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The Concurrent Validity of the Child and Adult Relationship Observation tool (CARO) for Mothers with Additional Health and Social Care Needs

and

**Clinical Research Portfolio** 

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BSc (Hons), MSc

Submitted in part fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology (D.Clin.Psy)

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# **CHAPTER 1: Systematic Review**

A Systematic Review of Psychological Outcomes for Women and their Babies Admitted to a Mother and Baby Unit: an Update on the Evidence 2015-2020

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# **Abstract**

## Background

Mother and baby units (MBUs) provide specialist inpatient care for women who suffer with severe mental illness and their babies in the first year after childbirth. MBUs provide intervention during what is a sensitive developmental period for both mother and infant. Only one previous review (Gilham & Wittowski, 2015) has assessed the psychological outcomes of MBU admission and found positive effects but noted variable methodological quality of the studies, limiting the ability to draw overarching conclusions.

# **Objective**

To update the review published by Gilham and Wittkowski (2015).

## Methods

A systematic search of five databases (PsychInfo, Medline, Embase, Health Information Consortium, and Maternity and Infant Care) from 2<sup>nd</sup> January 2015 to 14<sup>th</sup> February 2020 was conducted and identified 8 papers for inclusion. Studies were reviewed using the Quality Assessment Tool for Studies with Diverse Designs (QATSDD).

### **Results**

Studies were rated as being of moderate or good quality. Consistent with the previous review all studies found positive effects of MBU admission on maternal mental health. However, many of the methodological weaknesses identified in the earlier review

continue to limit the ability to draw strong conclusions about the outcomes for the mother-infant relationship. Only one study reported outcomes relating to child development.

# **Implications for future research**

Future studies should address the methodological weaknesses identified, in order to provide insight into the suitability of interventions being used. Attention should be paid to the long term outcomes following discharge.

## **Introduction**

MBUs provide specialist inpatient assessment and care for both women with a mental illness in late pregnancy, and women and their babies up to twelve months postnatally About 1 in 5 women are affected by mental illness in the year following childbirth (Jones et al., 2014) with 1/1000 requiring inpatient admission (Gilham & Wittkowski, 2015).

MBUs were first introduced in the UK in 1948 following the pioneering work of Thomas Main who observed that separating infants from their mothers during the first year of life due to maternal illness posed a risk to the developing attachment between mother and child (Chandra et al., 2015). MBU admission is reserved for mothers with the most severe mental health issues, where there is a high risk to the mother and/or the child. Affective disorders and psychosis are two of the most common presentations (Gilham & Wittkowski, 2015).

Maternal illness is the leading cause of death in the first postpartum year (Cantwell et al., 2018) and the relationship between maternal illness and poor developmental outcomes for children is well recognised (Goodman et al., 2011). There is increasing evidence that the mother-infant relationship is an important mediator in the transmission of risk from mother to infant (Stein et al., 2014) and therefore should be monitored (Scottish Government, 2019). Attachment theory is widely cited in literature in order to explain possible risks to the mother-infant relationship. However, newer integrated models have been proposed which incorporate parenting (most commonly explained by attachment theory) and other factors such as exposure to negative maternal cognitions, paternal mental health status and individual child characteristics (Goodman & Gotlib, 1999).

Both psychological and pharmacological interventions are recommended for perinatal mental illness by the National Institute for Health and Care Excellence (NICE; 2014) and the Scottish Intercollegiate Guideline Network (SIGN; 2012). Interventions which specifically target the mother-infant relationship are recommended, as there is increasing evidence that treating the mother's symptoms do not necessarily result in any improvement in the mother-infant relationship or buffer the risks to infant development (Murray et al., 2010; Forman et al., 2007). However, which specific interventions should be available is not indicated, due to a lack of available evidence specific to an MBU setting (Wittkowski et al., 2018).

Despite the identified role that MBUs play in treating maternal mental illness and encouraging both positive mother-infant relationships and positive developmental outcomes for infants, only one systematic review has focused on evaluating psychological outcomes. Gilham and Wittkowski (2015) identified 23 studies and found positive effects for both maternal mental health and the mother-infant relationship and an absence of adverse effects on child development. However, the authors identified that the included studies were of a varying quality, limiting the ability to draw overarching conclusions. They did not identify any randomised trials but they noted that this was unsurprising, considering the urgent care MBUs provide. Most studies used cohort designs and the few that included a control had substantially different diagnoses from the intervention group. Other limitations included small sample sizes, no follow-up period, a lack of detailed information about the setting (including size, staffing and intervention approaches limiting the ability to draw comparisons between units), a lack of reporting of sociodemographic details, and a diversity of measures, not all of which were validated to assess change over the course of an admission.

#### Aim

The aim is to update the review by Gilham and Wittkowski (2015) to establish whether more recent literature has addressed these limitations.

# **Research Questions**

- (1) How does MBU admission affect psychological outcomes for maternal mental health, the mother-infant relationship and child health and development?
- (2) What are the commonly used outcome measures?
- (3) Have recent studies strengthened their research designs?

## Methods

As this study updates an existing review, the search strategy, inclusion criteria and exclusion criteria and the quality assessment tool were those used by Gilham and Wittkowski (2015).

## **Search Strategy**

A systematic electronic search of the following databases was conducted:

PsychInfo, Medline, Embase, Health Management Information Consortium, and Maternity and Infant Care.

The following search terms were used to describe the <u>population of interest</u> and were combined using OR:

"mother and baby unit\$", "mother-baby unit\$", "Post-natal mental health\$", mother-baby psychiat\$", mother-infant unit\$", "postpartum depressi\$", "postpartum psychosis\$", "perinatal Psychia\$", "post-partum Psychai\$".

The following terms were used to describe the outcomes of interest and were combined

using OR:

"outcomes\$", "maternal clinical outcome\$", "parenting outcome\$", "attachment\$",

"bond\$", "mother-infant interaction\$".

Population terms were combined with outcome terms using AND.

The search range was January 2, 2015 (the end date of the Gilham and Wittkowski (2015)

review) to 14th February 2020. Searches of reference lists of included articles, and citation

searches were carried out on included papers.

**Inclusion criteria** 

1) English language, 2) published in a peer-reviewed journal, 3) reporting outcomes

relating to women admitted to a psychiatric MBU, 4) assessing maternal well-being, the

mother-infant relationship, child development, or another psychological outcome, and 5)

including assessment of change over time or functioning at discharge.

**Exclusion Criteria** 

Reviews looking only at relapse rates.

**Search results** 

Eight papers were identified for inclusion in this review (see Figure 1).

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# **PRISMA 2009 Flow Diagram**

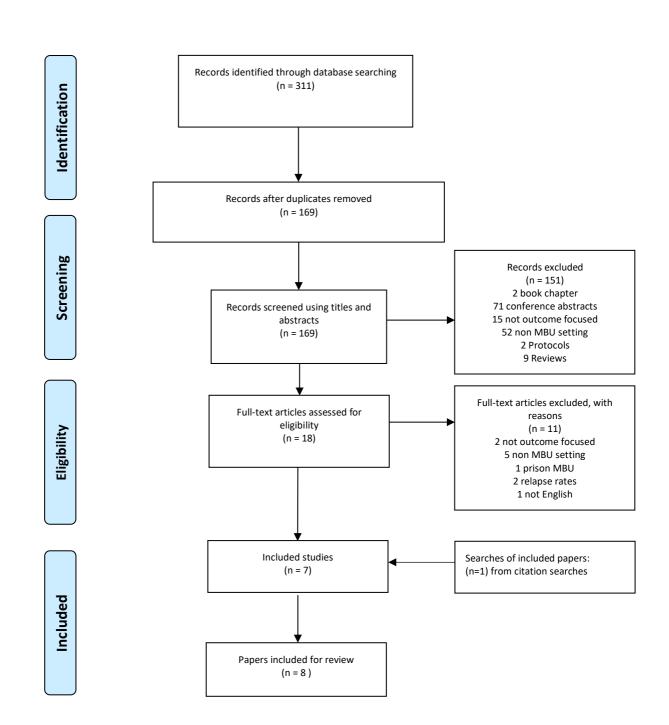


Figure 1: PRISMA flow chart demonstrating literature-review procedure.

## **Quality Assessment tool**

The Quality Assessment Tool for Studies with Diverse Designs (QATSDD; Sirriyeh et al., 2012) was chosen by Gilham and Wittkowski (2015) because the methodologies in the included studies were diverse.

The tool comprises 16 items, each scored from 0 "not at all" to 3"complete" (see Appendix 1.2) covering theoretical approach, research setting, data collection, and method of analysis. 14 of the items apply to qualitative studies, and 14 apply to quantitative studies, but all 16 items are applicable where mixed methods have been employed. The QATSDD has good face validity, good inter-rater reliability between researchers and substantial to good rest-retest reliability (Sirriyeh et al., 2012). Consistent with Gilham and Wittkowski (2015) percentage scores were reported and calculated using the actual score and the maximum total score (42). Papers scoring over 75% were considered "high" quality, those between 50 and 75% "good", those between 25-50 "moderate" and below 25% "poor". The first author was the primary reviewer with each paper being independently rated by one other reviewer (one of the two study supervisors) and any discrepancies were resolved through discussion. Interrater reliability was moderate ( $\kappa$  =0.5).

Effect sizes were calculated by dividing z-values or t-values by  $\sqrt{N}$ . For z-values N is the number of observations (the number of cases  $\times 2$ ). Using Cohen's (1988) criteria r, 0.1 to 0.3= small effect; 0.3 to 0.5= moderate effect; 0.5 and higher=strong effect.

# **Results**

### **MBU** characteristics

The unit sizes ranged from 3 to 13 beds with one study (3) in a day care setting. Four of the eight MBUs were in Australia (see table 1), two of which (2,6) were set at the same private unit where all admissions are voluntary and require private health insurance.

