (postnatal and control) 128/160 (80%). Missing data identical in both arms. Analysis not intention-to-treat. Drop outs not included in analysis. Completers and drop outs were not statistically different in demographics.	Unclear: All listed outcomes reported (weight reported but not BMI). Trial not registered on trial registries (proposed outcomes unavailable)	High
Lewis 2014 (102) (General postnatal population)	Low: Random number table used, with permuted blocks of varying sizes	Unclear: No details	Low: Follow up blinded to group allocation. Comparator was a wellness/support intervention, participants received the same level of contact as those in the exercise intervention.	Low: 124/130 (95.4%) participants included in the analysis. Not intention-to-treat analysis as drop outs excluded. Number of drop outs not balanced between arms (5 lost in intervention, 1 in comparator). No reasons given for drop outs. Differences between drop outs and those followed up not presented.	Unclear: Trial registered on clinical trials.gov NCT00961402. All outcome measures recorded have been reported in the results paper. Baseline EPDS not provided. PHQ-9 medians provided but not IQRs	Unclear

Trial	Sequence generation	Allocation concealment	Blinding of outcome assessor/analysis	Incomplete outcome data	Selective outcome reporting	Overall risk of bias
Norman 2010 (19) (General postnatal population)	Low: computer generated random list in blocks of 16, stratified by parity	Low: consecutively numbered, sealed, opaque envelopes	Low: Researcher scoring outcome questionnaires blinded. Unclear if researchers conducting analysis blinded but if data anonymised before imputing it is likely	High: Follow up: 135/161 (83.9%). A large amount of missing data in intervention versus control. Analysis not intention-to-treat. Non-starters excluded from analysis. No data on characteristics of non-starters. Data imputed by last observation carried forward for drop outs. Reasons for non-starters and drop outs given.	Low: All listed outcomes reported. Trial registered on ANZCTR	High
Robichaud 2008 (17) (Depressed postnatal population)	Low: Computerised Adaptive Randomisation Programme with controlled baseline characteristics	Unclear: No details	Unclear: Unclear if outcome assessor blinded. Unclear if researchers conducting analysis blinded	Low: 48/51 (94.1%) participants included in analysis. However, not intention-to-treat analysis. Three excluded: 1 non-adherent intervention participant, 1 participant in each group who commenced antidepressants.	High: Anxiety as measured by PPQ not reported. Trial not registered on trial registries (proposed outcomes unavailable)	High

Trial	Sequence generation	Allocation concealment	Blinding of outcome assessor/analysis	Incomplete outcome data	Selective outcome reporting	Overall risk of bias
Surkan 2012 (18) (General postnatal population)	Unclear: Stratified randomisation by BMI (<29, >=29) and trial region. No further details of how sequence was generated	Unclear: No details	Unclear: Unclear if outcome assessor blinded. Unclear if researcher conducting analysis blinded	High: Follow up: 403/679 (59.35%). Analysis was not Intention-to-treat. Only 322/679 included in analysis. Drop outs and those not receiving 'minimal intervention' excluded. Proportion breastfeeding significantly lower among drop outs. Reasons for non-completion given.	Unclear: Main outcome reported. No results on other primary outcomes listed in methods paper. Trial not registered on trial registries (proposed outcomes unavailable)	High
Thiruppathi 2014 (103) (General postnatal population)	Unclear: No details	Unclear: No details	Unclear: No details	Low: 41/45 (91.1%) participants included in analysis. Not intention to treat analysis. Two mothers who did not receive the intervention/ control excluded from analysis. Number of drop outs and reasons for dropping out balanced across arms. No detail provided on differences between those included/ lost to follow up.	Unclear: Listed primary outcome measures reported on. Trial not registered on trial registries (proposed outcomes unavailable)	Unclear

Low: Low risk of bias, High: High risk of bias, Unclear: Unclear risk of bias

BMI: Body Mass Index;

ISRCTN: International Standard Randomised Controlled Trial Number (Registry), ANZCTR: Australian New Zealand Clinical Trials Registry

EPDS: Edinburgh Postnatal Depression Questionnaire, PHQ-9: The Patient Health Questionnaire-9, PPQ: The Lederman Postpartum Self-Evaluation Questionnaire

6.3.7 Data analysis

6.3.7.1 Meta-analysis of depression scores

6.3.7.1.1 All populations

Exercise had a significant effect on reducing depressive symptoms when the eleven trials measuring depressive symptoms were combined. SMD: -0.55 (95% CI: -0.91 to -0.18), n=1176, I^2 : 87%, 11 trials (11-19, 102, 103). WMD: -1.80 EPDS units (95% CI: -3.25 to -0.35), n=521, I^2 : 87%, 8 trials (11-15, 17, 19, 103) (Figure 14).

6.3.7.1.2 Sensitivity analysis: All populations, RCTs only

After the exclusion of the quasi RCT (15), the significant effect of exercise in reducing depressive symptoms remained. SMD: -0.51 (95% CI: -0.90 to -0.13), n=1113, I^2 : 88%, 10 trials (11-14, 16-19, 102, 103).

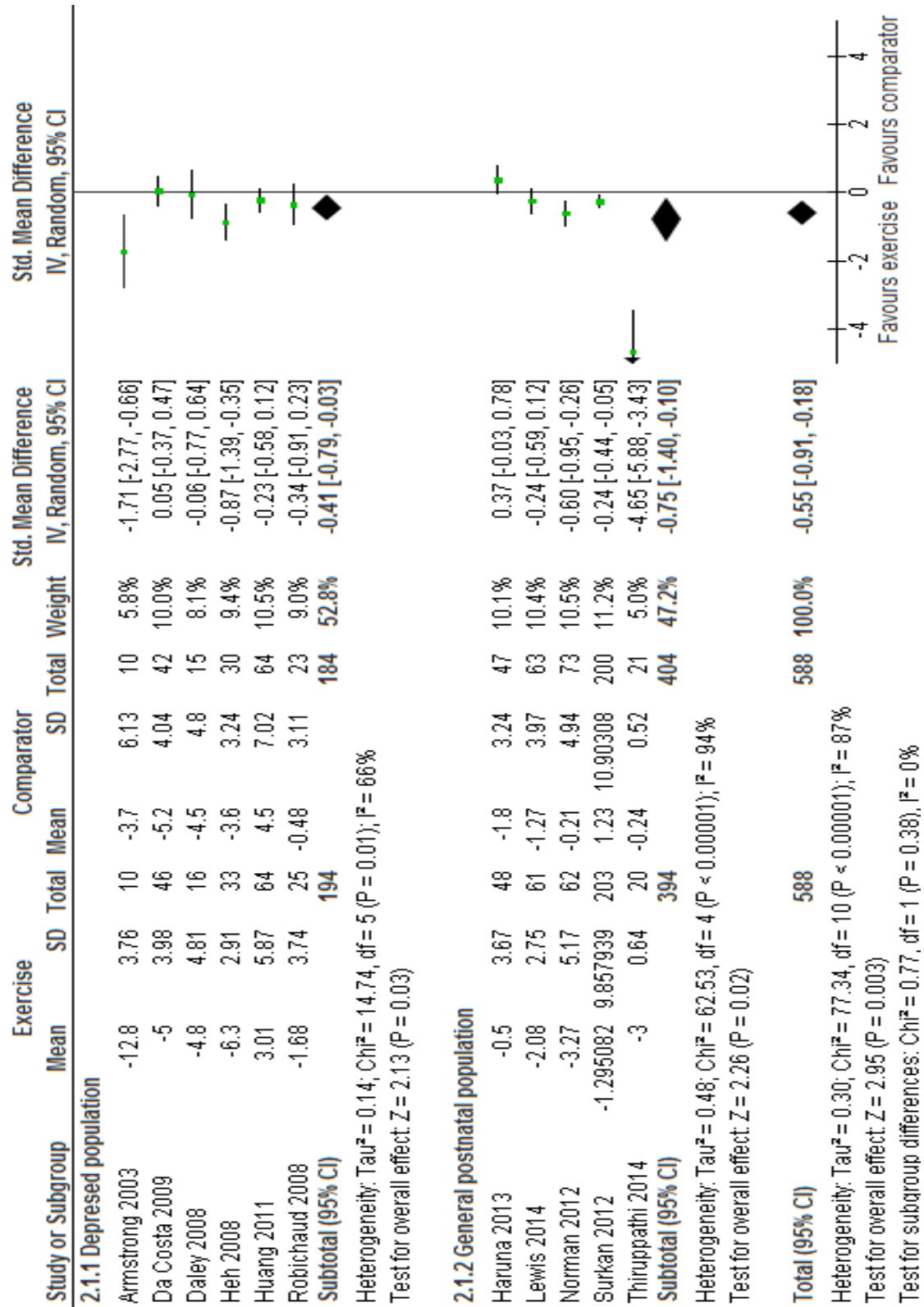
6.3.7.1.3 Sensitivity analysis: Unpublished data

The RCT described in chapter three of this thesis was unpublished at the point at which this systematic review was conducted, as other unpublished data has not been included in this review it was felt to be inappropriate to include this RCT in the main or subgroup analyses of this review. The main outcome of this review including this RCT is, however, reported below, to show the effect this trial would have on the findings of this review, if and when it is published (Appendix Figure 42).

SMD: -0.53 (-0.86 to -0.20), n=1261, I^2 : 86%, 12 trials (11-19, 102, 103, 308).

Figure 14: Meta-analysis of the effect of exercise on depressive symptoms in depressed and general postnatal populations

(Standardised mean difference)



6.3.7.2 Subgroup analyses: populations

6.3.7.2.1 Depressed postnatal populations

In subgroup analysis, exercise had a significant effect in reducing depressive symptoms in 'depressed' postnatal populations: SMD: -0.41 (95% CI: -0.79 to -0.03), n=378, I^2 : 66%, 6 trials (11, 13-17). WMD: -2.08 EPDS units (95% CI: -4.22 to 0.06), n=250, I^2 : 78%, 5 trials (11, 13-15, 17) (Figure 14, Table 21).

6.3.7.2.2 General postnatal populations

In subgroup analysis, exercise had a significant effect in reducing depressive symptoms in general postnatal populations. SMD: -0.75 (-1.40 to -0.10), n=798, I^2 : 94%, 5 trials (12, 18, 19, 102, 103). WMD: -1.52 EPDS units (95% CI: -4.10 to 1.06), n=271, I^2 : 94%, 3 trials (12, 19, 103) (Figure 14).

The effect of exercise in the 'depressed' and general postnatal populations was not found to be significantly different: test for subgroup differences: X^2 : 0.77 (P: 0.38), I^2 : 0% (Figure 14, Table 21).

6.3.7.3 Subgroup analysis: interventions

Subgroup analysis looking at the effect of intervention type within 'depressed' and general postnatal populations follows.

6.3.7.3.1 Co-interventions in depressed postnatal populations

Exercise interventions with co-interventions did not significantly reduce depressive symptoms in 'depressed' postnatal populations: SMD: -0.88 (95% CI: -2.33 to 0.56), n=148, I^2 : 85%, 2 trials (13, 16) (Table 21).

6.3.7.3.2 Exercise only interventions in depressed postnatal populations

Exercise only interventions did not significantly reduce depressive symptoms in 'depressed' postnatal populations: SMD: -0.31 (95% CI: -0.74 to 0.13), n=230, I^2 : 61%, 4 trials (11, 14, 15, 17) (Table 21).

6.3.7.3.3 Co-interventions in general postnatal populations

Exercise interventions with co-interventions significantly reduced depressive symptoms in general postnatal populations: SMD: -0.39 (95% CI: -0.74 to -0.05), n=538, I^2 : 68%, 2 trials (18, 19) (Table 21).

6.3.7.3.4 Exercise only interventions in general postnatal populations

Exercise only interventions did not significantly reduced depressive symptoms in general postnatal populations: SMD: -1.33 (95% CI: -2.94 to 0.27), n=260, I^2 : 97%, 3 trials (12, 102, 103) (Table 21).

Table 21: Effects of exercise on postnatal depression score, including subgroup analyses

Category	MD	CI	p	I ²	N trials	N participants
Depressed postnatal populations SMD	-0.41	(-0.79, -0.03)	0.03	66%	6	378
Depressed postnatal populations WMD (EPDS)	-2.08	(-4.22, 0.06)	0.06	78%	5	250
General postnatal populations SMD	-0.75	(-1.40, -0.10)	0.02	94%	5	798
General postnatal populations WMD (EPDS)	-1.52	(-4.10, 1.06)	0.25	94%	3	271
Exercise co-interventions in depressed postnatal populations SMD	-0.88	(-2.33, 0.56)	0.23	85%	2	148
Exercise only interventions in depressed postnatal populations SMD	-0.31	(-0.74, 0.13)	0.17	61%	4	230
Exercise co-interventions in general postnatal populations SMD	-0.39	(-0.74, -0.05)	0.03	68%	2	538
Exercise only interventions in general postnatal populations SMD	-1.33	(-2.94, 0.27)	0.10	97%	3	260

MD: mean difference

SMD: Standardised mean difference

WMD: weighted mean difference

N: number of

6.3.8 Meta-analysis of self-efficacy for exercise

Exercise had no significant effect on self-efficacy for exercise in 'depressed' postnatal populations: SMD: -0.62 (95% CI: -1.70 to 0.46), n=159, I^2 : 85%, 2 trials (14, 16) (Table 22).

The study by deRosset et al. was not included in this meta-analysis (297). Participants were not randomised on an individual level, instead two health care sites were randomised, one to the intervention, one to the comparator. The number of sites was felt to be insufficient to introduce a balance of patient characteristics; this trial was therefore not classed as a cluster randomised controlled trial, but as a controlled trial with a concurrent comparator. The authors reported that the intervention did not have a significant effect in increasing exercise self-efficacy compared to the comparator: Intervention baseline mean exercise self-efficacy score: 57.70 (14.0); mean at follow up 62.60 (21.87). Comparator baseline mean self-efficacy score 51.30 (15.5); mean at follow up 51.40 (22.53) (n=13) p=0.350.

6.3.9 Quality of life

Quality of life was measured by one trial (12), the intervention did not result in significant changes in either the physical or mental components of quality of life, relative to the comparator (Table 22).

Table 22: Trial outcomes (excluding depression)

Trial and outcome	Group	Baseline Mean (SD)	Follow up Mean (SD)	N	p value
Daley 2008 (14) Self-efficacy for exercise ¹	Intervention	10.5 (3.2)	13.6 (3.2)	16	<0.05
	Comparator	11.3 (3.8)	9.5 (3.1)	15	
deRosset 2013 (297) Exercise self-efficacy ²	Intervention	57.7 (14.0)	62.6 (21.9)	13	0.350
	Comparator	51.3 (15.5)	51.4 (22.5)	11	
Huang 2011 (16) Self-efficacy for physical activity ³	Intervention	14.5 (5.6)	19.2 (3.9)	64	<0.001
	Comparator	14.2 (6.0)	18.3 (2.9)	64	
Huang 2011 (16) Self-efficacy for nutrition and physical activity ³	Intervention	64.7 (10.5)	69.9 (13.0)	64	<0.001
	Comparator	63.9 (13.5)	67.5 (10.0)	64	
Haruna 2013 (12) Quality of life, physical component summary ⁴	Intervention	38.3 (14.7)	44.8 (12.3)	48	0.819
	Comparator	40.8 (14.3)	45.3 (10.7)	47	
Haruna 2013 (12) Quality of life, mental component summary ⁴	Intervention	50.7 (9.1)	52.3 (9.2)	48	0.858
	Comparator	48.5 (8.6)	50.6 (7.5)	47	

¹Measured using the Self-efficacy scale by Marcus et al.

²Measured using the Exercise Self-efficacy Scale by Bandura et al.

³Measured using the: Self-Rated Abilities for Health Practices Scale.

⁴Measured using the Short Form Health Survey-36 v2 (SF-36v2) questionnaire.

N: number of participants

6.4 Discussion

This review found that exercise may be an effective treatment for reducing depressive symptoms in postnatal women, including those at risk of PND, supporting the hypothesis stated in chapter six, section 6.1.2.1. This finding provides some support for the current guidance from NICE (4) and the American Psychological Association (174) recommending exercise for women with PND. Caution should be taken, however, when interpreting these results as a high level heterogeneity was present and the methodological quality of several trials was low. A lack of intention-to-treat analyses, insufficiently robust sequence generation and unclear blinding of outcome assessors may have resulted in an increased risk of bias.

Many of the included trials allowed participants to receive usual care, including psychological therapies and antidepressants; therefore exercise has been tested as an adjunctive intervention alongside any usual care that women might have been receiving. Whilst this may be a sound clinical decision given the limited evidence base for the use of exercise alone as treatment for PND, it introduces further uncertainty to these findings. It is also relevant that none of the trials included in the main analyses of this review recruited women with a confirmed diagnosis of depression (ICD-10 or equivalent); rather, screening questionnaires such as the EPDS were typically used to indicate a risk of depression, indicating that some trials may have included false positive cases. When published, the RCT presented in chapter three of this thesis will provide data from a clinically diagnosed depressed postnatal population, which can be included in future reviews.

This review found the effect sizes for exercise in both general and depressed postnatal populations to compare favourably with that reported by Bower et al. in a recent systematic review of low intensity psychological interventions versus usual care for depression in the general population (SMD: -0.42, 95% CI: -0.55 to -0.29) (309). Low intensity interventions provide guided self-help with limited professional support, such as cognitive behavioural therapy via written materials or information technology. Such interventions are often amongst the first treatments offered to individuals presenting with depression (62). Exercise interventions may have the potential to provide a similar level of benefit to standard self-help treatments for depression, while also potentially delivering the additional health benefits of improved physical fitness and weight loss. These outcomes are both particular health concerns for women in the postnatal period, during which exercise levels often decrease (194, 195) and excess weight is common, which has been found to be a contributing factor to poor psychological well-being and low self-confidence (310).

When compared to the findings of a recent Cochrane Library review of exercise versus no treatment or control interventions for depression in general populations (SMD: -0.62, 95% CI: -0.81 to -0.42) (28), the effect size reported in this review for general postnatal population was again comparable (SMD: -0.75, 95% CI: -1.40 to -0.10). A previous review of exercise trials within postnatal populations reported an overall effect size of -0.81 (95% CI: -1.53 to -0.10) (101). This moderate effect is comparable to the overall effect found in the present review (SMD -0.55, 95% CI: -0.91 to -0.18), however, all trials included in the previous review were in populations indicating a risk of depression, the trials included in the

present review included both depressed and general postnatal populations. The present review reported a smaller effect size of -0.41 (95% CI: -0.79 to -0.03) within depressed postnatal populations. A substantially greater number of trials (11 vs 5) and participants (1176 vs 221) were included in this, compared to the previous review and narrower confidence intervals were obtained, indicating that the present review has provided a more robust assessment of the effect of exercise on PND.

6.4.1 Anxiety

Data on anxiety symptoms was not reported by any of the included trials. Given that tentative estimates suggest its prevalence is comparable to that of PND and it is often comorbid with depressive symptoms (275, 288), there is clearly a need for more research into this outcome.

6.4.2 Self-efficacy for exercise

In meta-analysis, exercise interventions did not significantly increase self-efficacy for exercise or physical activity. However, only 159 participants from two trials were included in this analysis. In addition, one controlled trial with a concurrent comparator also reported no significant effect of their exercise intervention on self-efficacy. Significant heterogeneity was present in this meta-analysis, indicating that no conclusions can be drawn about the ability of such interventions to increase self-efficacy for exercise in this population. Further research into this outcome is needed.

6.4.3 Co-interventions

In subgroup analysis, within general postnatal populations, co-interventions were found to have a significant effect in reducing depressive symptoms; exercise only

interventions were not found to have a significant effect. In 'depressed' populations, neither exercise interventions alone nor those with co-interventions had a significant effect in reducing depressive symptoms. The suggestion that co-interventions supporting factors such as social support may be more effective in reducing depression than interventions supporting exercise alone, is consistent with the previous review of exercise for PND (101). Daley et al. reported that the removal of a trial with a social support co-intervention considerably reduced the overall effect size, such that the combined effect of the remaining exercise only trials was no longer statistically significant (101). PND has a mixed aetiology (311) and it is reasonable to suggest that trials with interventions that can also influence other factors such as social support, diet and lifestyle may be more successful in reducing the severity of depression, than interventions that aim only to encourage exercise.

6.4.4 Strengths and limitations

This review was conducted with robust systematic methods. It was a substantial advancement on the previous review in this field conducted over four years ago (101). Several more trials (eleven versus five) and five times as many participants (n=1176 versus n=221) were included in the primary meta-analysis of the present compared to the previous review. Narrower confidence intervals around the effect size were also obtained. For these reasons this review provides a more reliable estimate of the effects of exercise on postnatal depressive symptoms. The subgroup analyses indicated exercise to be effective in reducing depressive symptoms in both general postnatal populations and those at risk of depression. The subgroup analyses exploring the effects of exercise only interventions and exercise with co-

interventions were not included in the previous review (101) and may provide preliminary evidence to aid the development of effective interventions in postnatal populations.

As discussed previous, the findings of this review should be considered in the context of its potential limitations. Included trials had small samples (10 trials n=20-240, one trial n=679) and trial quality was variable. Intention-to-treat (ITT) analyses with either all participants included in the analysis or imputation of data were only conducted by two trials (11, 13). However, overall loss to follow up was relatively low at 27% (386/1586) and as no indication was found that the effect sizes of trials were related to degree of loss to follow up or the presence or absence of ITT analyses, an ITT meta-analysis was not undertaken.

Significant heterogeneity was present in the design of the trials included in this review. In particular, interventions varied between those only promoting exercise and those also promoting a healthy diet or opportunities for improved social support amongst peers. The methods of encouraging exercise also varied between specific exercise regimes to be conducted at home, group based exercise sessions and tailored exercise counselling. The effectiveness of these different strategies in decreasing depressive symptoms was likely to vary, as was reflected in the high levels of heterogeneity found in the analyses of this review. A random effects model was used in analyses to account for this and we have explored potential causes of this heterogeneity by conducting subgroup analyses.

Searches were conducted for trials that assessed the effects of exercise on other postnatal psychological health outcomes such as anxiety and self-efficacy for exercise, which no other review has done. However, the paucity of studies

investigating these outcomes has prevented any conclusions being drawn. All of the included trials used screening questionnaires (e.g. EPDS) to indicate a risk of PND, rather than using a clinical interview to obtain a diagnosis of depression. An inclusion criterion of a diagnosis of depression would be imperative for future trials. Not all included trials provided a measure of the intensity or duration of exercise undertaken by participants and those that did provide this information did not use objective measures. Actual intensity and duration of exercise performed can be difficult to determine accurately by self-reported measures. For future trials, objective measurement in the form of accelerometry would allow for greater accuracy and more meaningful comparison between intervention types.

6.5 Conclusions and implications for further research

The findings of this review suggest that exercise may be effective in reducing depressive symptoms in postnatal populations, including women at risk of PND. Current evidence suggests that interventions designed to influence both exercise and factors such as social support, diet and lifestyle may be more successful in reducing depression than those designed to encourage exercise alone. These conclusions are tentatively based on the limited evidence available regarding different types of intervention. Trials reporting other psychological outcomes including anxiety and self-efficacy for exercise would add considerably to the evidence base. All further research in this field should recruit women with a clinical diagnosis of depression and provide objective measures of exercise; these factors would substantially improve the reliability of the evidence for exercise as a treatment for PND.

CHAPTER SEVEN

7. OVERALL DISCUSSION AND CONCLUSIONS

This thesis has investigated the acceptability and effectiveness of exercise as a treatment for women at risk of depression in the postnatal period. This research has been conducted using three principal methods, a randomised controlled trial, a qualitative study and a systematic review with meta-analysis. In this concluding chapter, the principal findings of this body of evidence will be summarised and its strengths and limitations considered. The implications of these findings for mothers with PND, clinicians involved in their care and future research in this field, will be discussed.

7.1 Principal findings

7.1.1 An exercise counselling intervention and PND

A facilitated exercise counselling intervention, provided as an adjunctive to usual care, was found to reduce postnatal depressive symptoms to a greater extent than usual care alone. This finding was only significant when adjusted for the pre-specified covariates of baseline EPDS score, age, weight and ethnicity. The fully adjusted effect size of -2.26 (95% CI: -4.51 to -0.02) was greater than that reported by any of the previous trials investigating exercise counselling interventions (11, 14, 16, 18). In relation to previous trials of set exercise programmes, the present RCT was more successful in reducing depressive symptoms than three published trials which found no effect (12, 17, 19); reported a very similar effect size to one trial (15) and a smaller effect size than one trial of an exercise and social support co-

intervention by Armstrong et al. (13). For further discussion please see chapter three, section 3.5.2.

7.1.2 Exercise, social support and PND

It is possible that the intervention in this thesis was more successful than many of those in previous trials of exercise for PND due to significantly improving participants' self-reported social support. A previous systematic review and the review included within this thesis support the premise that social support may be an important element of behavioural interventions seeking to reduce depressive symptoms (101). Social support is known to be an important element in the aetiology of PND, with social isolation and low support from friends, family and partners known to be risk factors for PND (36). For further discussion please see chapter one, section 1.2.4. Previous research has investigated the relative effects of exercise and social support on depression in the postnatal period. In 2004 Armstrong et al. conducted an RCT of postnatal group exercise vs group social support (80). Improvements in depression were seen in both arms; however, the improvement in the group exercise arm was significantly greater (80). The relative influence of social support within previous research is therefore unclear, especially as an exercise intervention conducted in a group is also likely to include an element of peer social support. For further discussion please see chapter three, section 3.2.4.

The intervention of this RCT may have resulted in improved social support through two distinct pathways. The findings of the qualitative section of this thesis highlighted the propensity of exercise itself to reduce isolation and negative introspection. Physical activity was felt to improve social interaction. Interaction with

other mothers, who were felt to have shared experiences and thought processes, was felt to be of particular importance. This finding is in agreement with recent research by Doran et al. highlighting the value women place on supportive peer interaction in the postnatal period (283). For further discussion please see chapter five, section 5.4.9. The intervention itself may also have improved mothers feelings of social support by providing regular interaction and personalised support through the PAF. This concept is supported by findings that receiving non-judgemental support that validates experiences is much valued by mothers (122). Previous research has highlighted the ability of exercise counselling interventions to provide what participants feel to be reassurance and support through a ‘therapeutic relationship’ with an exercise facilitator (241), emphasising the potential role of social support in exercise counselling interventions. For further discussion please see chapter three, section 3.5.3.

7.1.3 Exercise interventions and PND

In agreement with the previous review of this field, the systematic review presented in this thesis concluded that exercise interventions may be an effective treatment for PND (101). In addition, the present review found that exercise may be effective in reducing depressive symptoms in both general postnatal populations and those at risk of PND, though these results should be interpreted with caution due to high levels of heterogeneity. For further discussion please see chapter six, section 6.4.

7.1.4 Exercise within the context of postnatal life and depression

When viewed alongside other treatments for PND such as antidepressants or counselling, exercise has the propensity to offer the additional benefits of improved physical fitness and weight loss. These may be particularly valuable in the postnatal period when women are more vulnerable to decreased physical activity and postnatal weight retention (194, 195). However, a range of barriers to exercise for mothers with PND were highlighted by the qualitative research in this thesis. These included factors common to many mothers after giving birth such as the physical recovery, the practicalities of childcare, time limitations and financial pressures. Psychological barriers raised by PND itself were also emphasised such as maladaptive coping strategies; the inhibitory effects of co-morbidity of anxiety and depression (275) and the effects of low motivation, which have been found in other depressed populations (188). For further discussion please see chapter five sections 5.4.1, 5.4.2, 5.4.3 and 5.4.4.

In line with previous research (187, 286), the qualitative study conducted for this thesis found that despite the many potential barriers to exercise for mothers with PND, many considered it to be an acceptable treatment, either on its own or in combination with other treatments. The accessibility of activities such as brisk walking and the fact no prior disclosure of PND was required, were seen as particular advantages of exercise compared to other current treatments. Exercise was reported to provide a range of benefits including improvements in depressive symptoms; improved energy for childcare; improved sleep; greater social interaction; distraction from unwanted thoughts; weight loss and improved body image and a sense of

achievement. For further discussion of reported exercise benefits please see chapter five, sections 5.4.7, 5.4.8 and 5.4.9.

7.1.5 Exercise, motherhood and identity

The transition to motherhood has been explored by a significant body of qualitative research. In 2003, Nelson et al. described motherhood as time of transition and transformation (119). This significant life event has been associated with a lost sense of personal identity (120). Within the present research mothers described the unrelenting demands of childcare and the detrimental effect this was felt to have on their psychological well-being.

A novel finding of this research was the positive influence of exercise at a time when, due to their changing role, and their experience of depression, many mothers described a lost sense of self. Exercise facilitated temporary freedom from the mothering role, allowing mothers to focus on themselves. Achieving exercise goals was also felt to provide a welcome sense of autonomy and personal achievement. A conflict was commonly reported between the desire to devote time to childcare and the need to undertake activities focused on oneself, such a conflict has been reported by previous qualitative research conducted with postnatal mothers. However, this conflict was to some degree alleviated by the knowledge that exercise was beneficial for a mother's physical and psychological health, which some mothers recognised as vital to their ability to care for their child. For further discussion please see chapter five, section 5.4.5.

7.2 **The strengths of this research**

The RCT conducted as part of this thesis was the first study in this field to include a clinically diagnosed population, in contrast to previous studies that have been based on general postnatal populations or mothers indicating a risk of depression on a screening questionnaire. Consequently, the present RCT is able to offer the first indication of the effects of exercise in mothers with PND. The systematic review included in this body of research has improved upon the previous review conducted by Daley et al. (101) by including a larger number of trials (eleven versus five) with substantially more participants (n=1176 versus n=221). This review also explored several new facets of the current body of research, including the effects of exercise in both general postnatal populations and those at risk of depression; the effectiveness of co-interventions providing additional dietary support and social support and the effects of exercise on a range of psychological outcomes such as self-efficacy for exercise and anxiety, highlighting the paucity of research into these outcomes. This thesis presented the first qualitative study of depressed mothers participating in an exercise intervention. The unique relationship between motherhood and identity and the interaction of exercise with this relationship was highlighted.