One unit admitted mothers of infants up to the age of three (2) diverging from the more common admission criteria of under one year. Two units (2,6) encouraged fathers by permitting them to stay at the unit for at least one night.

Four studies (2, 6, 7, 8) did not specify the composition of their staff team.

Seven studies (1-7) specified the interventions they had used. Pharmacological and psychological approaches were used to target problems of maternal mental health. Various approaches, and in some cases combined approaches, were used to target the mother-infant relationship.

The average length of stay ranged from 15-34 days with one exception; a UK MBU (4) where the median stay was 60 days (range 1-209 days).

## **Characteristics of participants**

For most studies, depression, was the most common primary diagnosis; exceptions were study 1, where psychosis was more common primary diagnosis.

Most women were admitted 3-4 months postnatally. The level of detail provided, regarding other participant descriptors, varied widely (see table 1).

### **Characteristics of studies**

All papers assessed change in maternal mental health over the course of the admission. Seven included mother-infant outcomes (1-7), with six (1,2,3,4,6,7,8) of these assessing change during admission and one (5) assessing functioning at discharge only (Table 1). All studies used cohort designs without a control group. Study 5 made reference to a comparison group for particular outcomes. Only one study (6) included a follow-up period (about 15 weeks).

# **QATSDD Quality ratings**

Scores ranged from 26% to 62%, with a mean of 40% (Table 2 & Appendix1.3). Four papers (1,3,6,8) scored in the 'moderate' category for quality and four (2,4,5,7,) in the 'good' category.

No study conducted an a priori power calculation. Few provided sufficient information about data collection to allow the study to be replicated. Four studies (2,3,6,8) received a low rating for 'sample representativeness' because of low recruitment rates (2,3), high attrition rates by (6,8), and insufficient comparison between those recruited and not recruited or those who completing measures at both time points and those who did not (3,8). Lastly, the two private MBUs (2,6) are unlikely to be representative of the majority of public funded units. Study 2 was unusual as the unit accepted women up to three years postnatally (2).

Studies were rated low on 'fit between research question and method of analysis' if they did not report descriptive statistics, did not provide the test statistic (table 3) or did not report on the distribution of the data. Study 6 was given a low rating as they chose to apply a group based latent class modelling approach despite the small size. Study 7 was also given a low rating as it performed 12 t-tests comparing change in psychopathology over the course of admission for 12 different self-reported personality styles increasing the chances of type 1 error.

More variation in ratings was observed between studies for the item "fit between research question and method of data collection" due to the wide variation in outcome measures used and their varying validity and reliability.

### **Outcome measures**

A summary of outcomes and the measures used to derive them can be found in Table 2. Descriptive statistics and effect sizes for individual outcomes for each study are provided in Table 3.

### Maternal mental health measures

#### Clinician rated

Clinician rated tools were used by two studies (4,5). Health of the Nation Outcome Scales (HoNOS), the Marce checklist and the Global Assessment of Functioning (GAF) are global measures of mental health outcome. The Brief Psychiatric Rating Scale (BPRS) is a specific measure of severe mental illness in those with psychosis. All of the scales were completed at admission and discharge, apart from the Marce checklist that was completed

at discharge only, consistent with its use which is to provide a general indication of improvement (Appleby & Friedman, 1996).

## Self-report

Self-report measures were used by five (2,3,6,7,8) studies. One study (7) used a global rating of distress and psychological symptoms. The remainder assessed specific outcomes with four studies assessing depression (2,3,6,8), two anxiety (3,6), one stress (1), one personality disorder (3) and one study assessed improvements in mental health quality of life (2).

## **Summary of maternal mental outcomes**

Independent of the type of outcome measure (clinician reported or self-report, or global or specific) statistically significant improvements were reported following MBU admission, with the exception of study 8 which did not conduct inferential statistics but noted a clinically significant reduction in symptomology in the majority of the sample. Three studies reported that women's symptomology remained in the clinical range at discharge (2, 6, 8). Effect sizes could be calculated for four studies (2,3,4,5). Effect sizes were large for clinician reported outcomes (study 4 & 5). Effect sizes ranged from moderate to large for self-reported depression (study 2,3) and small to large for the other self-reported outcomes.

## Measures of the mother-infant relationship

Seven studies included a measure to assess change in the mother-infant relationship (1-7).

#### Observational measures

Three studies (1,4,5) used observational ratings but with different rating scales. The Parent-Infant Relationship Global Assessment Scale (PIR-GAS) provides a global rating of parent-infant relationships on a 100 point scale. Study 1 reported using an Objective Bonding Instrument providing no other details about the instrument. The Crittenden CARE-Index is a measure of mother-infant interaction. It assesses dyadic interactional patterns and synchrony, that is the 'fit' between caregiver and infant.

# Self-report

Five studies (1,2,3,6,7,) used self-report questionnaires (the Postnatal Bonding Questionnaire (PBQ) or the Maternal Postnatal Attachment Scale (MPAS)).

Although designed to measure the same phenomenon, the (PBQ) and the (MPAS) differ significantly in content, design and terminology (one uses bonding to describe the emotional response of mother to baby whereas the other uses attachment). An example item on the MPAS scale is "When I am caring for my baby I get feelings of annoyance or irritation". An example item on the PBQ is "My baby makes me feel anxious".

## Parenting confidence

Two studies (2,6) used the Karitane Parenting Confidence Scale (KPCS) which has acceptable correlations with other measures of perceived parenting self-efficacy (Crncec et., 2008)

## **Summary of mother-infant relationship outcomes**

### **Observational**

The only study which used a validated tool (CARE-index), sensitive to change following intervention (Crittenden, 2004; Kenny et al., 2013), found statistically significant improvements in mother-infant interactions over the course of an admission. The effect size was moderate and the mean maternal sensitivity score at discharge only just fell into the clinical range. Study 1 reported positive outcomes but provided little information regarding the scale used and did not analyse by means of inferential statistics. Less favourable results were reported by study 5 (see Table 1) which used the PIR-GAS. However, the PIR-GAS was only applied at discharge and did not assess change over the admission. It relies on a clinician's individual judgement and is not a standardised tool (Thompson et al., 2019).

## Self-report

Studies using self-report tools to assess outcomes found a significant improvement in attachment scores with effect sizes ranging from small to moderate. Study 7 reported all women to be scoring below the clinical cut off on the PBS (indicative of no bonding disorder) at discharge. However, study 2 did not find scores improved to the levels typically found in community samples.

Parenting confidence significantly improved in both studies.

## Child development

Only one study (5) considered the development outcomes of children at discharge. The study employed one of the most widely used self-reported screening tools (ASQ) which

revealed developmental concerns far greater than what is found in an age matched population.

Table 1 Settings of studies included in review, interventions and reported demographic characteristics (In chronological order)

Author Paper number	Location	Unit size	Setting	Staff	Intervention	Mean maternal (M) and infant (I) age at admission (years, weeks respectively)	Length Of Stay (days)	Education/	Marital status	Primiparous	Ethnicity
1. Chandra et al., (2015)	Bengaluru, India	5 beds	MBU -mothers admitted with a family member (usually female) in keeping with local traditions to increase social support.	Psychiatrists, social workers, nurses, psychology & social work trainees, lactation experts & paediatric support	Education on mother-infant bonding, specific interventions for impaired mother-infant bonding (including video interventions). Sessions held for caregivers and spouses to reduce caregiver burden & relapse prevention strategies	M: 24.25, s.d. 4.27 I: 54% <8 weeks 37% 8wks-6 months 8% 6 months and 1 year	Mean: 17.23, s.d. 14.56 80% staying 3/4wks	Mean years of education 6.50, s.d.3.02	*	40%	*
2. Christl et al., (2015)	Sydney, Australia	10 beds	MBU - all admissions are voluntary and require private health insurance -more severely ill mothers requiring involuntary admission cared for in the public	*	Skills based group underpinned by DBT and CBT, attachment based groups, anxiety management, mindfulness, mothercraft groups, art and music therapy, medication, ECT approx. 10% cases, Support provided to mother and their partners with fathers being encouraged to stay overnight once a week.	M: 33.5, s.d. 4.8 I: 13.91, s.d.12.60	Mean: 22, s.d. 12.1 only recruited those who stayed >1 day.	*	96.6% Married/ de facto 2.6% Single/ never married/ separated 0.5% Unknown/not stated.	56%	*
3. Yellend et al., (2015)	Adelaide, Australia	6 beds	health system. MBU -admits women and their infants up to age of three years.	Psychiatric, nursing and allied health staff	Individual, group &mother-infant psychotherapy,,medication and ECT	M: 29.95, s.d.6.45 I: 34 s.d.24.57	Mean 22.34, s.d. 16.73	*	*	*	*