7.3 **The limitations of this research**

For the RCT included in this thesis, the sample size indicated by power calculation as required to detect a moderate difference in EPDS score between groups at follow up was not achieved. In agreement with previous literature (244) recruitment to this mental health trial was found to be challenging. Insights from the qualitative study

presented suggest the recruitment difficulties experienced may have been related to an unwillingness amongst women to be labelled with PND, due to the fear of being considered an unfit mother. Misappropriation of symptoms to postnatal tiredness or problems with a partner or the baby have also been found to result in a rejection of the diagnosis of PND (124).

This RCT of clinically diagnosed women, as opposed to women indicating depression on a screening questionnaire, is likely to have provided more clinically meaningful findings, however this criterion reduced the potential study population considerably. In the reported RCT, 436 women had a first EPDS of 10 or above, yet only 100 went on to receive a clinical diagnosis of depression. Findings from a detailed analysis of the recruitment methods of this trial suggest that it may be advisable for further studies in clinically depressed populations to cast the net as wide as possible by contacting all mothers who have recently given birth, regardless of depression status, before conducting diagnostic interviews to obtain a clinical sample. Use of a range of recruitment methods such as advertisement on relevant websites, via radio and the payment of service support costs to health care professionals may also improve recruitment rates in future PND trials (200).

In relation to the outcome measures of the reported RCT, Actiheart accelerometers did not prove an acceptable measure of physical activity in this postnatal population. Due to refusals to wear the device at follow up, a lack of both quantity and quality of physical activity data introduced uncertainty as to whether the intervention resulted in an increase in exercise. Consequently, the mechanisms by which this intervention resulted in a decrease in depressive symptoms were

unclear. A significant increase in social support was found in the intervention compared to the comparator group. In light of the support provided by reviews of this field for the importance of social support (101), it is unclear whether exercise, social support, or a combination of the two, was responsible for the effect of the intervention on depressive symptoms. For further discussion of the role of social support and the therapeutic relationship in exercise interventions please see chapter three, section 3.5.3 and chapter seven, section 7.1.2.

The trial reported in this thesis was a pragmatic RCT. As with all previous studies in the field of exercise and maternal depression, it was accepted that the participants would not be blinded to whether they were in the exercise intervention or usual care group. This lack of blinding was a reflection of the difficulties of providing a practical alternative to exercise for the comparator group that would be unlikely to influence depression. It is recognised, however, that contamination may have occurred in a study of this design, with the usual care group possibly altering their exercise behaviour. The participant's knowledge of their allocation may also have introduced responder bias by influencing participants' responses to questions regarding exercise. The use of an objective measure of physical activity was intended to counteract such bias; however, due to the apparent unacceptability of the Actiheart accelerometer in postnatal populations, this method was not successful.

7.4 Implications for women with PND

Conducting a qualitative study provided many insights into mothers' experiences of PND and their views of exercise as a potential treatment. Despite significant practical and psychological barriers to performing exercise, many mothers did in fact manage

to integrate some form of exercise into their daily lives. The ability of exercise to improve health and fitness was felt by mothers to provide a 'legitimate' justification for taking time to focus on themselves rather than their children. Fulfilling exercise goals provided sense of achievement as an individual rather than as a mother, which was valued by the many women who reflected on the sense of lost personal identity they had suffered, both in becoming a mother and through experiencing PND. However, many mothers reported the view that although exercise was appropriate for mild and moderate depression, for more severe depression, exercise was more appropriate as part of a treatment package alongside medication and counselling.

Exercise, whether alone or in combination with other treatments may have the potential to exert a positive influence on a mother's sense of identity and self-confidence in a way medication may not be able to. Importantly, mothers may be able to obtain a broad range of benefits from exercise including greater energy for childcare; weight loss and improved body image; improved sleep; reduced isolation; distraction from unwelcome thoughts through exercise and improved mood, as highlighted by this qualitative work.

7.5 Implications for clinicians

The systematic review conducted as part of this thesis concluded that exercise may be an effective treatment both for reducing depressive symptoms in the general postnatal population and for those at risk of PND. These findings provide some support for the current NICE guidance regarding the treatment of PND (4). However, the high level of bias and heterogeneity found within this evidence base indicates that caution should be used when recommending exercise to mothers with PND and

the uncertainty with regard to its effectiveness should be communicated to mothers seeking treatment. Nevertheless, mothers, especially those who are breastfeeding, frequently reject antidepressant medication when it is offered due to concerns about the potential harmful effects on their child (182). The qualitative research reported here revealed that antidepressants can be viewed as ‘a sledge hammer to crack a nut’ in relation to PND. It may be useful for clinicians to understand that many women view exercise as a more acceptable, natural alternative to medication.

7.6 Implications for future research

7.6.1 Points of methodology

If the effectiveness of exercise in PND is to be accurately assessed, further research must be conducted in clinically diagnosed populations. It is accepted that the use of certain thresholds on screening questionnaires such as the EPDS will generate a larger potential sample than diagnostic interviews such as the CIS-R. However, screening questionnaires provide only an indication of depression risk; they were not designed to be diagnostic tools and will not identify a clinical population. Further research in postnatal populations should also use a different objective measure of physical activity to the Actiheart used in this RCT. Wrist worn accelerometers may be preferable, especially in a population amongst whom some participants will be breastfeeding. Accurate physical activity data would enable further investigation and comparison of the effectiveness of different types and intensities of exercise in reducing depressive symptoms.

In order to improve the design of trials in this field, it is important that the blinding of participants is carefully considered. Historically there has been an

acceptance that blinding of the participants of exercise trials has not been possible. However, effective blinding has been recently achieved by a trial which provided comparator participants with a 'contact control' during which they received an equal amount of contact with researchers as the intervention participants and were provided with information unrelated to exercise (102). This blinded design has the potential to reduce contamination and responder bias and should therefore be taken as a model for future exercise trials. In addition, to reduce bias, ITT analyses with imputation should be adopted in all further studies.

7.6.2 Future research questions

The systematic review included in this thesis identified that our current understanding of exercise as a treatment for PND still has limitations. The most effective way to design an exercise intervention for PND has not yet been determined with any certainty. Future research will need to directly compare different formats (exercise counselling or set exercise sessions) structures (individual or group based) and settings (home or at a facility) of interventions. The effectiveness of different exercise intensities and types (aerobic and anaerobic) also requires investigation, especially in light of recent evidence that anaerobic exercise may be of comparable effectiveness to the more traditionally recommended aerobic exercise in reducing depression (28).

In light of the lack of clarity highlighted by the systematic review in this thesis over the mechanisms by which exercise may provide psychological benefit, it may be advisable to design future studies to explore such factors. It is particularly difficult to separate the effects of exercise and social support as almost all exercise

interventions will involve some degree of social interaction. One solution may be the design of a four arm RCT with an exercise counselling telephone intervention, a group exercise intervention, a purely social support group intervention and a usual care comparator. Mothers in the exercise counselling intervention and usual care comparator could be advised not to join any new exercise groups to limit intervention contamination. The three intervention groups provide exercise support with limited social support (telephone exercise counselling); exercise and peer social support (group exercise) and social support only (social support group intervention). The different degrees of exercise and social support provided by these groups should provide an indication of the relative influence of exercise and social support in treating PND.

The broader psychological benefits of exercise, as suggested during the qualitative interviews conducted during this thesis, also require further exploration, indicating the value of nested qualitative studies and the need for future RCTs to include a range of outcomes such as social support, self-efficacy for exercise and anxiety.

Due to the relatively small evidence base for the use of exercise in depression at the time the present RCT was conducted, exercise was investigated as an adjunctive treatment. The systematic review conducted, including all published trials up to August 2014, revealed that this evidence base has substantially improved in magnitude, though perhaps not quality. At the point at which there is felt to be sufficient evidence for the use of exercise as a treatment by itself, it would be advisable to conduct an RCT directly comparing exercise alone with antidepressants

and counselling. As both antidepressants and counselling are recommended in the treatment of severe depression (4), such a study should only be conducted in populations with mild to moderate depression.

7.7 Final conclusions

This thesis has explored the effectiveness and acceptability of exercise as a treatment for PND through an RCT, a qualitative study and a systematic review with meta-analysis. Collectively, this body of evidence has suggested that exercise may be both acceptable and effective in reducing depressive symptoms in postnatal women. However, a high degree of heterogeneity and substantial risk of bias has been found within the current evidence base. At present very little is known about the relative effectiveness of different intervention designs and types of exercise and their effectiveness relative to other standard treatments for PND. In view of the fact that one in ten mothers will suffer with postnatal depression (1), it is hoped that this thesis will provide a basis for continued research in this field.

Appendix

Appendix Figure 1: Participant screening invitation letter V1

Version: 1 5th May 2009

Dear Name

UNIVERSITY OF
BIRMINGHAM

PAMPeRS: A study of exercise and postnatal depression

Our practice is helping the University of Birmingham in a research study to assess the usefulness of exercise as a treatment for postnatal depression. **We have agreed to contact all our patients who have recently had a baby to ask if they are willing to take part, regardless of whether they have postnatal depression or not.** Receiving this letter does not mean that you have postnatal depression and if you do not wish to be part of this study, it will in no way affect your medical care.

Study purpose and reason for invitation

We would like to investigate whether exercise might help to reduce postnatal depression. Some women will be given the opportunity to participate in a home-based exercise programme in addition to usual care. At this stage, we are inviting **all new mothers** to participate in the study, regardless of whether they have postnatal depression or not.

What will happen if I do take part?

We are asking **all new mothers** to complete the enclosed EPDS questionnaire and reply form and return them to the research team.

If you have a high score on this questionnaire, we would like to ask you to complete a second questionnaire and some further questions during a home visit from a member of the University research team. If you continue to score high on this questionnaire, we will invite you to take part in the main study and allocate you randomly to participate in the home exercise programme or not. The exercise programme would involve a female physical activity advisor visiting you twice in your home to talk to you about ways in which you might become more physically active. They would also telephone you twice to offer you further support. We will also mail you information leaflets about exercise from time to time.

Do I have to take part?

You do not have to take part in the study, but we hope that as many people as possible will take part. Please complete the enclosed patient reply form indicating whether or not you are willing to take part and return it to the research team in the FREEPOST envelope provided. We hope that even if you are not interested or able to take part in the study, you will consider filling in section 2 of the reply form that asks about the reasons why you do not want to take part. If you require further information please contact Ruth Blamey on 0121 4146891 or your GP or Health Visitor.

Thank you very much for your time to consider taking part in this research.

Yours sincerely

GP SIGNATURE AND NAME

Appendix Figure 2: Participant information sheet V1

Version 1: 5th May 2009

UNIVERSITY OF
BIRMINGHAM

Patient information sheet:

PAMPeRS (Exercise and Postnatal Depression Study)

PART 1

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study). Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of the study?

We would like to investigate whether exercise might help to reduce postnatal depression.

Why have I been chosen?

Your responses to our questionnaire showed that you might be experiencing symptoms of postnatal depression so we have invited you to participate in the study.

What will happen to me if I take part?

You will continue to receive usual care from your health team regardless of whether you decide to take part or not. In addition, some women (randomly, like tossing a coin) will also receive a home based exercise intervention with a female physical activity advisor, who will visit you in your home twice for about 40 minutes. She will also telephone you twice to see how you are getting on and mail you information leaflets about exercise from time to time throughout the study.

If you are not randomly allocated to receive the home-based exercise intervention we will offer you an exercise consultation at the end of the study.

We will ask you to complete a questionnaire booklet 0, 24 and 52 weeks after entering the study. The questionnaires will focus on how you are feeling, how you are coping at home and your relationship with the baby. We will also ask you some questionnaires about your physical activity levels. They will take about 30 minutes to complete. We will also ask 50% of women in the study to wear a very small sensor (weighs 10g) on their chest for 7 consecutive days. The sensor measures your movement and heart rate. You can still take part in the study even if you do not want to wear the sensor.

We would need to look at the GP records for you and your baby to count up the number of consultations, referrals and prescriptions you and your baby have had since the baby was born.

Finally, we will ask you to agree to possibly being approached by our research associate (insert name) to be interviewed so we may hear your views about exercise and postnatal depression. We will contact you about this at a later date.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time, without giving a reason. A decision

to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive from your healthcare team.

What are the possible disadvantages and risks of taking part?

We do not anticipate any risks or side-effects from the exercise programme.

What are the possible benefits of taking part?

The results of this study will help us decide whether exercise is a useful treatment in helping women to recover from postnatal depression. We cannot promise that you will lose weight, but similar programmes have helped people in the past.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. We will not release any information about you to any external organisation. Once the study has been completed our record of your name and address will be destroyed.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in part 2 before making any decision.

PART 2

What will happen if I don't want to carry on with the study?

If you decide to stop participating in the study we do hope that you would be willing for the research team to follow you up at 6 and 12 months as it is important to find out why the exercise intervention did not suit some people. This would involve completing some questionnaires. However, if you do not want to take part in the research at any time you can withdraw without affecting your care.

What will happen to the results of the research study?

The results of the study will be published in 2013. No individual will be able to be identified in the published information. No person would be able to be identified in any published report.

Who is organising and funding the research?

The research is being organised through the University of Birmingham. It is being funded via the Department of Health and the University of Birmingham.

Who has reviewed the study?

The Local Research Ethics Committee and the Primary Care Trust Research Department have reviewed and approved the study.

What if I have a complaint about this study?



Further questions



Appendix Figure 3: Looking after yourself leaflet



Looking after yourself

Helpful hints for
new mums



PAM-PeRS Study

Involve your partner

The more you can share your baby's care, the more you will both enjoy your baby. your partner can help with bathing, changing and dressing, as well as cuddling and playing. Your partner may feel quite nervous of handling the baby and need encouragement. Be patient if they seem awkward at first.



Help at Home

You'll probably need a lot of full-time help at first, not just with the chores, but also to give you emotional support. You're bound to feel up and down and to get easily tired in the early days. Many women want to have their partners with them so that they will have a chance to get to know the baby properly, as well as helping with the work. It also gives you some time to start adjusting to the changes in your life.

If you're on your own, or your partner is unable to be with you, perhaps your mother or a close friend could be there. Even with help you will probably feel tired. Cut corners where you can.

- **Cut down on cleaning.** A bit of dust won't hurt.
- **Keep meals simple.** You need to eat well but this needn't involve a great deal of preparation and cooking.
- **Try to space visitors out.** Too many in a short time will be very tiring. If visitors do come, don't feel you have to tidy up or lay on a meal. Let them do things for you.
- **If you need extra help ask.** Friends or neighbours will probably be very willing to do some shopping for example.



Rest



During the weeks or months that you are feeding your baby at night and your body is recovering from childbirth, finding time to rest is essential. It can be tempting to use your baby's sleep times to catch up on chores, but try to have a sleep or a proper rest at least once a day.

Activities

*Continue with any postnatal exercises you were shown in hospital.
You can also do this deep stomach exercise when you feel well enough.*

- Lie on your side with your knees slightly bent.
- Let your tummy sag and breathe in gently.
- As you breathe out, gently draw in the lower part of your stomach like a corset, narrowing your waistline.
- Squeeze your pelvic floor also.
- Hold for the count of 10 then gently release.
- Repeat 10 times.