Author Paper number	Location	Unit size	Setting	Staff	Intervention	Mean maternal (M) and infant (I) age at admission (years, weeks respectively)	Length Of Stay (days)	Education/	Marital status	Primiparous	Ethnicity
4. Stephens on et al., (2018)	London, UK	13 beds	MBU	Psychiatrist, mental health nurses, developmental psychologist, nursery nurses	Antenatal/Postnatal care plans, medication, intensive mental health nursing, OT, assistance with social needs, psychological therapies including 2 sessions video feedback from developmental psychologist or nursery nurse	M: 30.9, s.d. 5.9 I: 14.14, s.d.13.19	Median 60 Range (1-209)	*	Married /Civil partner 45.9% Single 39% Cohabiting 9.4% Separated 4% Not known 1.9% Not disclosed 1.3%		White 49.7% Black 27.7 % Asian 11.3% Mixed 2.5 % Other 5.7% Missing 3.1%
5. Wright et al., (2018)	Auckland, New Zealand	3 bed	MBU -family inclusive (partners encouraged to stay at night)	Psychiatrist trained in infant mental health Nursing staff to provide practical support and advice on infant care	Medication, Electroconvulsive therapy, CBT, ACT, Mindfulness, VIG, Psychodynamic approaches based on maternal representations. Family inclusive, Key tenet to primacy of the mother in deciding the caregiving approach for her baby	M: 32.4, s.d. 5.93 I: 15.8, s.d. 14.43	Mean: 23.89, s.d. 13.1 (Only recruited stayed >4 days.	22.2% Fifth Form/NCE A1 (any credits) or below Sixth/ Seventh Form/NCE A 2-3 (any credits) Any Higher Education 53.3%	82.2% Living with Partner/ Father of Baby	62.2%	New Zealand European 60% Maori 20% Pacific Island 11.1% Asian 8.1% Indian 0%
6. Reilly et al ., (2019)	Sydney, Australia	12 beds	MBU - all admissions are voluntary and require private health insurance -more severely ill mothers requiring involuntary admission cared for in the public health system.	*	Skills based group underpinned by DBT and CBT, attachment based groups, anxiety management, mindfulness, mothercraft groups, art and music therapy, Support provided to mother and their partners.	M: 31, s.d. 5.2 I: 15.2 s.d. 15.09	Mean 25.35 s.d. 12.45	*	Married/De facto 97.3 Separated/ Divorced 1.30% Single 1.30%	61.3%	*

Author Paper number	Location	Unit size	Setting	Staff	Intervention	Mean maternal (M) and infant (I) age at admission (years, weeks respectively)	Length Of Stay (days)	Education/	Marital status	Primiparous	Ethnicity
7. Bittner et al ., (2020)	Dresden, Germany	N/A day care setting??	MBU -offering a day care setting		Video intervention therapy, CBT, family therapy, group psychotherapy, medical treatment, baby massage, childcare/parenting counselling, relaxation therapy, body therapy and 68.4% received medication.	M: 31, s.d. 5.2 I: 24, s.d. 13	Median 34 Range (14- 59)	4% No graduation 11% 9 <sup>th</sup> grade 46% 10 <sup>th</sup> grade 58% university entrance qualificatio n 4% n/a	83% in a relationship 30% of the above married. 12% not in a relationship 5% other	*	*
8. Wang et al., (2019)	Victoria, Australia	*	MBU	*	*	M: 30, s.d. 6 I: 14.35, s.d. 12.17	Mean: 31 s.d. 23	Highest educational attainment: 22% secondary 30% tertiary 2% Vocational 46% did not respond to education screening question.	75% Married/ de facto 7.5% Separated/ divorced 10.7% Never married 7.2% Unknown	*	*

Notes: \*Information not provided.

Abbreviations: MBU, Mother and Baby Unit; OT, Occupational Therapist; CBT, Cognitive Behavioural Therapy; ACT, Acceptance and Commitment therapy; VIG, Video Interaction Guidance; DBT, Dialectical Behaviour Therapy; s.d., standard deviation;

 Table 2 Designs and outcomes of included studies

-Paper -Title	Diagnosis	-N(% those admitted) - study period	Design Control/ Cohort	Maternal Outcomes	M-I Outcomes	Infant Outcomes	Time of measurement	Quality rating	Summary of outcomes
1	14% Depression 7% OCD or PD	Maternal outcome	Cohort	Unclear	PBQ^	N	A&D	29%	80% mothers noted to have improved completely at discharge
The establishment of a mother-baby inpatient unit in India: Adaptation of a Western model to meet local cultural and resource needs.	36.2% Bipolar 34.5% Acute and transient Psychosis 6% Schizophrenia 7% Severe OCD, dissociative and personality disorders	N= 237 (100) M-I-R N= 94.8(40) 48 months			Unknown Bonding Instrument ~			Moderate	Based on admission scores specific interventions for the M-I-R were offered in 40% of mothers. 89.7% had ratings on the scales indicative of normal bonding at discharge. The remaining mothers required close supervision at discharge.
Clinical profile and outcomes of women admitted to a psychiatric mother-baby unit	disorders 42.9% Unipolar depression (Severe) 9.4% Unipolar depression (Mild/moderate) 25.7% Anxiety 4.7% PD 8.9% Bipolar Disorder 6.3 % Acute Psychotic disorder 2% Schizophrenia 1% Mental illness due to substance misuse 1% No diagnosis	months EPDS N= 191 (52) SF-14 N=153 MPAS N= 191 KPCS N=191 43 months	Cohort	PNRQ^ EPDS^ SF-14^	MPAS ^ KPCS ^	N	A&D	52% Good	Significant improvement in all measures from admission to discharge.  EPDS  73% recovered .Improvement associated with increasing maternal age and lower levels of psychosocial risk. (Trauma history)  KPCS  Only 20.3% scoring in clinical range at follow-up whereas MPAS scores did not improve to levels found in the community. MPAS unrelated to Trauma history.

-Paper -Title	Diagnosis	-N(% those admitted) - study period	Design Control/ Cohort	Maternal Outcomes	M-I Outcomes	Infant Outcomes	Time of measurement	Quality rating	Summary of outcomes
Clinical characteristics and mental health outcomes for women admitted to an Australian Mother-Baby Unit: a focus on borderline personality disorder and emotional dysregulation	46.2% Major depressive order 10.3% Psychotic disorders 3.4% Bipolar Disorders 12.8% BPD	EPDS N= 34 (29)  BAS N= 36  MSI- BPD N=34  MPAS N=27	Cohort	EPDS^ BAS^ MSI-BPD^	MPAS^	N	A&D	29% Moderate	Significant improvement on maternal depression, anxiety, mother-infant relationship and self-reported BPD symptoms which fell from 46.6% to 38.9%.
Mother and Baby Units matter: Improved outcomes for both	50.3 % Depression 22.0% Mania 12.6% Anxiety/OCD 10.7% Schizophrenia 4.4% No current psychiatric symptoms	BPRS N= 151 (87.7) HoNOs N= 113 CCI N= 62 29 months	Cohort	BPRS~ HoNOs~	CCI~	N	A&D	64% Good	Significant improvement in total and subscale scores for BPRS and HoNOs scales except for HoNOs subscale living conditions. All results irrespective of diagnosis. Mothers significantly more sensitive towards their infants at discharge. 15% of mother-infant dyads did not show improvement in mother-infant interaction  Improvements in HoNOS total scores and (including improved mood) associated with improvements in mother-infant interaction. BPRS scores and diagnosis unrelated.

-Paper -Title	Diagnosis	-N(% those admitted) - study period	Design Control/ Cohort	Maternal Outcomes	M-I Outcomes	Infant Outcomes	Time of measurement	Quality rating	Summary of outcomes
Mothers and their infants co-admitted to a newly developed mother-baby unit: characteristics and outcomes	-45 dyads24.4% Schizophrenia/ Nonaffective Psychosis 15.6% Bipolar Disorder 34.7% Depression(with or without Psychotic features) 11.1% Primary Anxiety Disorder (Including OCD) 4.4% Borderline Personality Disorder	45 dyads for all measures (86.7) 18 months	Cohort	HoNOS~ GAF~ Marce Clinical Checklist ~	PIR-GAS~	DC:0-3R~ ASQ-3^	A&D D only for mother-infant relationship and infant outcomes	50% Good	Marce Clinical Checklist:  13.3 % symptom free 68.9% Considerably better, symptoms persist 15.6% Slightly improved 2.2% No change or worse  Statistically significant improvement in GAF, HoNOS, from admission to discharge 51.1% GAF score that would indicate adequate ability to provide care to the infant at discharge.  PIR-GAS Adapted relationship 2.5% Features of a disordered relationship 66.7% Disordered relationship 28.9%  DC:0-3R Any diagnosis found in 51.1% Age-matched population based US study 8.5%  ASQ-3  Problem identified in 51.4% Age-matched population based US study 13%

-Paper -Title	Diagnosis	-N(% those admitted) - study period	Design Control/ Cohort	Maternal Outcomes	M-I Outcomes	Infant Outcomes	Time of measurement	Quality rating	Summary of outcomes
6	-76% Mood disorder	N=75 all measures	Cohort	EPDS^ DASS-	KPCS^ MPAS^	N	A&D & 15 months after	43% Moderate	Depression and anxiety disorders were associated with a mean PIS-GAS of 19.37 (SE=8.92) higher than the mean score for psychotic illnesses and bipolar disorder.  Analysed using: Group based latent class modelling
Trajectories of clinical and parenting outcomes following an admission to an inpatient mother-baby unit.	16% Anxiety 8.0% Puerperal psychosis	(17) 50 al months		21(stress)^ DASS-21 (anxiety)^ KPCS^	MAIS		discharge		Depression, anxiety, stress, and maternal attachment scores reduced for all groups at discharge. Not all groups maintained improvement apart from for anxiety. 93.3% followed trajectories that were characterised by deterioration in maternal attachment after discharge.
									Improvement in parenting confidence was observed and maintained for most women. However, those with very low scores did not show improvements
									Anxious and avoidant attachment styles were associated with high anxiety, lower parental confidence and lower quality of attachment.
									Older women were less likely to have maintained improvement in depression scores post-discharge.

-Paper -Title	Diagnosis	-N(% those admitted) - study period	Design Control/ Cohort	Maternal Outcomes	M-I Outcomes	Infant Outcomes	Time of measurement	Quality rating	Summary of outcomes
									Psychosocial risk was a significant predictor of trajectories for anxiety
Maladaptive personality styles in a clinical sample of women with postpartum depression	-100% Depression	N= 123 ( 82.6% of those meeting inclusion criteria) 96 months	Cohort	PSSI^ BSI^ PSOC^	PBQ^	N	A&D	52% Good	Maladaptive personality styles were frequent. Statistically significant improvements on psychopathology (BSI), bonding and parenting with those with maladaptive personality styles exhibiting a higher decrease of psychopathology. Mothers with maladaptive personality styles still had higher psychopathology(remaining in the clinical range) and impaired motherchild bonding( although this was below clinical cut off of 26) at discharge compared to mothers with non-clinical PSSI.

-Paper -Title	Diagnosis	-N(% those admitted) - study period	Design Control/ Cohort	Maternal Outcomes	M-I Outcomes	Infant Outcomes	Time of measurement	Quality rating	Summary of outcomes
8	40% Unipolar	N=125 (40.7)	Cohort	BDI^	N	N	A&D	26%	Clinically significant reduction in depression scores.
A retrospective	depression	(1011)						Moderate	
audit of joint	13.3%								However, of the respondents 23%
mother-baby	GAD or anxiety	53							continued to report depressive symptoms
admissions to the	NOS	months							in the moderate to severe category at
Werribee Mercy	10%								discharge.
mother and baby	Postpartum								
unit (MBU) and	psychosis								
of the severity of	9.5%								
maternal	BPD								
depression over									
the course of									
admission.									

Abbreviations: ^, self-report; ~, Observer; N, not assessed; D, discharge only; A&D, Admission and Discharge; OCD, Obsessive Compulsive Disorder; PD, Personality Disorder; BPD, Borderline Personality Disorder; M-I-R, Mother-Infant Relationship; EPDS, Edinburgh Postnatal Depression Scale; SF-14, Quality of Life measure; MPAS, Maternal Postnatal Attachment Scale; KPCS, Karitane Parenting Confidence Scale; BAS, Beck Anxiety Scale; MSI-BPD, McLean Screening Instrument for Borderline Personality Disorder; BPRS, Brief Psychiatric Rating Scale; HoNOS, Health of the Nation Outcome Scales; GAF, Global Assessment of Functioning; PNRQ, Postnatal Risk Questionnaire, DASS, Depression, Anxiety and Stress Scale; PSSI, Personality Style and Disorder Inventory; BSI, Brief Symptom Inventory; PBQ, Postpartum Bonding Questionnaire; PSOC, Parenting Sense of competence scale; BDI, Beck Depression Inventory, PBQ, Postpartum bonding questionnaire; CCI, Crittenden CARE-Index; PIR-GAS Parent-Infant Relationship Global Assessment Scale.

Table 3 Means, standard deviations, and effect sizes for maternal and mother-infant relationship outcomes

Paper	Maternal outcome	Mean/Median Admission SD	Mean/ Median Discharge SD	Test statistic	P-value	Effect size d r	M-I outcome	Mean/ median Admission	Mean/ median Discharge	Test Statistic	P-value	Effect size
1	Not explained	*	*	*	*	Unable to derive	PBQ	*	*	*	*	Unable to derive
	explained					derive	Objective Bonding Instrument	*	*	*	*	Unable to derive
2	EPDS	M= 19.28 SD 5.32	M=8.83 SD 4.47	Z=-11.67	P<0.001	r=0.63	MPAS	M=64.04 SD 14.74	M=76.15 SD9.63	Z=-10.45	P<0.001	r=0.49
	SF-14	M= 28.5 SD 17.2	M= 66.5 SD 16.7	Z=-9.61	P<0.001	r=0.55	KPCS	M= 32.51 SD 7.40	M=39.14 SD4.26	Z=-9.61	P<0.001	r=0.53
3	EPDS	*	*	t=5.92	P<0.001	r=0.44	MPAS	*	*	t=2.95	P=0.006	r=0.25
	BAS	*	*	t=5.06	P<0.001	r=0.39						
	MSI-	*	*	t = 2.88	P=0.007	r=0.25						
	BPD											
4	BPRS	Med= 49.5 SD= *	Med=24 SD=*	Z=10.54	P<0.001	r=0.60	CCI (Maternal Sensitivity)	M=6.92 SD= 2.80	M=5.03 SD=2.29	Z=-4.27	P<0.001	r=0.38
	HoNOs	M=14.05 SD= 5.30	M=5 SD=4.83	t=17.51	P<0.001	r=0.64	•					
5	GAF	Med=35 Range 10-65	Med 65 Range 35-80	Z=5.85	P=0.0005	r=0.62						
	HoNOS	Mdn= 13 Range 5-29	Mdn= 5.0 Range 0-28	Z=4.77	P=0.0005	r=0.50						
6	Means and	p values not provide		vhole due to stu	ıdy analysis							
7		erence not provided for				a whole or for	those without perso	onality styles				
8	BDI-II	Mean =28 SD 13.71	Mean=12 SD 10.18	*	P=<0.001	Unable to derive without correlatio n co- efficient	Not assessed	*	*	*	*	Unable to derive

## **Discussion**

Eight papers were identified for inclusion since the last review in 2015. Consistent with Gilham and Wittkowski (2015), all studies reported positive outcomes for both maternal mental health and the mother-infant relationship following admission to an MBU. Two studies (1&8) did not conduct inferential statistics but noted clinically significant improvement in line with clinical guidelines for the majority of the sample. The remaining studies detected statistically significant change. Four studies did not supply sufficient information needed to calculate effect sizes.

Gilham and Wittkowski (2015) identified a number of weaknesses in the research, limiting the interpretation of the results some of which persists in current studies including: a lack of control groups and long term follow-ups; in some cases insufficient reporting of sociodemographic data, the use of a diverse range of outcome measures with few studies using validated measures of the mother-infant relationship.

In the current review, none of the studies included a control group, but a reference group comparison was provided for child outcomes in one study. Interventions were suitably described in most studies, but staff composition was not. Reporting on sociodemographic factors, known to influence outcome such as perceived social support, parity and education remains unsatisfactory.

Only one study included a follow-up period (15 months) with most women showing an increase in stress and depression scores and a deterioration in the mother-infant relationship, although this was self-reported as opposed to being objectively assessed.

Only 55 percent of mothers agreed to follow-up calling into question the generalisability of the results.

Gilham reported positive outcomes for child development at discharge. Since then, the only study reporting on this, identified problems in 50% of the sample.

The current review noted low recruitment rates as an issue. Adequate information regarding the reasons for low recruitment rates were not provided by all studies and not all studies conducted adequate statistical comparisons to ensure the representativeness of their sample. Two of the included studies were conducted at MBUs which required private health insurance limiting the generalisability of these studies to publicly funded units.

The majority of studies monitored outcomes by means of self-report in spite of clinician rated tools being considered the gold standard and self-reported tools of the mother-infant relationship having a low correlation with observational measures (Alderfer et al., 2008; Noorlander et al., 2008). Depressive symptomology remains the most commonly assessed outcome despite the research being inconclusive with regard to differences in the quality of mother-infant interaction between diagnostic groups (Pawlby et al., 2010; Healy et al., 2016). Only one of the included studies used a measure of mother-infant interaction (CCI; a video-observational tool) that is validated as being sensitive to change following intervention for those with severe mental illness (Crittenden, 2004; Kenny et al., 2013). There was an improvement for the majority of mother-infant dyads. However, only 40% of mothers admitted took part in the video based intervention and the study did not assess

differences in symptomology between those who did and did not choose to participate limiting the ability to generalise this result to all mothers admitted to an MBU.

### Limitations of this review

Some criteria on the QATSDD tool were difficult to operationalize making consistency in scoring papers difficult. Furthermore, this reduced certainty that scoring was consistent with the previous review. It was noted that in some cases individual criteria encompassed many different aspects of study design which made the application of an overall score to a particular item difficult. In addition, the tool gave equal weighting to each criteria which led to particular studies being rated as high in quality, despite key methodological weaknesses being identified because they provided, for example, a clear theoretical rationale and clearly defined their aims. Although it is recognised such items are important they are not as integral as other items of study design. Although initial investigation suggests the QATSDD has good face validity and good test-retest reliability, it still has to be assessed in a large-scale validation study (Sirriyeh et al., 2011).

### **Recommendations for future research**

With regard to the recruitment process, future studies should supply more detailed information and comment on the reasons behind low recruitment rates. Studies should report on sociodemographic and clinical factors (including co-morbid diagnoses) known to influence outcome. Changes to routine care or staffing during the recruitment period should be recorded.

Studies should consider the advantages and disadvantages of various approaches to assessing outcome. Clinician rated tools of maternal mental health are considered the

'gold standard' however, self-report tools benefit from putting less pressure on clinicians' time. Sample size is likely to be larger for studies that make use of clinician-rated routine outcome measures (CROMS), particularly for mothers with severe mental illness who may initially lack capacity to consent and whose motivation to participate may be reduced. In addition, many CROMS chosen for MBUs are valid, reliable, sensitive to change and strengths-based (i.e. they focus on changes in functioning in addition to changes in symptom symptomology) (Burgess et al., 2017). However, with regards to the maternal-infant relationship, coding of the CCI is complex, requires extensive training to become reliable and cannot be done in real time.

In this review only three studies reported on associations between maternal and infant outcomes. Future studies should report on such associations in order that the intergenerational transmission of risk to children can be further investigated.

Studies should pay more attention to the long term outcomes of MBU admission and consider the most acceptable way of collecting this information.

It is difficult to define the ideal control group in which to compare outcomes following MBU admission. The possible options identified would either result in there being fundamental differences between the groups at baseline, and/or key ethical issues requiring careful consideration. Possible options include using mothers from community or inpatient settings. However, mothers admitted to MBUs differ from mothers being treated in the community with regards to the severity of their symptomology. Mothers admitted to MBUs differ from mothers being treated in general psychiatric wards with regards to diagnoses and sociodemographic profile, with those mothers admitted to

MBUs being less likely to come from deprived areas (Martin et al., 2017). Furthermore, it would not be possible to measure outcomes of the mother-infant relationship in other inpatient settings, as mothers are often admitted without their babies. In conclusion, a controlled trial is perhaps not the best paradigm for exploring outcomes following MBU admission.