You should not move your back at any time. Besides these exercises, try to fit in a walk with your baby. A short walk in the fresh air will make you feel good.

If a gap or bulge line appears vertically down the centre of your stomach you should ask your physiotherapist or health visitor for special exercises.

Food

It's very important to continue to eat properly. If you want to lose weight, don't rush it. A varied diet without too many fatty foods will help you lose weight gradually.

Try to make time to sit down, relax, enjoy your food and digest it properly. It doesn't have to be complicated.



Try food like baked potatoes with baked beans and cheese, salads, pasta, French bread pizza, scrambled eggs or sardines on toast, for example, followed by fruit mixed with yoghurt or fromage frais.

A healthy diet is especially important if you're breastfeeding. Breastfeeding uses up a lot of energy. Some of the fat you put on in pregnancy will be used to help produce milk, but the rest of the nutrients will come from your diet.



This means that you may be hungrier than usual. If you do need a snack, try having cheese or beans on toast, sandwiches, bowls of cereal or fruit.

If you have any concerns about your health contact your GP or your health visitor

This information was taken from the NHS website:
www.nhs.uk/Planners/pregnancyareplanner/

Appendix Figure 4: Pam-PeRS Self-harm Protocol

PAMPeRS SELF-HARM RISK PROTOCOL

I.I. OVERVIEW

Risk of self-harm is defined as

- a) A score of 2 or 3 in the relation to question 10 on the EPDS *'The thought of harming myself has occurred to me'*. An answer of *'Sometimes'* scores 2 and an answer of *'Yes, Quite Often'* scores 3.
- b) A response of 'Yes' to the H8 *"In the past week, have you felt that life isn't worth living"* or H9 *"In the past week, have you thought of killing yourself on CISR-R"*.

Whenever these instances occur, or if at any time, the researcher believes that there is a significant risk of a patient who is participating in the study self-harming that has not been communicated to their GP, the researcher will consult the PI or the nominated deputies (Drs Kate Jolly at the University of Birmingham or Mary McGuinness at the Mother and Baby unit).

The PI or deputies will examine the patient's data and if it is considered necessary, will assess the patient. If it is concluded that there is a significant risk, the patient's GP will be notified **with or without** the patient's consent. However, the PI or the deputies would contact the GP without first assessing the patient themselves if the situation was urgent, again with or without the patient's consent.

1 2 ACTION

At EPDS-1 (6 weeks postnatally)

On receipt of the EPDS-1 questionnaire, the research associate will screen the woman's response to item 10 relating to self-harm to assess risk. Regardless of consent status or total EPDS score, women who score 2 or 3 should be contacted by the researcher (see suggested script on page 3) and the self-harm protocol should be actioned. If for any reason the woman cannot be contacted, the researcher should inform the PI or nominated deputies to discuss.

At EPDS-2 (8-10 weeks (postnatally) (during home visit)

Once the EPDS-2 is completed (during home visit) the woman's response to item 10 relating to self-harm must be screened to assess risk.

Regardless of consent status or total EPDS score, for women who score 2 or 3 the self-harm protocol must be actioned immediately, and regardless of whether the woman is eligible to continue to complete the CIS-R.

The person conducting the home visit should advise the woman to discuss these thoughts with her GP or Health Visitor as soon as possible. It should be explained to the woman that because of the way she is feeling at the moment it is better to complete the home visit at a later date, and once the woman's response has been discussed with the GP and the GP is happy for the woman to participate in the study (see suggested script on page 3). The person doing the home visit should inform a member of the University research team as soon as possible of the situation. If not already notified, the PI or deputies should be notified, and the PI or nominated deputies must document any action in the Self Harm Action Pro Forma.

If the woman does not agree for information to be passed to the GP the PI or deputies will examine the patient's data and if it is considered necessary, will assess the patient. If it is concluded that there is a significant risk, the patient's GP will be notified **without** the patient's consent. All action and decisions must be documented in the Self-Harm Action Proforma.

On completing the CIS-R during the home visit

If a woman indicates suicidal intent during the completion of the CIS-R (as defined above in 1.1b) the Self Harm Pro forma should be actioned regardless of whether the woman is eligible to continue to randomisation. A suggested script can be found on page 3.

Women eligible to continue with the study:

If the woman agrees for the information to be passed to the GP, randomization should be delayed until the woman's response has been discussed with the GP and the GP is happy for the woman to participate in the study.

If the woman does not agree for information to be passed to the GP, randomization may proceed but the researcher should delay

randomisation until they have discussed with the PI or nominated deputies. The PI or deputies will examine the patient's data and if it is considered necessary, will assess the patient. If it is concluded that there is a significant risk, the patient's GP will be notified **without** the patient's consent. All action and decisions must be documented in the Self-Harm Action Proforma.

EPDS-3 and EPDS-4 (6 and 12 months after randomization)

On receipt of the EPDS-3 and EPDS-4 questionnaires, the research associate will screen the woman's response to item 10 relating to self-harm to assess risk. Regardless of consent status or total EPDS score, women who score 2 or 3 should be contacted by the researcher and the Self-Harm Protocol should be actioned. If for any reason the woman cannot be contacted, the researcher should inform the PI or nominated deputies to discuss. A suggested script can be found on page 3.

PAMPeRS SELF HARM ACTION PRO FORMA

If at any time during the study a woman expressed risk of self harm (as defined in the self harm protocol) the following procedures **MUST** be implemented

- a) The researcher should contact the woman as soon as possible and advise her to discuss these thoughts with her GP or Health Visitor. If this is the first time that the woman has expressed these thoughts or if the GP has not previously been informed, offer to pass this information to the GP or Health Visitor concerned (see suggested script below).
- b) If the woman agrees, the GP or Health Visitor should be contacted by telephone to discuss and giving the opinion of withdrawing the woman from the study
- c) If the woman refused to give her permission, the researcher should notify the PI or deputies who will then decide the next course of action.
- d) The ACTION PRO FORMA FORM must be completed by a member of the research team. Signed by the PI or deputies and stored with the woman's confidential data.
- e) If the woman cannot be contacted, the researcher should inform the PI or deputies to discuss.

Suggested telephone script (EPDS-1, EPDS-3 & EPDS-4)

"Thank you for completing the questionnaire we sent recently. It is a big help and it allows us to see how women feel in the week/months after giving birth. I notice that during the last few weeks you have had thoughts of harming yourself and I wondered how you were feeling now? Is this something you feel you need or want help with?"

I will pass this information onto my clinical colleagues in charge of the study and they may want to call you just to check that you are ok. It is also a good idea to talk to your own GP or Health Visitor about these feelings, but sometimes it is a bit difficult to bring the subject up. If you like I can contact your Health Visitor or GP and let them know how you are feeling".

If a woman states that she does not want her GP or HV to be contacted the following statement must be used:

"I understand that you do not want me to contact your GP or health visitor and I will discuss this with my clinical colleagues who may call you.

Suggested conversation script (when EPDS-2 and CIS-R completed at home visit)

"Thank you for completing this questionnaire. It is a big help to us. I noticed that you have had thoughts of harming yourself. Is this something you feel you want or need help with? Because of the way you are feeling at the moment it is probably better that we complete the rest of the questionnaires another time. I will pass this information onto my clinical colleagues in charge of the study and they may want to call you just to check that you are ok. It is also a good idea to talk to your own GP or Health Visitor about these feelings, but I understand it is sometimes a bit difficult to bring the subject up. If you like I can contact your Health Visitor or GP for you and let them know how you are feeling".

If a women states that she does not want her GP or HV to be contacted the following statement must be used:

"I understand that you do not want me to contact your GP or health visitor. I will discuss this with my clinical colleagues who may give you a call.

PAMPeRS SELF HARM ACTION PRO FORMA

PATIENT ID: _____ **NAME** _____
DOB _____ **PRACTICE** _____

HISTORY:

Assessment	Date	Risk identified	Name of researcher	Name of person informed	GP informed	Name of GP	Date GP informed
EPDS-1 (6 wks) postnatal		Yes/No			Yes/No		
EPDS-2 (8-10wks) postnatal		Yes/No			Yes/No		
EPDS-3 (6 months) follow-up		Yes/No			Yes/No		
EPDS-4 (12 months) follow-up		Yes/No			Yes/No		

Any other action.....

Notes.....

Appendix Figure 5: The analysis of the RCT



UNIVERSITY OF
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College of Medical and
Dental Sciences

Primary Care Clinical Sciences

23rd June 2015

To whom it may concern,

I confirm that Ruth Blamey conducted the statistical analyses presented in her PhD thesis. The analyses were carried out independently of the published PAM-PerS trial analysis. I can confirm that this is her own work and that I was involved in an advisory capacity only.

Yours faithfully



Andrea Roalfe

Head of Statistics

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w: www.mds.bham.ac.uk/phyass.shtml

Appendix Figure 6: Taxonomy of behavioural change techniques

Taxonomy of behavioural change techniques to promote change in physical activity and eating behaviours (184)

<p>1. Provide information on consequences of behaviour in <u>general</u></p>	<p>Information about the relationship between the behaviour and its possible or likely consequences in the general case, usually based on epidemiological data, and not personalised for the individual (contrast with technique 2).</p>
<p>2. Provide information on consequences of behaviour <u>to the individual</u></p>	<p>Information about the benefits and costs of action or inaction to the individual or tailored to a relevant group based on that individual's characteristics (i.e. demographics, clinical, behavioural or psychological information). This can include any costs/ benefits and not necessarily those related to health, e.g. feelings.</p>
<p>3. Provide information about others' approval</p>	<p>Involves information about what other people think about the target person's behaviour. It clarifies whether others will like, approve or disapprove of what the person is doing or will do. NB Check that any instance does not also involve techniques 1 (Provide information on consequences of behaviour in <u>general</u>) or 2 (Provide information on consequences of behaviour <u>to the individual</u>) or 4 (Provide normative information about others' behaviour).</p>
<p>4. Provide normative information about others' behaviour</p>	<p>Involves providing information about what other people are <u>doing</u> i.e., indicates that a particular behaviour or sequence of behaviours is common or uncommon amongst the population or amongst a specified group – presentation of case studies of a few others is not normative information. NB this concerns other people's actions and is distinct from the provision of information about others' approval (technique 3 [Provide information about others' approval]).</p>
<p>5. Goal setting (behaviour)</p>	<p>The person is encouraged to make a behavioural resolution (e.g. take more exercise next week). This is directed towards encouraging people to decide to change or maintain change. NB This is distinguished from technique 6 (Goal setting - outcome) and 7 (Action planning) as it does not involve planning exactly how the behaviour will be done and either when or where the behaviour or action sequence will be performed. Where the text only states that goal setting was used without specifying the detail of action planning involved then this would be an example of this technique (not technique 7 [Action planning]). If the text states that 'goal setting' was used if it is not clear from the report if the goal setting was related to behaviour or to other outcomes, technique 6 should be coded. This includes sub-goals or preparatory behaviours and/or specific contexts in which the behaviour will be performed. The behaviour in this technique will be directly related to or be a necessary condition for the target behaviour (e.g. shopping for healthy eating; buying equipment for physical activity). NB check if techniques applied to preparatory behaviours should also be coded as instances of</p>

	technique 9 (Set graded tasks).
6. Goal setting (outcome)	The person is encouraged to set a general goal that can be achieved by behavioural means but is not defined in terms of behaviour (e.g. to reduce blood pressure or lose/maintain weight), as opposed to a goal based on changing behaviour as such. The goal may be an expected consequence of one or more behaviours, but is not a behaviour per se (see also techniques 5 [Goal setting - behaviour] and 7 [Action planning]). This technique may co-occur with technique 5 if goals for both behaviour and other outcomes are set.
7. Action planning	Involves detailed planning of what the person will do including, as a minimum, when, in which situation and/or where to act. "When" may describe frequency (such as how many times a day/week or duration (e.g., for how long). The exact content of action plans may or may not be described, in this case code as this technique if it is stated that the behaviour is planned contingent to a specific situation or set of situations even if exact details are not present NB The terms "goal setting" or "action plan" are not enough to ensure inclusion of this technique unless it is clear that plans involve linking behavioural responses to specific situational cues, when only described as "goal setting" or "action plan" without the above detail it should be regarded as applications of technique 5 and 6.
8. Barrier identification/Problem solving	This presumes having formed an initial plan to change behaviour. The person is prompted to think about potential barriers <u>and</u> identify ways of overcoming them. Barriers may include competing goals in specified situations. This may be described as "problem solving". If it is problem solving in relation to the performance of a behaviour, then it counts as an instance of this technique. Examples of barriers may include behavioural, cognitive, emotional, environmental, social and/or physical barriers. NB Closely related to techniques 7 (Action planning) and 9 (Set graded task) but involves a focus on specific obstacles to performance. It contrasts with technique 35 (Relapse prevention/ Coping planning) which is about maintaining behaviour that has already been changed.
9. Set graded tasks	Breaking down the target behaviour into smaller easier to achieve tasks and enabling the person to build on small successes to achieve target behaviour. This may include increments towards a target behaviour, or incremental increases from baseline behaviour. NB The key difference to technique 7 (Action planning) lies in planning to perform a sequence of preparatory actions (e.g. remembering to take gym kit to work), task components or target behaviours which are in a logical sequence or <i>increase in difficulty over time</i> - as opposed to planning " if-then " contingencies when/where to perform behaviours. General references to <i>increasing</i> physical activity as intervention goal are not instances of this technique.
10. Prompt review of behavioural goals	Involves a review or analysis of the extent to which previously set <u>behavioural</u> goals (e.g. take more exercise next week) were