However, controlled trials currently being undertaken to assess the effectiveness of specific parenting interventions are welcomed (the IMAGINE study; Wittkowski et al., 2018). It is noteworthy that only four of the included MBUs used video feedback interventions despite increasing recognition of their effectiveness in an MBU setting (O'Hara, 2019).

In future reviews, researchers could consider using a different tool, such as the Crowe Critical Appraisal Tool (CCAT), to assess quality for the reasons previously identified. However, it is noted that both the QATSDD and the CCAT tools have their own set of advantages and disadvantages. When using the QATSDD, researchers could consider the use of a weighted Cohen's kappa, as in the current research it was noted that the procedure involved in calculating interrater reliability led to a different qualitative descriptor being applied to some studies, despite in some cases, studies only differing by a few points on the QATSDD tool.

## **Recommendations for clinical practice**

The routine collection of generic outcome data as advised in clinical guidelines and reviews (NICE, 2014; Royal College of Psychiatrists, 2018) should be implemented. This will help to compare outcomes across MBUs. Staff should also consider specific outcome measures in accordance with diagnostic profiles. Monitoring outcomes for different

constructs may prove the most informative. Increasing a mother's confidence to care for her infant is one of the main goals for MBU admission but improvements are not always reflected in the outcomes for the mother-infant relationship.

When choosing a self-report measure for depression in a perinatal population, the EPDS is preferable over the BDI as it focuses less on physical symptoms of depression which can be a normal part of post-partum recovery (Moraes et al., 2017). Efforts should be taken to reduce social desirability effects.

Session-by-session measurement is advised in most settings. However, staff should consider the time period covered by the instruments they are using as no two ratings should overlap (Burgess et al., 2017) and MBU admissions are typically very short. At a minimum, ratings should be made as close to the point of admission as possible and again at discharge, but researchers should be aware that those who choose to discharge themselves before it is recommended may be underrepresented.

### Conclusion

With regards to maternal mental health outcomes, this review does not change the position of Gilham and Wittkowski (2015) suggesting a positive effect of MBU admission with particular support for improvements in depressive symptomology. Future studies with improved methodology are required before any over-arching conclusions can be drawn regarding the influence on the mother-infant relationship or that of developmental outcomes for children.

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**Systematic review Appendices** 

(Chapter 1)

# **Appendix 1.1 Publication Guidelines**

This is an extract of the guidelines for submission to the International Journal of Women's

health.

# **Manuscript Preparation**

- While the editors fully understand the extra challenges posed to authors whose native language is not English, we must ask that all manuscripts be reviewed and edited by a native speaker of English with expertise in that area prior to submission
- Double-spacing
- o 3-cm margins
- o Page numbers
- o Line numbers
- o Clear concise language
- o American spelling (all components of a manuscript must be in English)
- o Ensure tables and figures are cited
- o The preferred electronic format for text is Microsoft Word
- Manuscripts will be accepted in LaTeX as long as the native LaTeX and a PDF is also supplied
- Use International Systems of Units (SI) symbols and recognized abbreviations for units of measurement
- o Do not punctuate abbreviations eg, et al, ie
- o Spell out acronyms in the first instance in the abstract and paper
- Word counts are not specified. In general, shorter items range from 1000 to 3000 words and reviews from 3000 to 7,500

#### Figures and tables

#### **Figures**

## Checklist

Before you submit any figures, please check this list to ensure your files meet our criteria:

- o Files are provided in our required file formats, .jpg, .tif or .pdf (see the 'Preparation' section below)
- o If your figure is not in .jpg, .tif or .pdf, please convert to the accepted file type that allows the highest quality
- o Artwork is of high quality (correct resolution, not blurred, stretched or pixelated)
- o One file provided per figure
- o All figures have white space and unnecessary elements removed
- o All text is in English and contains no spelling or grammar errors
- All fonts used are embedded and are the journal's standard font style Arial or Symbol
- o Font size is consistent
- o Lines are a minimum of 0.3pt
- o Images do not contain any layers, or transparent objects
- o Files are named using the naming convention ([manuscript ID] Figure [number])
- o Figures are provided separate from the manuscript
- o All multi-panel figure parts are labelled (eg, A, B, C, D)

All copyrights and permissions for use of third-party content have been obtained.
 Graphics downloaded from web pages are not acceptable.

# **Preparation and Submission**

Recommended image resolutions:

- o Colour photographic images: minimum 300 dpi
- o Grayscale photographic images: minimum 600 dpi
- o Line art or monochrome images: minimum 1200 dpi
- o Combination images (photographs and labelling): minimum 600 dpi

The manuscript should not contain any pasted figures. Please provide figures as high quality .jpg, .tif or .pdf files separate from the manuscript. Please ensure that any files in .pdf format are not 'locked' files, as these are incompatible with our workflow software. Image colour should be RGB.

# File naming conventions

Name figure files as Figure 1, 2, 3... etc. according to the order they appear in the text. In multi-part figures, each part should be labelled (eg Figure 1a, Figure 1b). Check and ensure all figures have been cited in the text of the manuscript.

#### **Size**

Figures should be supplied in the highest resolution (highest quality) possible. Remove any elements that are not intended for publication, including any excess space around the image. Make sure that the image files do not contain any layers, or transparent objects.

#### **Fonts**

Use the journals standard font, Arial, and Symbol (Roman). If providing a .pdf file, ensure your fonts are embedded. Keep the font size consistent throughout your work. Do not use effects such as outlining and shadows on any lettering.

# Figure legends

Figure legends must begin with the number of the figure being described (eg 'Figure 1: '). If subfigures are present, each subfigure must be labelled and described in the figure legend.

Captions should be succinct but descriptive. Explanatory notes or a key should be present if the figure contains patterns, colours, symbols, or other formatting that indicates significant data. If symbol or alphabetical indicators have been used (e.g. \*, \*\*, #, ##, a, b, etc) a key should be included in the figure legend.

If the figure, or a subfigure, is copyrighted and you have obtained permission for use, please ensure that the necessary credit line or acknowledgments are included in the figure legend. If the image is the property of the author, then this should be acknowledged in the caption. A copy of the permission to reuse must be provided to the journal.

#### **Tables**

Tables should present new information rather than duplicating what is in the text. Readers should be able to interpret the table even if presented separately from the text. Ensure that each table is cited within the text of the manuscript.

- Provide tables in their original, editable format (eg in Microsoft Word or Excel).
   Our production team cannot accept tables as images (eg tables in .jpg, .tif or other image format).
- Tables may be provided within the manuscript, or as separate files (one file per table).
- Present table legends above each table, rather than including these as the first row
  of the table. Table footnotes should be separate from the titles, and included
  beneath the table to which they apply.
- o Explanatory notes or a key should be present if the table includes indicators, symbols, abbreviations, bolding or other formatting that indicates significant data.
- o If using indicators for footnotes, please use superscript letters (a, b, c). These letters should follow alphabetical order from the top left of the table to the bottom right.
- All reference citations included in a table must have the relevant reference list number included (in superscript Arabic numeral). Please ensure these numbers align with the reference list included in the manuscript.
- When submitting multiple tables, consistency in presentation is advised.
- When representing information numerically, use as many decimal places as is appropriate for your purposes. This number should be consistent throughout the column, or table, if possible.
- o All text in the tables should be in English.
- Tables must not contain images.

Consider the size of each table and whether it will fit on a single journal page. If the table is cramped in a Microsoft Word document, where the default setting represents an A4 page (210 x 297 mm), it will be difficult to represent it clearly on a B5 journal page (176 x 250 mm). If this is the case, please consider splitting the data into two or more tables.

# Reference Style Guidelines

DMP follow the style adopted by the American Medical Association (AMA),\* (pp39–79) which, in turn, is based on the style developed by the International Committee of Medical Journal Editors in 1978 in Vancouver.

# **Reference Management systems**

Users of the EndNote<sup>®</sup> software should select the <u>JAMA reference style</u> when preparing references for any Dove Medical Press Journal. Please disable EndNote<sup>®</sup> before you submit your manuscript.

To disable EndNote<sup>®</sup> first save a copy of the document. Then in Word, use the EndNote<sup>®</sup> tab and click on "Convert Citations and Bibliography" and select "Convert to Plain text" This will remove the EndNote<sup>®</sup> encoding but leave the citations and bibliography.

**Please note** that authors are responsible for the accuracy and completeness of their references.

**Text citations:** Cite references sequentially in text, tables, and legends by superscript Arabic numerals with no parentheses, eg, <sup>1</sup> or <sup>3,4</sup> or <sup>10</sup>\_15. Numbers should be placed **after** punctuation marks, eg, <sup>3,4</sup> **Do not use** Microsoft Word's footnote/endnotes function to build the reference list as this can introduce errors during the typesetting process.