	<p>achieved. In most cases this will follow previous goal setting (see technique 5, 'goal setting-behaviour') and an attempt to act on those 29 goals, followed by a revision or readjustment of goals, and/ or means to attain them. NB Check if any instance also involves techniques 6 (goal setting - behaviour), 8 (Barrier identification/Problem solving), 9 (Set graded tasks) or 11 (Prompt review of outcome goals).</p>
<p>11. Prompt review of outcome goals</p>	<p>Involves a review or analysis of the extent to which previously set <u>outcome goals</u> (e.g. to reduce blood pressure or lose/maintain weight) were achieved. In most cases this will follow previous goal setting (see technique 6, goal setting-outcome') and an attempt to act on those goals, followed by a revision of goals, and/ or means to attain them. NB Check that any instance does not also involve techniques 5 (goal setting - outcome), 8 (Barrier identification/Problem solving), 9 (Set graded tasks) or 10 (Prompt review of behavioural goals).</p>
<p>12. Prompt rewards contingent on effort or progress towards behaviour</p>	<p>Involves the person using praise or rewards for attempts at achieving a behavioural goal. This might include efforts made towards achieving the behaviour, or progress made in preparatory steps towards the behaviour, but not merely participation in intervention. This can include self-reward. NB This technique is not reinforcement for performing the target behaviour itself, which is an instance of technique 13 (Provide rewards contingent on successful behaviour).</p>
<p>13. Provide rewards contingent on successful behaviour</p>	<p>Reinforcing successful performance of the specific target behaviour. This can include praise and encouragement as well as material rewards but the reward/ incentive must be explicitly linked to the achievement of the specific target behaviour i.e. the person receives the reward if they perform the specified behaviour but not if they do not perform the behaviour. This can include self-reward. Provision of rewards for completing intervention components or materials are not instances of this technique. References to provision of incentives for being more physically active are not instances of this technique unless information about contingency to the performance of the target behaviour is provided. NB Check the distinction between this and techniques 7 (Action planning) and 17 (Prompt self-monitoring of behavioural outcome) and 19 (Provide feedback on performance).</p>
<p>14. Shaping</p>	<p>Contingent rewards are first provided for any approximation to the target behaviour e.g., for any increase in physical activity. Then, later, only a more demanding performance, e.g., brisk walking for 10 minutes on three days a week would be rewarded. Thus, this is graded use of contingent rewards over time.</p>
<p>15. Prompting generalization of a target behaviour</p>	<p>Once a behaviour is performed in a particular situation, the person is encouraged or helped to try it in another situation. The idea is to ensure that the behaviour is not tied to one situation but becomes a more integrated part of the person's life that can be performed at a variety of different times and in</p>

	a variety of contexts.
16. Prompt self-monitoring of behaviour	The person is asked to keep a record of specified behaviour/s as a method for changing behaviour. This should be an explicitly stated intervention component, as opposed to occurring as part of completing measures for research purposes. This could e.g., take the form of a diary or completing a questionnaire about their behaviour, in terms of type, frequency, duration and/or intensity. Check the distinction between this and techniques 17 (Prompt self-monitoring of behavioural outcome).
17. Prompt self-monitoring of behavioural outcome	The person is asked to keep a record of specified measures expected to be influenced by the behaviour change, e.g. blood pressure, blood glucose, weight loss, physical fitness. NB It must be reported as part of the intervention, rather than only as an outcome measure. Check the distinction between this and techniques 16 (Prompt self-monitoring of behaviour).
18. Prompting focus on past success	Involves instructing the person to think about or list previous successes in performing the behaviour (or parts of it). NB This is not just encouragement but a clear focus on the person's past behaviour. It is also not feedback because it refers to behaviour preceded the intervention.
19. Provide feedback on performance	This involves providing the participant with data about their own recorded behaviour (e.g., following technique 16 [Prompt self-monitoring of behaviour]) or commenting on a person's behavioural performance (e.g., identifying a discrepancy with between behavioural performance and a set goal – see techniques 5 [Goal setting - behaviour] and 7 [Action planning] – or a discrepancy between one's own performance in relation to others' – note this could also involve technique 28 [Facilitate social comparison]).
20. Provide information on <u>where and when</u> to perform the behaviour	Involves telling the person about when and where they might be able to perform the behaviour this e.g. tips on places and times participants can access local exercise classes. This can be in either verbal or written form. NB Check whether there are also instances of technique 21 (Provide instruction on how to perform the behaviour).
21. Provide instruction on how to perform the behaviour	Involves telling the person how to perform a behaviour or preparatory behaviours, either verbally or in written form. Examples of instructions include; how to use gym equipment (without getting on and showing the participant), instruction on suitable clothing, and tips on how to take action <i>Showing</i> a person how to perform a behaviour without verbal instruction would be an instance of technique 22 only. NB Check whether there are also instances of techniques 5, 7, 8, 9, 22. Instructions to follow a specific diet or programme of exercise without instructions how to perform the behaviours are not included in this definition. Cooking and exercise classes as well as personal trainers and recipes should always be coded as this technique, but may also be coded as 22 (Model/ Demonstrate the behaviour).

22. Model/ Demonstrate the behaviour	Involves <i>showing</i> the person how to perform a behaviour e.g., through physical or visual demonstrations of behavioural performance, in person or remotely. NB This is distinct from just providing instruction (technique 21) because in “demonstration” the person is able to <i>observe</i> the behaviour being enacted. This technique and techniques 21 (Provide instruction on how to perform the behaviour) and may be used separately or together. Instructing parents or peers to perform the target behaviour is not an instance of this technique as fidelity would be uncertain.
23. Teach to use prompts/ cues	The person is taught to identify environmental prompts which can be used to remind them to perform the behaviour (or to perform an alternative, incompatible behaviour in the case of behaviours to be reduced). Cues could include times of day, particular contexts or technologies such as mobile phone alerts which prompt them to perform the target behaviour. NB This technique could be used independently or in conjunction with techniques 5 (goal setting - behaviour) and 7 (Action planning) (see also 24 [Environmental restructuring]).
24. Environmental restructuring	<i>The person</i> is prompted to alter the environment in ways so that it is more supportive of the target behaviour e.g. altering cues or reinforcers. For example they might be asked to lock up or throw away or their high calorie snacks, or take their running shoes to work. Interventions in which the interveners directly modify environmental variables (e.g. the way food is displayed in shops, provision of sports facilities) are not covered by this taxonomy and should be coded independently.
25. Agree behavioural contract	Must involve written agreement on the performance of an explicitly specified behaviour so that there is a written record of the person’s resolution witnessed by another.
26. Prompt practice	Prompt the person to rehearse and repeat the behaviour or preparatory behaviours numerous times. Note this will also include parts of the behaviour e.g., refusal skills in relation to unhealthy snacks. This could be described as “building habits or routines” but is still practice so long as the person is prompted to try the behaviour (or parts of it) during the intervention or practice between intervention sessions, e.g. as “homework”.
27. Use of follow up prompts	Intervention components are gradually reduced in intensity, duration and frequency over time, e.g. letters or telephone calls instead of face to face and/or provided at longer time intervals.
28. Facilitate social comparison	Involves explicitly drawing attention to others’ performance to elicit comparisons. NB The fact the intervention takes place in a group setting, or have been placed in groups on the basis of shared characteristics, does not necessarily mean social comparison is actually taking place. Social support may also be encouraged in such settings and this would then involve technique 29 (Plan social support/ social change). Group classes may also involve instruction (technique 21 [Provide instruction on how to perform the behaviour]) demonstration (technique 22 [Model/ Demonstrate the behaviour]) and

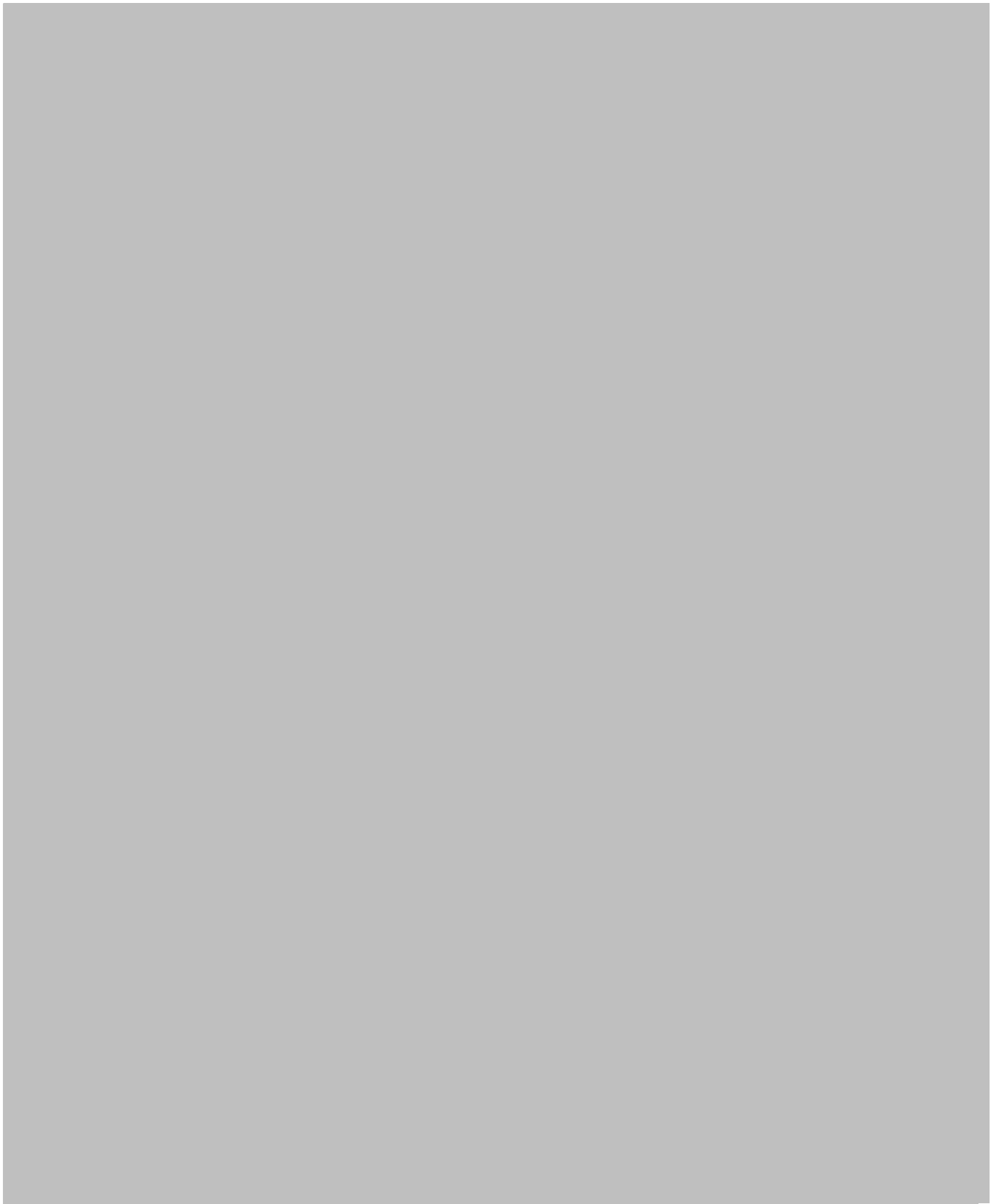
	practice (technique 26 [Prompt practice]).
29. Plan social support/ social change	Involves prompting the person to plan how to elicit social support from other people to help him/ her achieve their target behaviour/ outcome. This will include support during interventions e.g., setting up a “buddy” system or other forms of support and following the intervention including support provided by the individuals delivering the intervention, partner, friends, family.
30. Prompt identification as role model/ position advocate	Involves focusing on how the person may be an example to others and affect their behaviour e.g., being a good example to children. Also includes providing opportunities for participants to persuade others of the importance of adopting/ changing the behaviour, for example, giving a talk or running a peer-led session.
31. Prompt anticipated regret	Involves inducing expectations of future regret about the performance or non-performance of a behaviour. This includes focusing on how the person will <i>feel</i> in the future and specifically whether they will feel regret or feel sorry that they did or did not take a different course of action. Do not also code instances of this technique as the more generic providing information on consequences (techniques 1 [Provide information on consequences of behaviour in <u>general</u>] and 2 [Provide information on consequences of behaviour <u>to the individual</u>]).
32. Fear Arousal	Involves presentation of risk and/or mortality information relevant to the behaviour as emotive images designed to evoke a fearful response (e.g, “smoking kills!” or images of the grim reaper). Do not also code instances of this technique as the more generic providing information on consequences (techniques 1 [Provide information on consequences of behaviour in <u>general</u>] and 2 [Provide information on consequences of behaviour <u>to the individual</u>]).
33. Prompt Self talk	Encourage the person to use talk to themselves (aloud or silently) before and during planned behaviours to encourage, support and maintain action.
34. Prompt use of imagery	Teach the person to imagine successfully performing the behaviour or to imagine finding it easy to perform the behaviour, including component or easy versions of the behaviour. Distinct from recalling instances of previous success without imagery (technique 18 [Prompting focus on past success])
35. Relapse prevention/ Coping planning	This relates to planning how to maintain behaviour that has been changed. The person is prompted to identify in advance situations in which the changed behaviour may not be maintained and develop strategies to avoid or manage those situations. Contrast with techniques 7 (Action planning) and 8 (Barrier identification/ Problem solving) which are about initiating behaviour change.
36. Stress management/Emotional control training	This is a set of specific techniques (e.g., progressive relaxation) which do not target the behaviour directly but seek to reduce anxiety and stress to facilitate the performance of the

	behaviour. It might also include techniques designed to reduce negative emotions or control mood or feelings that may interfere with performance of the behaviour, and/ or to increase positive emotions that might help with the performance of the behaviour. NB Check whether there are any instances of technique 8 (Barrier identification/ Problem solving), which includes identifying emotional barriers to performance, in contrast to the current technique, which addresses stress and emotions, whether they have been identified as barriers or not.
37. Motivational interviewing	This is a clinical method including a specific set of techniques involving prompting the person to engage in change talk in order to minimize resistance and resolve ambivalence to change (includes motivational counselling). NB Only rate this technique if explicitly referred to by name, not if one identifies specific elements of it, this may happen if you have prior experience with this technique.
38. Time management	This includes any technique designed to teach a person how to manage their time in order to make time for the behaviour. These techniques are not directed towards performance of target behaviour but rather seek to facilitate it by freeing up times when it could be performed. NB Only rate this technique if explicitly referred to by name, not if one identifies specific elements of it, this may happen if you have prior experience with this technique.
39. General communication skills training	This includes any technique directed at general communication skills but not directed towards a particular behaviour change. Often this may include role play and group work focusing on listening skills or assertive skills. NB Practicing a particular behaviour-specific interpersonal negotiation e.g., refusal skills in relation to cigarettes or alcohol would not be an instance of this technique.
40. Stimulate anticipation of future rewards	Create anticipation of future rewards without necessarily reinforcing behaviour throughout the active period of the intervention. Code this technique when participants are told at the onset that they will be rewarded based on behavioural achievement.

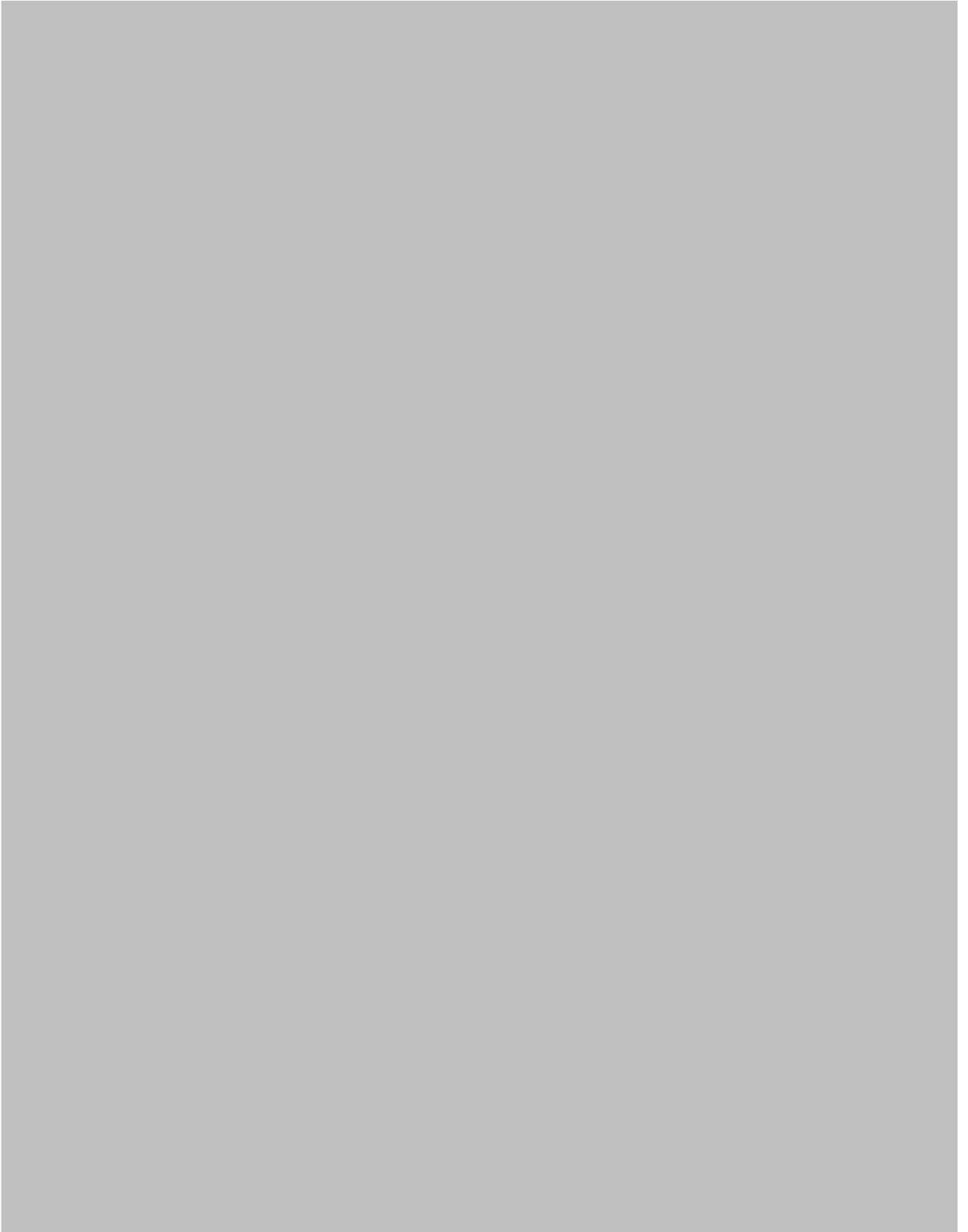
Appendix Figure 7: Exercise diary

Week of _____							
	Activity	Distance/ duration	Intensity	Mood before (scale 1-10)	Mood after (scale 1-10)	Mood change	Comment
Mon							
Tues							
Wed							
Thurs							
Fri							
Sat							
Sun							

Appendix Figure 8: Ethical approval







Appendix Figure 9: Participant screening invitation letter V2

Version 2 4th March 2010

Dear Name

PAMPeRS Study: Keeping active after having a baby

Our practice is helping the University of Birmingham in a research study to assess whether keeping active can help women who experience low mood after having their baby. **We have agreed to contact all our patients who have recently had a baby to ask if they are willing to take part, regardless of whether they have low mood or not.** If you do not wish to be part of this study, it will in no way affect your medical care.

What will happen if I do take part?

We are asking **women who have recently had a baby** to complete the enclosed questionnaire and reply form and return them to the University research team. The questionnaire measures whether new mothers have low mood or not. If you have a high score on this questionnaire, we would like to ask you to complete a second questionnaire and some further questions during a home visit from a member of the University research team. If you continue to score high on this questionnaire, we will invite you to take part in the main study and randomly allocate you to participate in our physical activity programme or not.

The physical activity programme will encourage mothers to do what ever type of physical activity they enjoy and prefer doing, either at home or in their local community. A female physical activity advisor will visit you twice in your home to talk to you about ways you might become more physically active. The advisor would also telephone you on two further occasions to offer you extra support to become more active. In addition, from time to time, we will mail you information leaflets about physical activity.

Do I have to take part?

You do not have to take part in the study, but we hope that as many women as possible will take part. Please complete the reply form indicating whether you are willing to take part and return it in the FREEPOST envelope. We hope that even if you are not interested or able to take part, you will complete section 2 of the reply form that asks about the reasons why you do not want to take part. If you would like further information please contact Ruth Blamey (the study co-ordinator) on 0121 414 6891 or your GP or Health Visitor.

Thank you very much for your time to consider taking part in this research.

Yours sincerely

GP NAME

Appendix Figure 10: Participant screening invitation letter V3

Version 3: 19th October 2010

Dear Name

PAM-PeRS Study

Would you like to be more active after having your baby?

Our practice is helping the University of Birmingham with a study to find out whether being active can influence mood after having a baby. **We have agreed to contact all our patients who have recently had a baby to ask if they are willing to take part.** If you do not wish to be part of this study, it will in no way affect your medical care.

We have enclosed a leaflet to explain what the study is about. If you are interested in taking part please fill in enclosed questionnaire and reply form and return these in the FREEPOST envelope.

If you would like further information please contact Ruth Blamey (study co-ordinator) on

0121 414 6891 or your GP or Health Visitor.

Thank you very much for your time.

Yours sincerely

GP NAME

Appendix Figure 11: Participant reply form V1

Version 1 5th May 2009



Patient Reply Form

Please complete SECTION 1 or SECTION 2 as appropriate

SECTION 1:

I am interested in taking part in the PAMPeRS study
(please tick)

Name:

Forename Surname

Address:

.....

.....Postcode:

Tel Nos: (home) (mobile)

.....

Email:

Name of your GP and GP surgery:

.....

If you would like to take part in the study please also complete the consent form for screening overleaf and the green EPDS questionnaire and return them in the envelope provided. No stamp is required. A member of the research team will contact you.

SECTION 2

I am NOT interested in taking part in the PAMPeRS study
(please tick)

Even if you're not interested in taking part in this study we would like you to complete the EPDS questionnaire on the green paper. Please also sign the consent form overleaf and return this page in the envelope provided. No stamp is required and we will not contact you again.

To help us understand why some people do not want to, or are unable to take part in research, it would be helpful if you would complete the questions below. This information will be treated in strict confidence.

Please tick all that apply

- I do not want to take part in a research study I am not feeling low
I do not want to participate in exercise I am too busy
I have a disability preventing exercise I am already physically active

Other:(please specify)

Name of your GP surgery:

In order to help us further understand the reasons why some people do not want to take part, or are unable to take part, we would like to contact individuals to discuss their reasons. We would do this by telephone. Not everyone who agrees to be contacted will be telephoned.

Can we contact you by telephone to discuss your reasons for NOT taking part in the PAMPeRS study? Yes No

If **Yes**, please fill in your name and telephone number below.

.....
Forename Surname Tel no Email

Thank you.

Appendix Figure 12: Participant reply form V2

Version 2: 19th October 2010 Reply form

Patient Reply Form

I am interested in taking part in the PAMPeRS study
(please tick)

If you are interested in taking part please fill in the box below with your contact details.

Please also complete the consent form overleaf and the green EPDS questionnaire and return them in the **FREEPOST** envelope provided.

First name
Surname.....
Address:
.....
.....
Postcode:
Tel Nos: (home) (mobile)
Email:

Thank you



PAM-PeRS Study

Appendix Figure 13: Participant information sheet V2

Version 2: 21st July 2009



Patient information sheet:

PAMPeRS (Exercise and Postnatal Depression Study)

PART 1

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of the study?

We would like to investigate whether exercise might help to reduce postnatal depression.

Why have I been chosen?

Your responses to our questionnaire showed that you might be experiencing symptoms of postnatal depression so we have invited you to participate in the study.

What will happen to me if I take part?

You will continue to receive usual care from your health team regardless of whether you decide to take part or not. In addition, some women (randomly, like tossing a coin) will also receive a home based exercise intervention with a female physical activity advisor, who will visit you in your home twice for about 40 minutes. She will also telephone you twice to see how you are getting on and mail you information leaflets about exercise from time to time throughout the study.

If you are not randomly allocated to receive the home-based exercise intervention we will offer you an exercise consultation at the end of the study.

Your involvement in the study will last 12 months. We will ask you to complete a questionnaire booklet at the start of the programme, at the end of the programme and again 12 months after entering the study. The questionnaires will focus on how you are feeling and how you are coping at home. We will also ask you some questionnaires about your physical activity levels. They will take about 15 minutes to complete. We will also ask 50% of women in the study to wear a very small sensor (weighs 10g) on their chest for 5 consecutive days. The sensor measures your movement and heart rate. You can still take part in the study even if you do not want to wear the sensor. We have included a photograph of the sensor on page 3.

We would need to look at the GP records for you and your baby to count up the number of consultations, referrals and prescriptions you and your baby have had since the baby was born.

Finally, we will ask you to agree to possibly being approached by our research associate to be interviewed so we may hear your views about exercise and postnatal depression. We will contact you about this at a later date.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive from your healthcare team.

What are the possible disadvantages and risks of taking part?

We do not anticipate any risks or side-effects from the exercise programme.

What are the possible benefits of taking part?

The results of this study will help us decide whether exercise is a useful treatment in helping women to recover from postnatal depression. You may also experience some physical benefits to your health from participating in exercise.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. We will not release any information about you to any external organisation. Once the study has been completed our record of your name and address will be destroyed.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in part 2 before making any decision.

PART 2

What will happen if I don't want to carry on with the study?

If you decide to stop participating in the study we do hope that you would be willing for the research team to follow you up at 6 and 12 months as it is important to find out why the exercise intervention did not suit some people. This would involve completing some questionnaires. However, if you do not want to take part in the research at any time you can withdraw without affecting your care.

What will happen to the results of the research study?

The results of the study will be published in 2013. No individual will be able to be identified in the published information. No person would be able to be identified in any published report.

Who is organising and funding the research?

The research is being organised through the University of Birmingham. It is being funded via the Department of Health and the University of Birmingham.


Who has reviewed the study?

The Local Research Ethics Committee and the Primary Care Trust Research Department have reviewed and approved the study.

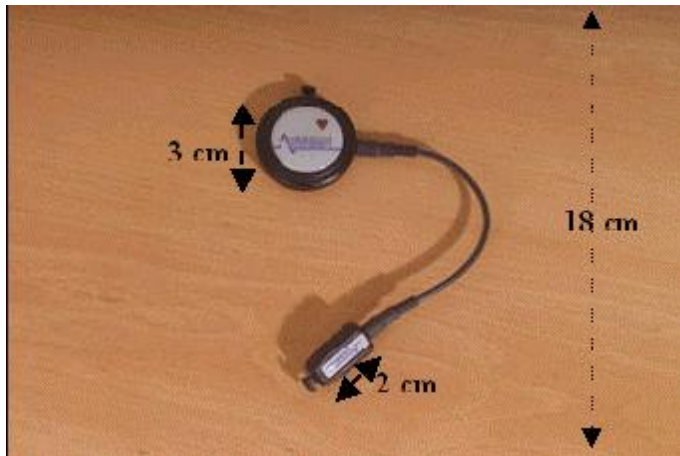
What if I have a complaint about this study?

If you have a complaint about this study you can phone Dr Amanda Daley on 0121 4143762 who is overseeing the research, or the usual NHS complaints procedure is available to you. You can also contact the Patient Advice and Liaison Service on 0121 627 8820 or email pals@uhb.nhs.uk.

Further questions



Photograph of sensor



Appendix Figure 14: Participant screening consent form V1

Version 1
Date: 5th may 2009

Patient consent to screening

Our reference: <<GP Practice and search number>>

PAMPeRS: Exercise and Postnatal Depression

<i>initial box</i>	<i>Please</i>
I have read and understand the information letter from my GP practice (version 1 5 th May 2009)	<input type="checkbox"/>
I am agreeing to Complete the enclosed questionnaire and return it to the research team	<input type="checkbox"/>
Allow the score from my EPDS questionnaire to be used anonymously for statistical purposes	<input type="checkbox"/>
Allow the study centre to contact me again to ask me some further questions about how I have been feeling	<input type="checkbox"/>
I agree to my health visitor and GP being informed of my score on the EPDS questionnaire	<input type="checkbox"/>
I agree to participate	<input type="checkbox"/>

Name (block letter)

Appendix Figure 15: Participant screening consent form V2

Patient consent to screening
Version 2
Date: 21/07/ 09



Patient ID _____

Our reference: <<GP Practice and search number>>

PAMPeRS: Exercise and Postnatal Depression

initial box

Please

I have read and understand the information letter from my GP practice (version 1 5th May 2009)

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.

I am agreeing to

Complete the enclosed questionnaire and return it to the research team

Allow the score from my EPDS questionnaire to be used anonymously for statistical purposes

Allow the study centre to contact me again to ask me some further questions about how I have been feeling

I agree to my health visitor and GP being informed of my score on the EPDS questionnaire

I agree to participate

Name (block letter)

Date

Signature

Appendix Figure 16: Participant screening consent form V3

Patient consent to screening

Version 3
Date: 4/03/ 10



PAMPeRS Study: Keeping Active after Having a Baby

Please initial box

I have read and understand the information letter from my GP
(version 2 4th March 2010)

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.

I am agreeing to

Allow the study centre to contact me again to ask me some further
questions about how I have been feeling

I agree to my health visitor and GP being informed of my score on
the

EPDS questionnaire

Name (block letter)

Date

Signature

Appendix Figure 17: Trial consent form V1

Trial consent form version 1: 5/05/09

Title of Project: PAMPeRS: Exercise and postnatal depression

Please initial box

1. I confirm that I have read and understood the information sheet dated 5th may 2009 (version 1) for the above study and have had the opportunity to ask questions.

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 understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the research team at the University of Birmingham), 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 to allow access to data when auditing etc.