**Reference list:** List items **numerically** (eg. 1, 2, 3, 4) in the order they are cited in the text, eg, 4. Kapur NK, Musunuru K. Clinical efficiency and safety of statins in managing cardiovascular risk. *Vasc Health Risk Manag.* 2008;4(2):341–353. **Some commonly used sample references follow.** 

# **Appendix 1.2 Quality Rating Tool**

Table 1 Quality assessment tool and scoring guidance notes

Structure & content allows for detailed data to be gathered around all relevant issues required to address the stated research question(s). Method of analysis selected is the most suitable appracach for attempt answer the research question in detail e.g. for qualitative IPA preferable for experiences vs. content analysis to elicit frequency of occurrence of Suitable and thorough statistical assessment of reliability and validity of measurement tool(s) with reference to the quality of evidence as a result of the measures population in the context of the study, e.g. nurses and doctors from GP practices in the east midlands. Detailed description of each stage of the data collection procedure, including when, where and how data were gathered. collection toolls), e.g. relevance to the study aims and assessments of tool quality either statistically, e.g. for reliability & validity, or relevant qualitative assessment. Explicit consultation with steering group or statement or formal consultation with users in planning of study Discussion of strengths and limitations of all aspects of study including design, measures, procedure, sample & analysis. information redundancy/saturation was reached or to fit exact calculations for analytical requirements. Sample includes individuals to represent a cross section of the target population, considering factors such as Specific description of the research problem and target Complete data regarding no. approached, no. recruited, attrition data where relevant, method of recruitment. Method of data collection selected is the most suitable Use of a range of methods to assess reliability, e.g. triangulation, multiple researchers, varying research Explicit statement of aims/objectives in main body of approach to attempt answer the research question events, etc. Detailed explanation for choice of analytical method Explicit statement of theoretical framework and/or constructs applied to the research. Detailed explanation of rationale for choice of data Explicit statement of data being gathered until based on nature of research question(s). experience, age and workplace. backgrounds. design. report. Some recruitment information but not complete account of the recruitment process, e.g. recruitment figures but no information on strategy used. Sasic explanation of rationale for choice of data collection broadly addressing the stated research question(s) but could benefit from greater detail. Method of analysis can address the research question but there is a more suitable alternative that could have been used or used in addition to offer greater detail. imited attempt to assess reliability, e.g. reliance on one Fairly detailed explanation of choice of analytical method. Pilot study with feedback from users informing changes to the design. sample is required to be representative.
States each stage of data collection procedure but with imited detail, or states some stages in details but omits others. Some attempt to assess reliability and validity of measurement tool(s) but insufficient, e.g. attempt to establish test-retest reliability is unsuccessful but no question but there is a more suitable alternative that could have been used or used in addition. General description of research problem in the target evidence of consideration of sample size in terms of saturation/information redundancy or to fit generic analytical requirements. experience but only one workplace. Requires discussion of target population to determine what Reference to broad aims/objectives in main body of Method of data collection can address the research tool(s), e.g. based on use in a prior similar study. tructure & content allows for data to be gathered representative, e.g. inclusive of all age groups, population, e.g. 'among GPs in primary care'. Discussion of some of the key strengths and weaknesses of the study but not complete. Sample is somewhat diverse but not entirely Reference to a specific theoretical basis. action is taken. Method of data collection can only address some aspects Use of pilot study but no involvement in planning stages Reliability and validity of measurement tool(s) discussed, but not statistically assessed. General reference to aim/objective at some point in the Minimal recruitment data, e.g. no. of questionnaire sent Very basic and brief outline of data collection procedure, that size of the sample has been considered in study Very limited mention of strengths and limitations with omissions of many key issues. report including abstract. General description of research area and background, Basic explanation for choice of sample size. Evidence design.
Sample is limited but represents some of the target group or representative but very small. Structure and/or content only suitable to address the research question in some aspects or superficially. Very limited explanation for choice of data collection More than one researcher involved in the analytical process but no further reliability assessment. Method of analysis can only address the research question basically or broadly. e.g. 'using a questionnaire distributed to staff'. Basic explanation for choice of analytical method Reference to broad theoretical basis. of the research question. e.g. 'in primary care'. 1 = Very slightly (s)loo No mention at all. question stated. question stated. No mention at all. No statement of target group. 0 = Not at all No research question and format and content of data collection tool e.g. Fit between research question and method of analysis Statistical assessment of reliability and validity of measurement rengths and limitations critically Description of procedure for data considered in terms of analysis Representative sample of target Evidence of user involvement in Statement of aims/objectives in question and method of data Good justification for analytical Explicit theoretical framework Clear description of research group of a reasonable size Fit between stated research Fit between stated research Rationale for choice of data Assessment of reliability of Detailed recruitment data Evidence of sample size main body of report interview schedule Qualitative) method selected analytical process collection tool(s) Quantitative only) Qualitative only) Quantitative) collection Criteria

# **Appendix 1.3 Quality Assessment Scores for each Included Paper**

# QATSDD scores for each paper

Assessment Criteria [1]	Chandra et al., 2015	Christl er al., 2015	Yellend et al., 2015	Stephenson et al., 2018	Wright et al., 2018	Reilly et al., 2019	Bittner et al., 2020	Wang et al., 2020
Explicit theoretical framework	1	2	1	2	1	2	3	1
Statement of aims/objectives in main body of report	2	3	2	3	2	2	3	3
Clear description of research setting	2	3	2	3	3	3	1	1
Evidence of sample size considered in terms of analysis	0	0	0	0	0	0	0	0
Representative sample of target group of a reasonable size	2	1	1	1	2	1	1	1
Description of procedure for data collection	1	1	1	2	2	1	1	1
Rationale for choice of data collection tool(s)	1	1	1	2	2	1	2	1
Detailed recruitment data	1	2	1	2	1	2	2	1
Statistical assessment of reliability & validity of measurement tool(s) (Quantitative only)	0	0	0	3	1	0	3	0
Fit between stated research question & method of data collection (Quantitative)	1	1	1	3	1	2	2	1
Fit between stated research question & format & content of data collection tool (Qualitative)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Fit between research question & method of analysis	1	3	1	2	2	1	1	0
Good justification for analytical method selected	0	3	0	2	2	1	1	0
Assessment of reliability of analytical process (Qualitative only)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Evidence of user involvement in design	0	0	0	0	0	0	0	0
Strengths & limitations critically discussed	0	2	1	2	2	2	2	1
Total	12	22	12	27	21	18	22	11
Maximum score possible	42	42	42	42	42	42	42	42
Score as Percentage (%)	29%	52%	29%	64%	50%	43%	52%	26%

n/a = not applicable

# References for appendix 1.3

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- Christl, B., Reilly, N., Yin, C., & Austin, M. P. (2015). Clinical profile and outcomes of women admitted to a psychiatric mother-baby unit. *Archives of women's mental health*, *18* (6), 805-816.
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# **CHAPTER 2: Major Research Project**

The concurrent validity of the Child and Adult Relationship Observation tool (CARO) for mothers with additional health and social care needs.

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Word Count: 6547

# **Plain English Summary**

# **Background**

The relationship between mother and child, especially during the first two years of a child's life, has been linked to many different outcomes for children. One influence on this relationship is the way that mothers talk to, play with, and manage behaviour with their child, also known as mother-infant interaction. Some, but not all, previous research studies have shown mothers having depression when a child is still very young is associated with less sensitive mother-infant interactions, but little is known about why this is.

The Child and Adult Relationship Observational tool (CARO) is a tool used to identify positive and negative interaction behaviours between parent and child. It involves observing parenting behaviours during one-to-one interactions at, for example, mealtime or playtime. It has recently been developed with the aim of making the observation tools we already have more simple. However, it has not been compared with other tools to check if it is an accurate way of measuring mother-infant interaction.

## **Aims**

This study's aim was to establish how CARO compared with one other available tool (the CARE index). A second aim was to explore the relationship between depression and maternal sensitivity within the sample.

# Methods

This study used data collected from another research trial (THRIVE; Trial of healthy relationship initiatives for the very early years). Participants had already given their

permission for their data to be used in other studies. The data from 30 participants were chosen to be used in this study based on who scored the highest on depression six months after having their baby. Videos of mothers and babies playing at this time point had already been coded using a tool called the CARE-index as part of the THRIVE trial. The CARE-index has already shown to be useful measure of maternal sensitivity. The videos were viewed again and coded using CARO so that scores could be compared with those from the CARE-index.

#### **Results**

Maternal sensitivity measured using the CARE-index was not associated with maternal sensitivity measured using CARO. Unexpectedly, those with higher depression scores had higher maternal sensitivity scores on the CARE-index. Maternal sensitivity, as measured by CARO, was not associated with depression.

## **Discussion**

The study does not demonstrate CARO's ability to accurately measure maternal sensitivity. However, there were problems relating to the study's design which should be addressed in future studies and which make it difficult to make firm conclusions.

#### References

Thompson, L., Taylor E., Puckering, C., and Wilson, P. (2019) Streamlining of the Mellow Parenting Observation System for research and non-specialist clinical use. *Community Practitioner*, **92** (8), 45-47.

## **Abstract**

# **Background**

Mother-infant interactions, especially in the first two years of a child's life, have been consistently linked to a wide variety of developmental outcomes for children. Depression is commonly associated with less sensitive mother-infant interactions. Currently, most systems used to assess such interactions are complex and are therefore not a helpful aid to primary care mental health professionals who wish to monitor mother-infant relationships.

#### **Aims**

The primary aim was to establish how the Child and Adult Relationship Observation tool (CARO), corresponds with another measure of mother-infant interaction (CARE-Index), which has known predictive validity, in a sample of mothers identified as having additional health and social care needs in pregnancy and who score highly on depression six months post-partum. The relationship between maternal sensitivity and depression, measured using the subscale of the Hospital Anxiety and Depression Scale (HADS-D; Bjelland et al., 2002), was also explored.

#### Method

This study used the data from 30 mothers from the THRIVE trial (Trial of healthy relationship initiatives for the very early years). Ten of the highest scoring mothers on depression at follow-up (six months post-partum) from each of the three study arms were selected. Videos of 3-5 minutes in length, which had already been rated using the CARE-index, were analysed using CARO. Concurrent validity with the CARE-Index, and any

relationship between depression and the two tools used to assess mother-infant interaction, was explored using Spearman's correlations.

# **Results**

The association between CARO and the CARE-Index was non-significant  $((r_s)=.119;\ p=.530)$ . There was a moderate, positive relationship between CARE-Index and depression scores  $((r_s)=.407;\ p=.026)$  and no significant relationship between CARO and depression scores  $((r_s)=.221;\ p=.241)$ .

# Conclusion

CARO does not have good concurrent validity with the CARE-index. Other psychometric properties of CARO require to be assessed to establish the extent of its clinical utility.