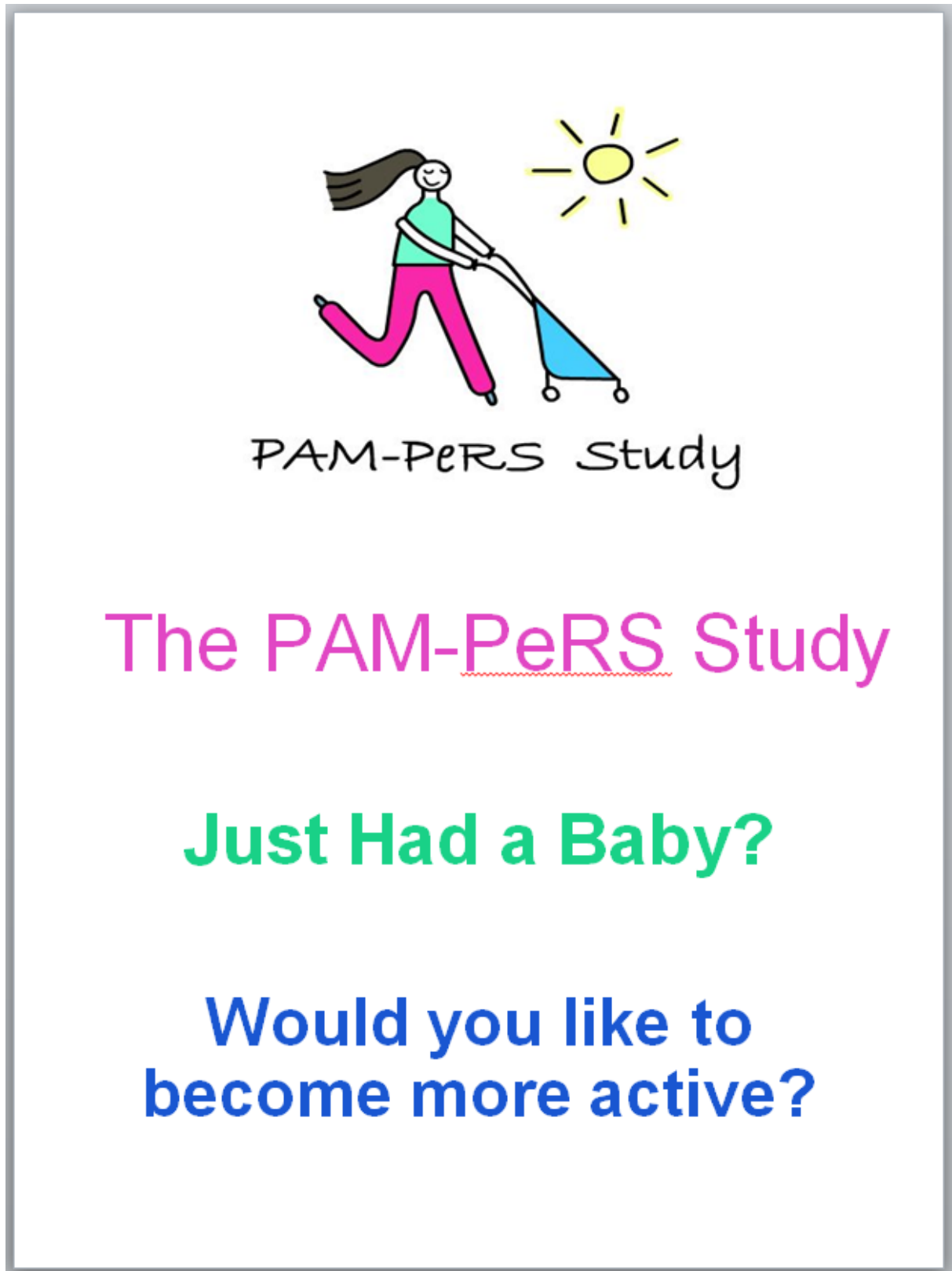
4. I agree to my GP being informed of my participation in the study

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

Name of Patient	Date	Signature
-----------------	------	-----------

Name of Researcher taking consent	Date	Signature
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Appendix Figure 19: Participant screening leaflet



What's the study about ?

- The PAM-PeRS study is being run by the University of Birmingham. We would like to find out whether physical activity, when fitted around mothers busy lives, is helpful for low mood after having a baby.

What's involved ?

- We would like you to complete the enclosed questionnaire and reply form and return them to the research team. The questionnaire measures whether new mothers have low mood.
- Depending on your answers in the questionnaire we may contact you and invite you to take part in the study. Half of the women who agree to take part will receive activity support and half will receive written advice about healthy living after having a baby.

What kind of activity?

- If you are in the group that receive activity support, a female activity advisor will visit you on two occasions in your home to offer support and encouragement to become more active. She will also telephone you on two occasions to offer you support with your activity and you can call her if you want additional advice.
- You can choose the type of activity you do. The advisor will offer you support to do whatever activity you enjoy doing, either at home or in your local community.

What do I do next?

- If you are interested in taking part please complete the questionnaire and reply form and return them in the FREEPOST envelope.
- If you would like more information about the study please contact Ruth Blamey on [REDACTED]



This study is funded by the NHS

Appendix Figure 20: First screening EPDS with physical activity question

Patient ID _____



UNIVERSITY OF
BIRMINGHAM



EPDS PA Baseline Home visit questionnaire

As you have recently had a baby, we would like to know how you are feeling now. Please **tick** the answer that comes closest to how you have felt in **the past week**, not just today.





Physical Exercise

1. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, jogging, bicycling at a regular pace? Do not include walking.

(Anything that increases your heart rate and gets you a bit sweaty)

_____ days per week

No moderate physical activities

2. How much time did you usually spend doing moderate physical activities on one of those days?

_____ hours per day

_____ minutes per day

Thank you for completing this questionnaire

Appendix figure 21: Second EPDS

UNIVERSITY OF
BIRMINGHAM

EPDS Questionnaire



As you have recently had a baby, we would like to know how you are feeling now. Please **tick** the answer that comes closest to how you have felt in **the past week**, not just today.

[A large grey rectangular area representing the questionnaire content, which is currently blank.]



Thank you for completing this questionnaire

Appendix Figure 22: Goal setting form

	Activity	Goal	Reward for meeting my goal	Comments
Mon				
Tues				
Wed				
Thurs				
Fri				
Sat				
Sun				

No time?

Get exercise to fit around
you!



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10 WAYS TO INCREASE YOUR DAILY PHYSICAL ACTIVITY

1. Take the stairs instead of the lift.

2. Walk short distances instead
of driving.



3. Walk your dog. If you don't have a dog
borrow a friend's dog- they will help keep
you motivated!

4. Have a dance around to music in the
comfort of your own home.

5. Climb the stairs 10 times a day.

6. Instead of waiting for the bus, walk to the next bus stop.

7. Park as far away as possible from your destination for example, when out shopping.



8. Walk your child to and from school or nursery.

9. Pace up and down walking whilst you are on your mobile phone or waiting for the train or bus.

10. Invest in some home gym equipment and exercise whilst watching your favorite TV shows.



Contact Details

Should you have any questions relating to this booklet or wish to discuss your exercise in more detail please contact:



Feeling tired?

Eat your way to more energy!



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FOOD FOR FUEL!



Here's 10 top healthy eating tips:

1. Over half of your daily diet should come from carbohydrates- wholemeal bread and pasta, brown rice and oats are good options.
2. Aim for 2-3 portions of protein daily. Chicken, turkey, fish and eggs are good choices.
3. Opt for low fat dairy products such as skimmed milk, natural yoghurt and low fat cheese.
4. Try not to buy sugar, salt or fat rich foods- if they are not in the house you can't eat them!



5. Aim for at least 5 portions of a variety of fruit and vegetables a day.

6. Dried fruits, nuts and seeds are great snacks for between meals.



7. Aim to drink 8 glasses of water a day.



8. Avoid fizzy drinks- they contain empty calories and really try to limit your alcohol and caffeine intake.

9. Avoid frying foods- grill, steam or oven cook instead.

10. Try to eat 3 meals a day to keep your blood sugar levels constant and prevent bingeing .

***Extra Tip:** You may find it useful to keep a food diary so you can record what you eat, how much you eat, when you eat and why you eat.

Contact Details

Should you have any questions relating to this booklet or wish to discuss your exercise in more detail please contact:



**Want a successful exercise
routine?**

Set SMARTER Goals!



PAM-PeRS Study

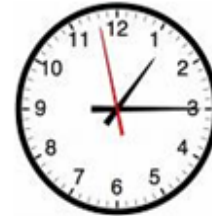
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Make your goals SMARTER!

- **S- Specific**- goals need to be specific not vague. They also need to be suited to you as an individual and take into account your everyday life.
- **M- Measureable**- set exercise goals that allow you to easily measure your success.
- **A- Adjustable**- sometimes life just gets in the way of our plans so goals may need to be adjusted from time to time.



- **R- Realistic**- goals need to be attainable. Setting unrealistic targets will demotivate you. Focus on achieving short term easier goals to help you achieve long term success.
- **T- Time framed**- open ended goals will not be motivational. Set a date for achieving your goals.
- **E- Enjoyable**- find activities that you enjoy taking part in to help motivate you.



R- Recorded- write down your goals and record whether or not you achieve them -this will help you set future goals.

Contact Details

Should you have any questions relating to this booklet or wish to discuss your exercise in more detail please contact:



Feeling low?

Boost your mood with happy hormones!



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Physiological benefits of physical activity!

- Reduced risk of heart disease and stroke.
- Prevent high blood pressure or reduce it if already high.
- Increased levels of 'good' cholesterol.
- Promote healthy blood sugar levels. Reduced risk of osteoarthritis and lower back pain.
- Reduced risk of some cancers.
- Helps to manage weight.
- Reduces body fat and increases muscle tone.
- Makes heart and lungs stronger.
- Combats aging process.



Psychological benefits of physical activity!

- Increased confidence and self esteem.
- Enhanced mood due to release of



endorphins ('happy hormones').

- Increases levels of various brain chemicals essential for function, mood and memory.

- Decreased feelings of stress and tension.



- Reduced frustration at daily problems and improves ability to cope with everyday life.

- Helps you to sleep well and reduces insomnia.

- Makes you feel more alert and energetic.



Contact Details

Should you have any questions relating to this booklet or wish to discuss your exercise in more detail please contact:



Appendix Figure 27: Intervention leaflet 5



Exercise an uphill struggle?

Motivation Tips Inside!



PAM-PERS Study

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Top 10 Motivation Tips!

1. **Plan** your activity. Write down when you are going to exercise and how long you are going to do it for.



2. Keep an **exercise diary**. It will help you keep track of how much exercise you do.

3. Exercise with a **friend or relative**- having some company can help make exercise more fun.



4. Set yourself some **realistic** short, medium and long term **goals** based on the frequency and duration of your exercise.

5. Make **your friends and family** aware of your exercise goals so they can support you.

Top 10 Motivation Tips!

6. **Listen** to your favorite **music** whilst exercising, it will help to keep you uplifted and energized!



7. **Prepare in advance**- get your exercise kit and trainers out ready or in the car boot the night before.
8. If you do have a bad week, **don't give up**. Instead, try to take small steps to get you back on track.
9. Give yourself options, repetition can become boring so have a **variety of activities** to suit your own lifestyle, the weather conditions and your fitness level.
10. **Enjoy it!** 😊 You are much more likely to continue with exercise in the long term if you enjoy doing it.

Contact Details

Should you have any questions relating to this booklet or wish to discuss your exercise in more detail please contact:





Want to get fit?

Fitness principles & overcoming barriers



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Think **F.I.T.T.**

To improve fitness levels the body systems must be put under more stress than normal (overloaded). This will allow adaptations to take place and a new level of fitness to be achieved. Here are some ways to help you increase your fitness levels:

F- Frequency: Increasing the number of times you are physically active each week.

I- Intensity: Increasing the difficulty of the activity for example, adding hills to your walking route.

T-Time: Increasing the length of time that you spend doing an activity for example, increasing the duration of your walk from 30 to 40 minutes.

T- Type: Increase the difficulty of the activity you are doing for example, progress from walking to running.

Top Tips: Make changes to your activity levels gradually. Only increase one thing at a time. Focus on increasing the frequency of your exercise first, then the duration.

Barriers to being more active

No Time? Suggestions: Try to do a few 10 minute walks throughout the day, go out for walks with friends or family when they come to visit, get up a little earlier twice a week, use your baby's sleep time as your exercise time. If childcare is an issue in the day, exercise with your baby- a brisk walk with the pram is a great way to stay active.



Feel self conscious? Suggestions: focus on the health benefits of exercise (see 'Feeling Low?' booklet), exercise alone at first if group classes don't appeal, invest in some workout DVD's to do at home or home gym equipment, listen to music to distract your attention.

Too Tired? Suggestions: Focus on how much energy you will have after exercise, do shorter 10-15 min intervals of exercise- once you have warmed up chances are you will feel like doing more! Exercise at the time of the day you feel most energetic. Tell friends and family your exercise goals so that they can support you and encourage you to be active even when you feel tired.

Contact Details

Should you have any questions relating to this booklet or wish to discuss your exercise in more detail please contact:



Appendix Figure 29: Consultation one post session summary sheet

Date of Session:		
Session Location:		
Session Start Time:	Session End Time:	Length:
Physical Activity History		
<p>Info on previous exercise experiences</p> <p>What physical activity they currently do</p> <p>What they think they may enjoy:</p> <p>Barriers/pros/cons that concern them:</p>		
Depression Information		
<p>Info on treatments</p> <p>Info on history of depression (if possible)</p>		
Other relevant notes e.g.–typical day, work, social support etc, likes and dislikes		

Notes about patient availability for appointments and phone calls
Summary of patient goals
Things for PAF to do before next session
Arrangements for next session

Appendix Figure 30: Consultation two post session summary sheet

Date:		
Session Location: (home, general practice, phone call etc)		
Session Start Time:	Session End Time:	Length:
Patient self reported physical activity		
Patient self-reported well-being		
Goals, plans for next few weeks in between session		
Notes about patient availability for phone calls		
Things for PAF to do before next session		
Arrangements for next session		

Appendix Figure 31: Contact monitoring form

Date and Time	Type of contact e.g. text, email, phone (specify mobile/landline calling to/from)	If phone length of call	Comments – which session trying to arrange – messages left – arrangements about next contact etc...

Appendix Figure 32: Reflective worksheet

Session	Control/Choice (Working with them to explore options and preferences)	Competence (What did you discuss to help them with their confidence?)	Relatedness (Did you ask about social support and how they feel about fitting in with others?)
Session 1			
Session 2			
Session 3			
Session 4			

Appendix Figure 33: Characteristics of mothers contacted and those randomised

Characteristic	All women contacted via CHS (n=9767)	Randomised participants (n=94)
	n (%)	n (%)
Age (years) mean (SD)	29.3 (6.0)	30.5 (5.6)
Ethnic origin		
White	5836 (59.8)	59 (62.8)
Mixed	848 (8.7)	5 (5.3)
Indian	392 (4.0)	6 (6.4)
Pakistani	840 (8.6)	12 (12.8)
Bangladeshi	131 (1.3)	1 (1.1)
Black-African	398 (4.1)	3 (3.2)
Black-Caribbean	326 (3.3)	1 (1.1)
Chinese	72 (0.7)	1 (1.1)
Other	621 (6.4)	6 (6.4)
Unknown	303 (3.1)	0 (0.0)
IMD quartile		
1 (least deprived)	358 (3.7)	7 (7.4)
2	1065 (10.9)	13 (13.8)
3	2116 (21.7)	22 (23.4)
4 (most deprived)	6197 (63.4)	52 (55.3)
unknown	31 (0.3)	0 (0.0)

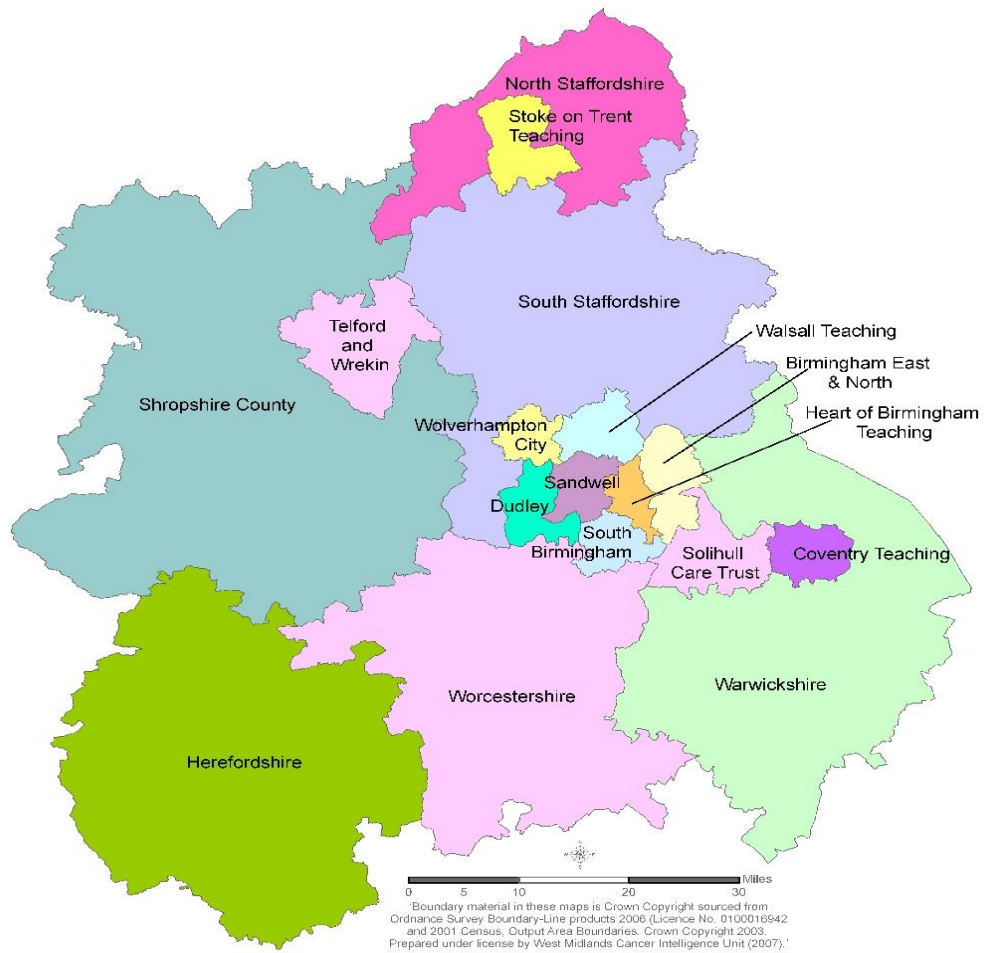
IMD: Index of Multiple Deprivation

Appendix Figure 34: CIS-R diagnoses across study groups

CIS-R Diagnosis	Intervention	Comparator
Severe depressive episode	7	10
Moderate depressive episode	25	25
Mild depressive episode	10	5
Mixed Anxiety and Depressive disorder	5	7

CIS-R: Clinical Interview Schedule-Revised

Appendix Figure 35: Map of PCTs at the point this RCT was conducted



Appendix Figure 36: Sampling Framework

Participant	Study arm	Age	Ethnicity	Parity	Socioeconomic deprivation	Employment status	Severity of depression	Severity of depression	Severity of depression
	Intervention/ comparator		White/ Black- African/ Pakistani/ Indian/ Mixed	Number of children	IMD category 1-4	Paid employment/ self-employed/ unemployed/ student/ looking after home/ sick or disabled/ other	Baseline EPDS Score	Six month EPDS score	ICD-10 diagnosis

Appendix Figure 37: Participant information sheet for qualitative interviews

Version 1: 05/05/09

initials surname

Address 1

Address 2

Address 3

Address 3

Postcode



Date:

Dear

The PAM-PeRS Study

About six months ago you kindly agreed to participate in the PAMPeRs study and we would like to thank you very much for your support so far, particularly for completing the questionnaires. In order to gain as much information as possible about women's experiences of the study, we are planning to interview some of the women involved, both those who did and did not participate in the exercise programme and also those who dropped out during the study.

We would really appreciate it if you were willing to be interviewed either at your home or here at the University about your experiences of the study. You would be interviewed by a female colleague (Ruth Blamey) who is a Research Associate at the Department of Primary Care. The interview would be arranged for a date and time to suit you and would last no longer than one hour. Any travel expenses would be reimbursed if you wanted to be interviewed at the University.

Taking part in the interview is of course entirely voluntary, but if you are happy to take part please could you return the attached reply slip or call Ruth Blamey on [REDACTED]

We will contact you again in six months time to complete the final questionnaires. Thank you for participating in the PAMPeRs study.

Yours sincerely

[REDACTED]

Ruth Blamey
Trial co-ordinator
Primary Care Clinical Sciences
Birmingham University
Tel. [REDACTED]

Appendix Figure 38: Consent form for interviews

Version 1: 5th May 2009



PAM-PeRS Study

Patient ID _____

Title of Project: PAMPeRS: Exercise and depression (Interview study)

Name of Researcher: Dr Amanda Daley

Please initial boxes

(as appropriate)

1. I confirm that I have read and understood the information sheet dated 5th May 2009 (version 1) for the above study and have had the opportunity to ask questions.
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 agree to this interview being recorded.
4. I agree to quotations being used.
5. I want to see any quotations before they are used.
6. I do not agree to quotations being used.
7. I agree to take part in the above study.

Name of Patient

Date

Signature

Name of Researcher taking consent

Date

Signature

Appendix Figure 39: Interview schedule for intervention participants

The trial

- Can you remember how you heard about the study (RCT)?
- How did you feel about being asked to take part in a trial about postnatal depression?
- Why did you decide to take part?
- What did you understand the aims of the study to be? Is this still your understanding?
- What type of care were you hoping to get? Why?
- What are you hoping to achieve by taking part? Improved mental health or were there other things you would like to achieve, e.g. improved physical health?
- What exercise, if any, were you doing at the time?
- In what ways did you think exercise might help your depression?
- Did you think it might help in other ways? e.g. meeting people, improved exercise.
- Do you enjoy exercising?

Diagnosis

- How did you feel when you found out that you had PND and were eligible to take part in the study?
- Did you think you had PND?
- How were you feeling at the time?
- Why do you think you felt like this?
- Had you had depression or PND before?
- What care were you receiving at the time from you GP or health visitor?
- Did you have any other forms of support? (family, friends, clinics, groups)
- Did friends and family know how you were feeling?
- Once diagnosed did you tell people about your PND? If so, who and how did they respond?

Views on exercise as a treatment for PND

- What do you think about exercise being used as a treatment for PND – do you think it might work? Why/why not?
- Do you see it as having a particular appeal to certain groups of individuals? e.g. active, first time mothers?
- Do you think only certain activities would help? If so, which activities?
- Do you think an effect will depend on the intensity or length of the activity? If so, why?
- What do you see as the pros and cons of exercise as a treatment for PND?
- Have you ever used exercise to improve your mental well-being? Why/why not?
- What about your health in general? Why/why not?
- Do you think exercise should be used alone or alongside other treatments, e.g. antidepressants?
- Do you think PND can impact on someone's ability to engage with exercise? Why/why not?

Experiences of the trial

- How did you feel when you were allocated to the exercise arm?
- Was this the arm you wanted? Why/why not?
- What were your expectations of the Physical activity facilitator?
- What were your expectations about what information and support would be given?

- What treatment have you received so far, i.e. number of visits and telephone calls?
- Tell me about the visits? What did you do, what information was given, what do you think the PAF was trying to do, what goals were set etc?
- What was helpful and unhelpful about these visits?
- Tell me about the telephone calls? What information or support was given, what was discussed?
- What was helpful and unhelpful about these calls?
- And what about the information on local activities? What information have you received? Useful/not useful?
- And what did you think of the PAF? Do you feel she has the knowledge and skills to support and motivate you to exercise?
- What could be done better?
- What else should be offered?

Exercise undertaken and barriers and support

- Since joining the study (RCT), can you tell me what exercise you have engaged in? Why these activities, how regularly do you do them?
- How do you feel at the time of exercise?
- How do you feel afterwards?
- How do you think exercise has affected your mental well-being?
- If done a range of activities
 - Which activities did you enjoy the most?
 - Which activities did you feel had the most impact on your mental health? Why?
 - Where there any you did not enjoy? Why?
 - Where they any you felt had a negative impact on your well-being? Why?
- What situations make it difficult for you to exercise?
- Are there issues that affect you engaging in physical activity? E.g. cost, facilities, time, feeling safe, feeling low?
- What helps/motivates you to engage in exercise? E.g. feeling less depressed, friend's encouragement?
- Have you told family/friends that you are taking part in the study (RCT)? If so, what was their reaction? Have they encouraged/discouraged you in any way?

Other treatment received

- During the trial, what other treatment have you received?
- What contact have you had with your GP and your health visitor?

Final questions

- How are you feeling now? What do you attribute this to?
- What exercise do you hope to do/maintain for the rest of the trial?
- What factors do you think will help you maintain the changes you have made?
- What will prevent you?
- Are you glad you are taking part in the study?
- Have the questionnaires been ok to complete?
- Are there any ways you think the trial could be improved?
- Is there anything else you would like to say about PND, your experiences of a particular treatment, views on treatments available and/or the trial?

Appendix Figure 40: Interview schedule for control group participants

The trial

- Can you remember how heard about the study (RCT)?
- How did you feel about being asked to take part in a trial about postnatal depression?
- Why did you decide to take part?
- What did you understand the aims of the study to be? Is this still your understanding?
- What type of care were you hoping to get? Why?
- What are you hoping to achieve by taking part? Improved mental health or were there other things you would like to achieve, e.g. improved physical health?
- What exercise, if any, were you doing at the time?
- In what ways did you think exercise might help your depression?
- Did you think it might help in other ways? e.g. meet people, improved physical exercise.
- Do you enjoy exercising?

Diagnosis

- How did you feel when you found out that you had PND and were eligible to take part in the study?
- Did you think you had PND? Prompt surprise, relief, agreement with diagnosis.
- How were you feeling at the time?
- Why do you think you felt like this?
- Had you had depression or PND before?
- What care were you receiving at the time from your GP or health visitor?
- Did you have any other forms of support? (family, friends, clinics, groups)
- Did friends and family know how you were feeling?
- Once diagnosed, did you tell people about your PND? If so, who and how did they respond?

Views on exercise as a treatment for PND

- What do you think about exercise being used as a treatment for PND – do you think it might work? Why/why not?
- Do you see it as having a particular appeal to certain groups of individuals? E.g. active, first time mothers?
- Do you think only certain activities would help? If so, which activities?
- Do you think an effect will depend on the intensity or length of the activity? If so, why?
- What do you see as the pros and cons of exercise as a treatment for PND? E.g. time intense but 'healthy'.
- Have you ever used exercise in order to improve your mental wellbeing? Why/why not?
- What about your health in general? Why/why not?
- Do you think exercise should be used alone or alongside other treatments, e.g. antidepressants?
- Do you think PND can impact on someone's ability to engage with exercise? Why/why not?

Experiences of the trial

- How did you feel when you were allocated to the control arm?
- Was this the arm you wanted? Why/why not?
- Are you exercising anyway? If so:
 - Is this more than you were doing before?
 - What exercise are you doing? Why these activities, how regularly do you do them?
 - How do you feel at the time of exercise?
 - How do you feel afterwards?
 - How do you think exercise has affected your mental wellbeing?
 - If done a range of activities
 - Which activities did you enjoy the most?
 - Which activities did you feel had the most impact on your mental health? Why?
 - Where there any you did not enjoy? Why?
 - Where they any you felt had a negative impact on your wellbeing? Why?
 - What situations make it difficult for you to exercise?
 - Are there issues that affect you engaging in physical activity? E.g cost, facilities, time, feeling safe, feeling low?
 - What helps/motivates you to engage in exercise? E.g. feeling less depressed, friend's encouragement?
- Have you told family/friends that you are taking part in Pampers? If so, what was their reaction? Have they encouraged/discouraged you in any way?

Other treatment received

- During the trial, what other treatment have you received?
- What contact have you had with your GP and your health visitor?

Final questions

- How are you feeling now? What do you contribute this to?
- What exercise do you hope to do/maintain for the rest of the trial?
- What factors do you think will help you maintain the changes you have made?
- What will prevent you?
- Are you glad you are taking part in the study?
- Have the questionnaires been ok to complete?
- Are there any ways you think the trial could be improved?
- Is there anything else you would like to say about PND, your experiences of a particular treatment, views on treatments available and/or the trial?

Appendix Figure 41: Search strategy for Medline

1. Exercise
2. Exercise.tw
3. Physical activity
4. Physical activity.tw
5. Activity
6. Activity.tw
7. 1 OR 2 OR 3 OR 4 OR 5 OR 6
8. Postpartum
9. Postpartum.tw
10. Postnatal
11. Postnatal.tw
12. Mother
13. Mother.tw
14. Birth
15. Birth.tw
16. Perinatal
17. Perinatal.tw
18. 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17
19. 7 AND 18
20. Depression
21. Depression.tw
22. Postnatal depression
23. Postnatal depression.tw
24. Postpartum depression
25. Postpartum depression.tw
26. Anxiety
27. Anxiety.tw
28. Mother and infant bonding
29. Mother and infant bonding. tw
30. Self efficacy
31. Self efficacy.tw
32. Quality of life
33. Quality of life.tw
34. Child development
35. Child development.tw
36. 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31
OR 32 OR 33 OR 34 OR 35
37. 19 AND 36
38. Limit 37 to female
39. Limit 38 to human
40. Remove duplicates from 39

Appendix Figure 42: Related publications

Publications:

Blamey R, Daley A, Jolly K. Exercise for postnatal psychological outcomes: a systematic review and meta-analysis. *The Lancet* 2012; **380**: S25 (abstract).

Daley A, Jolly K, Sharp D, Turner K, Blamey R, Coleman S, McGuinness M, Roalfe A, Jones I, Macarthur C. The effectiveness of exercise as a treatment for postnatal depression: study protocol. *BMC Pregnancy Childbirth* 2012; **12**: 45-52.

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Daley AJ, Blamey RV, Jolly K, Roalfe AK, Turner KM, Coleman S, McGuinness M, Jones I, Sharp D, MacArthur C. A pragmatic randomised controlled trial to evaluate the effectiveness of a facilitated exercise intervention as a treatment for postnatal depression: the PAM-PerS trial. *Psychol Med*.

Oral Presentations:

National School for Primary Care Research. Research Showcase. October 2012.

Royal College of Physicians, London. Exercise and postnatal depression: an RCT.

Poster Presentations:

Public Health Science. November 2012. The Royal Society of Medicine, London.

Exercise for postnatal psychological outcomes: a systematic review and meta-analysis.

UK Society for Behavioural Medicine 8th Annual Scientific Meeting. December 2012.

Manchester. Mothers' views and experiences of exercise as a treatment for postnatal depression.

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11. Da Costa D, Lowensteyn I, Abrahamowicz M, Ionescu-Iltu R, Dritsa M, Rippen N, et al. A randomized clinical trial of exercise to alleviate postpartum depressed mood. *J Psychosom Obstet Gynaecol* 2009; **30**: 191-200.
12. Haruna M, Watanabe E, Matsuzaki M, Ota E, Shiraishi M, Murayama R, et al. The effects of an exercise program on health-related quality of life in postpartum mothers: a randomized controlled trial. *Health* 2013; **5**: 432-9.
13. Armstrong K, Edwards H. The effects of exercise and social support on mothers reporting depressive symptoms: a pilot randomized controlled trial. *Int J Ment Health Nurs* 2003; **12**: 130-8.
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15. Heh SS, Huang LH, Ho SM, Fu YY, Wang LL. Effectiveness of an exercise support program in reducing the severity of postnatal depression in Taiwanese women. *Birth* 2008; **35**: 60-5.
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