# **Introduction**

The quality of the mother-infant relationship, especially in the first two years of a child's life, has been consistently linked to a wide variety of developmental outcomes for children (Moss et al., 2011). One of the indicators of a secure adaptive relationship is the infant's ability to use their care-giver as a "secure-base from which to explore" (Ainsworth, 1967, pp.447-448). Ainsworth (1963) suggests that the likelihood of an infant displaying an adaptive relationship towards their caregiver is dependent on the mother's ability to respond sensitively to his/her needs, and there is increasing evidence to support this view (e.g. Moran et al., 2008). Demonstrating sensitivity in one's behaviours can therefore be considered necessary for positive parenting. Predictors of positive parenting include a higher maternal age, and a higher maternal education (Thompson et al., 2014), and also the ending of relationships where mother has experienced domestic violence (Fujiwara et al., 2011). Mental illness during the postnatal period is another factor that is specifically associated with less sensitive interactions between mother and infant (Bernard et al., 2018; Steadman et al., 2007). Of all the mental health diagnoses, the relationship between depression (the most common postpartum mental health problem) and the mother-infant relationship, is the most widely studied. A meta-analysis of studies which examined the effects of post-partum depression on mother-infant interactions during the infant's first three months of life, found that depressed mothers were more hostile to their infants, less engaged with their infants, exhibited less emotion and warmth, and had lower levels of play (Lovejoy et al., 2000).

In addition to that of a less sensitive mother-infant relationship, poor maternal mental health is another factor that has been linked to poor developmental outcomes for children (Goodman et al., 2011; Fraser et al., 2013) but little is known about the mechanisms

involved in the transmission of risk (Goodman et al., 2011). There is literature that supports the idea that the negative impact of poor maternal mental health may be mediated by less sensitive mother-infant interactions (Garai et al., 2009) but there are other studies that do not support this hypothesis (van Doorn et al., 2016). Regardless of the mode of transmission, clinical levels of post-natal depression are consistently associated with less sensitive mother-infant interactions prior to targeted intervention (Bernard et al., 2018). Prevalence rates of postpartum depression range from 7 to 13% in high income countries (O'Hara & Swain., 1996). Evidence suggests that interventions which only target the mother's mental illness are not associated with an improvement in mother-infant interactions (Murray et al., 2003). It is a therefore a priority that those with a professional responsibility to assess and monitor the developing mother-infant relationship (i.e. health visitors) have a valid, reliable method to do so. This is made more necessary as health visitors' judgements of mother-infant relationships, based on their existing knowledge, have shown to be inconsistent with ratings based on validated observational measures (Appleton et al., 2013). Observer-led systems of analysing interaction such as the CAREindex (Crittenden, 2010) or the PIRAT (The Parent-Infant Relational Assessment Tool; Broughton, 2010) involve time-consuming training and scoring, and are therefore not a practical option for many primary care professionals. Self-report tools have been developed to address these limitations (Wittowski et al., 2007) but it has not yet been demonstrated whether they are reliably able to predict high risk from low risk dyads. They also have a low correlation with observational measures (i.e., gold standard) (Alderfer et al., 2008).

Recent work has focused on simplifying one of the existing observational systems, the Mellow Parenting Observation System (MPOS; Puckering et al., 2014), to make it more

applicable in a time-limited service context (Thompson et al., 2019). MPOS is used to analyse positive and negative parenting behaviours during one-to-one interactions at, for example, mealtime or playtime. The Child and Adult Relationship Observation (CARO; Thompson et al., 2019) condenses the key dimensions of MPOS by placing limits on how each interaction can be coded and has good agreement with MPOS with relation to coding of behaviours (Thompson et al., 2019). Due to CARO's simplicity and brevity, it is hoped that it can be used by early years and non-specialist professionals, to analyse behaviours in real time, thus guiding their overall assessment of parent-infant relationships.

#### Aim

The aim was to determine how CARO compares with a more established measure of mother-infant interaction: the CARE-Index (Crittenden, 2010), for women identified as having additional health and social care needs in pregnancy and who score highly on depression six months post-partum. The strength and direction of the relationship between depression and mother-infant interactions will also be explored.

# **Hypothesis**

It was predicted that the correlation between the total rate of positive interactions observed using CARO and the CARE-index sensitivity scale would be greater than 0.7 ( $\pm~0.7$  is representative of a strong correlation; Dancey & Reidy, 2007) as it was hypothesised these scales are measuring the same domain.

# **Ethical Approval**

This was a secondary data analysis study. Permission was obtained from the THRIVE study's Chief Investigator to access an anonymised data subset from the main THRIVE dataset. Ethical approval for the THRIVE study was obtained from the NHS West of Scotland Research Ethics Service (Reference GN12KH589). THRIVE was sponsored by NHS Greater Glasgow and Clyde. Participants had indicated consent for their data to be used in related studies, within the broad remit of THRIVE. The aims of this study fitted within the given approvals and were subject to review and approval by the data owners for THRIVE.

# Methods

## **Design**

This study used a within-participants design to test the concurrent validity of CARO with the CARE-index six months post-partum.

#### **Participants**

The sample consisted of 30 participants from THRIVE. The details on the recruitment and procedure of THRIVE can be found in Henderson et al. (2019). Participants in THRIVE were identified as being at social risk by the Special Needs in Pregnancy Protocol (SNiPS; Glasgow Child Protection Committee, 2008) (see table 2 for list of criteria). The sample for the current study was ten of the highest scoring mother-infant dyads on depression at follow-up from each of the three study arms in THRIVE and where there were many mothers with the same depression score, high anxiety scores were used to select those for inclusion.

#### **Inclusion and Exclusion Criteria**

The selection of the mother-infant dyads was based on two conditions: Firstly, mother-infant dyads must have participated in a recorded episode of interaction which had been coded using the CARE-Index sensitivity score. Secondly, those meeting the first condition with the highest depression scores, as assessed using the HADS-D, were selected for inclusion. The inclusion and exclusion criteria for THRIVE can be found in the study protocol paper (Henderson et al., 2019;).

#### **Procedure**

Ten mother-infant dyads were selected from each of the three intervention arms used in THRIVE (see appendix 2.3) in line with this study's inclusion criteria. Contained within this dataset is a measure of mother-infant interaction (CARE-index sensitivity score) taken at 6 months post-partum (following completion of the interventions delivered in THRIVE) by researchers who were reliability trained, blind to intervention and independent of the study's main researchers. The academic supervisor on the current study was responsible for coding the same videos that were used to derive the CARE-Index Score using CARO and is reliability trained. These ratings were added to the existing THRIVE dataset by the Principle Investigator (student) and the data was analysed in line with the study hypotheses.

#### Measures

## Maternal depression

The depression subscale of the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was used to measure symptoms of depression. The HADS-D is a 7 item self-report questionnaire used to assess symptoms of depression (e.g. "I still enjoy the

things I used to enjoy"). Participants rate items on a Likert scale between 0 and 3 in accordance with how they have been feeling in the last seven days. There is reverse coding of three items. The possible range of scores is 0-21, with higher scores indicating a higher degree of symptom severity. There are two commonly used cut-off scores: 8/21 and 11/21. However, a literature review concluded a cut-off score of 8/21 is considered the optimal balance between sensitivity and specificity when screening for clinical levels of depression in both primary care and inpatient psychiatric settings (Bjelland et al., 2002).

# Quality of mother-child interaction

A single video recorded session, lasting no more than ten minutes, of mothers interacting with their babies has already been analysed using the CARE index as part of the THRIVE study. The same videos were analysed using CARO for the present study. Table 1 provides a comparison of key features of CARO and the CARE-index.

#### CARE-index

The procedure for the CARE-index (Crittenden, 2004) consists of coding of 3-5 minutes of mother-infant interaction during unstructured play. The coding system is based on seven aspects of interaction behaviour: Facial Expression, Verbal Expression, Position and Body Contact, Affection, Turn–Taking, Contingencies, Control and Choice of Activity. The adult and the infant are separately evaluated on each of the aspects, and the scoring of each item contributes to one of seven scales; three adult scales and four infant scales. The three adult scales are sensitivity, unresponsiveness and control. The four infant scales (birth to 15 months of age) are cooperativeness, difficultness, compulsivity and passivity. On the adult scale, sensitivity is defined in play as "any pattern of behaviour

that pleases the infant and increases the infant's comfort and attentiveness and reduces its distress and disengagement" (Crittenden, 2004, p. 3). The score ranges between 0-14 with 14 being outstandingly sensitive. The CARE-index has been shown to be a valid measure of assessing mother-infant interaction in high risk populations, such as mothers with psychiatric disorders (Kemppinen et al., 2006b).

#### **CARO**

The procedure for CARO (Thompson et al., 2019) requires coding of one-to-one interactions such as mealtime or playtime. The coding system for CARO consists of counting specific positive or negative parenting behaviours across three domains: Cooperation, Autonomy and Responsiveness. There is a limit of one positive and/or one negative code per 10 second segment of interaction. This provides rates of positive and negative interactions per minute overall and per each of the three dimensions. It is recommended this rate is calculated following observation of an interaction of at least 3 minutes. Previous analysis using MPOS has shown that using total positive rates, as opposed to using negative rates or any of the individual domains, is the strongest predictor of negative outcomes for children (Puckering et al., 2014). Therefore it was decided to assess the concurrent validity of CARO using positive rates per minute.

Sociodemographic characteristics including age, ethnicity, education, employment and parity were obtained from the THRIVE database as well as an estimate of socioeconomic status according to the Scottish Index of Multiple Deprivation 2016 (SIMD). SIMD defines deprivation according to postcode with all areas of Scotland ranked according to area-level deprivation (The Scottish Government, 2016). Data are provided in quintiles with quintile 1 representing the most deprived and the quintile 5 the least deprived.

**Table:** 1\_Comparison of key features of CARE-index and CARO with examples of how behaviours are coded.

Feature	CARE-index	CARO
Interaction behaviour/	Facial Expression	1.Co-operation
Dimensions	Position & Body Contact	2. Autonomy
	Affection	3. Responsiveness
	Turn Taking	
	Contingencies	
	Control	
	Choice of Activity	
Output	Scoring of sensitivity on	Each of the 3 dimensions
	each interaction behaviour	contribute to overall <b>total</b>
	contributes to overall score	positive interactions and total
	on the Adult Sensitivity	negative interactions. Can
	Scale	convert to 'rates per minute'
		_
		for both <b>positive</b> and <b>negative</b>
		_
Examples of		for both <b>positive</b> and <b>negative</b>
Examples of coding		for both <b>positive</b> and <b>negative</b>
	Contributes towards overall	for both <b>positive</b> and <b>negative</b>
coding	Contributes towards overall insensitivity on the Adult	for both <b>positive</b> and <b>negative</b> interactions.
coding  1.Mum says "you		for both <b>positive</b> and <b>negative</b> interactions.  This would count towards a
coding  1.Mum says "you are very grumpy	insensitivity on the Adult	for both <b>positive</b> and <b>negative</b> interactions.  This would count towards a
coding  1.Mum says "you are very grumpy today".	insensitivity on the Adult Sensitivity Scale	for both <b>positive</b> and <b>negative</b> interactions.  This would count towards a

# **Justification of sample size**

There was no basis to estimate sample size for the primary aim using previously reported correlations, as CARO is a newly developed tool and its concurrent validity with other tools has never previously been investigated. Additionally, there is no explicit basis for estimating sample size in validation studies (Antoine et al., 2014). However, it was estimated that 17 mother-infant dyads would result in the study having 90% power to detect a correlation of 0.7. However, a sample size of 30 was chosen in order to provide equal representation across the three study arms. Ten participants from each of the three study arms (at post-intervention follow-up) were selected to sample a range of mother-infant interaction scores, thus enabling CARO's validity to be tested in as wide a range of scores as possible, given the study population. Sample size estimates were provided by SAS v9.3 and were calculated by Nicola Greenlaw, Consultant Biostatistician, University of Glasgow. The study was powered solely on the study's primary research question.

# **Data Analysis**

Demographic information and HADS cut-off scores, and categories used to demonstrate maternal sensitivity as specified by the CARE-Index, are presented as percentages. Normality plots revealed that the CARO variable was normally distributed therefore means and standard deviations were used to describe positive interactions observed per minute.

Both normality plots (including boxplots; see figure 1) and descriptive statistics suggested the CARE-index scores had a distribution that was skewed to the left -.623. The Shapiro-Wilk test of normality only just fell into the non-significant range p=.057. Therefore the choice was made to analysis the data via the most conservative approach by performing

a non-parametric correlation analysis (Spearman's) to explore the relationship between CARO and the CARE-index. The alternative parametric analysis did not alter the strength or magnitude of the observed association. Normality plots suggested the HADS-D variable were not normally distributed and the Shapiro-Wilk test of normality narrowly missed significance p=.071. Therefore Spearman's correlation was used to assess the correlation between depression and both mother-infant interaction variables.

# **Results**

# Sample characteristics

All but two of the mother-infant dyads participated in a recorded episode of free play which is a requirement for coding the CARE-index scales and consistent with the inclusion criteria for this study. The remaining two mothers were recorded interacting with their infants at mealtime whereby infants were spoon fed by their mother. Videos varied in length between 2.28-9.67 minutes, with a mean clip length of 5.01 minutes (SD 1.99).

Table 2 provides a summary of participant demographics and clinical characteristics. Where possible the information provided is consistent with the time of the recorded interaction between mother and baby (approximately 6 months postnatally; the primary outcome endpoint on the THRIVE trial. Where data was not available for this time point, information is provided at baseline (between 12-24 weeks pregnant). At what timepoint the data was collected in indicated in table 2.

The mean age of mothers was 27.9 years (SD 5.5) and the mean age of infants was 7.6 months (SD 1.8). The majority of infants had been born at full-term and the ratio of males

to females was fairly even (47% female). The majority of mothers (63%) were not primiparous. Over half of the mothers lived with a partner or husband. The majority of mothers had obtained an educational qualification usually achieved after completing at least four years of secondary school (standard grade level or above). Most women fell within the most deprived quintile on the Scottish index of Multiple Deprivation (SIMD, 2016). SNiPs criteria indicated high levels of substance misuse, homelessness and domestic violence at baseline, with most women meeting more than one criterion.

 Table 2: Summary of participant demographics and clinical characteristics

Maternal age baseline	<20	2	(6.7)
(years): n (%)	20-24	8	(26.7)
(years). II (/0)	25-29	10	(33.3)
	30-34	8	(26.7)
	35+	2	(6.7)
Infant age follow-up	3-6	3	(10)
(months): n (%)	6-9	22	(73.3)
(months): 11 (70)	9-12	3	(10)
	>12	2	(6.7)
<b>Infant prematurity:</b> n (%)	>37weeks	26	(86.7)
mant prematurity. If (70)	34-37 weeks	4	(13.3)
Infant gender: n (%)	Male	14	(46.7)
imant gender. If (70)	Female	16	(53.3)
Ethnicity: n (%)	White	27	(90)
<b>Ethnicity</b> . If (70)	Black	1	(3.3)
	Asian	2	(6.7)
Highest educational	None	4	(13.3)
qualification: n (%)	Standard Grades,	8	(26.7)
quantication. If (70)	intermediate 1 or 2, O	0	(20.7)
	Grades, O levels,		
	GCE/GCSEs		
	Higher, Advanced Higher,	5	(16.7)
	A levels	3	(10.7)
	Aleveis		
	HNC/HND	4	(13.3)
	HNC/HND Undergraduate degree	3	(13.3) (10.0)
	Undergraduate degree		(10.0)
		3	(10.0) (13.3)
	Undergraduate degree  Postgraduate qualification Vocational	3	(10.0) (13.3) (3.3)
Employment at baseline:	Undergraduate degree  Postgraduate qualification	3 4 1	(10.0) (13.3) (3.3) (3.3)
Employment at baseline: n (%)	Undergraduate degree  Postgraduate qualification Vocational Missing	3 4 1 1	(10.0) (13.3) (3.3)
2 0	Undergraduate degree  Postgraduate qualification Vocational Missing	3 4 1 1	(10.0) (13.3) (3.3) (3.3)
2 0	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously	3 4 1 1 3	(10.0) (13.3) (3.3) (3.3) (10) (56.7)
n (%)	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently	3 4 1 1 3 17	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3)
n (%)  Marital status (Lives	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently Partner	3 4 1 1 3 17 10 14	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3) (46.7)
n (%)	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently Partner Husband	3 4 1 1 3 17 10 14 4	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3) (46.7) (13.3)
n (%)  Marital status (Lives	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently Partner Husband Lives with other family	3 4 1 1 3 17 10 14	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3) (46.7)
n (%)  Marital status (Lives	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently Partner Husband Lives with other family member	3 4 1 1 3 17 10 14 4 12	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3) (46.7) (13.3) (40)
n (%)  Marital status (Lives with): n (%)	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently Partner Husband Lives with other family member Unknown	3 4 1 1 3 17 10 14 4 12	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3) (46.7) (13.3) (40) (0.1)
n (%)  Marital status (Lives with): n (%)  Primiparous: n (%)	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently Partner Husband Lives with other family member Unknown Yes	3 4 1 1 3 17 10 14 4 12 3 11	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3) (46.7) (13.3) (40) (0.1) (36.7)
n (%)  Marital status (Lives with): n (%)  Primiparous: n (%)  Scottish index of Multiple	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently Partner Husband Lives with other family member Unknown Yes 1 (most deprived)	3 4 1 1 3 17 10 14 4 12 3 11 20	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3) (46.7) (13.3) (40) (0.1) (36.7) (66.7)
Marital status (Lives with): n (%)  Primiparous: n (%) Scottish index of Multiple Deprivation follow-up:	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently Partner Husband Lives with other family member Unknown Yes 1 (most deprived) 2	3 4 1 1 3 17 10 14 4 12 3 11 20 3	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3) (46.7) (13.3) (40) (0.1) (36.7) (66.7) (10)
n (%)  Marital status (Lives with): n (%)  Primiparous: n (%)  Scottish index of Multiple	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently Partner Husband Lives with other family member Unknown Yes 1 (most deprived) 2 3	3 4 1 1 3 17 10 14 4 12 3 11 20 3 2	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3) (46.7) (13.3) (40) (0.1) (36.7) (66.7) (10) (6.7)
Marital status (Lives with): n (%)  Primiparous: n (%) Scottish index of Multiple Deprivation follow-up:	Undergraduate degree  Postgraduate qualification Vocational Missing Never  Previously  Currently Partner Husband Lives with other family member Unknown Yes 1 (most deprived) 2	3 4 1 1 3 17 10 14 4 12 3 11 20 3	(10.0) (13.3) (3.3) (3.3) (10) (56.7) (33.3) (46.7) (13.3) (40) (0.1) (36.7) (66.7) (10)

Special Needs in	Domestic Violence	19	(63.3)
Pregnancy Protocol	Homelessness	15	(50)
(SNiPS) baseline : N (%)	Substance Misuse	14	(46.6)
	Social Work involvement	11	(36.7)
	Child Protection	9	(30)
	Involvement		
	Looked after	8	(26.7)
	Partner substance Misuse	5	(16.7)
	History of mental ill health	4	(13.3)
	Family History of Severe	4	(13.3)
	mental illness		
	Partner Criminal Justice	1	(3.3)
	involvement		
	Young Mum	1	(3.3)
	Learning Disability	1	(3.3)
	Lives in Supported	1	(3.3)
	Accommodation		

# **Concurrent validity**

Table 3 provides a breakdown of CARE-index sensitivity scores and the associated categorisation based on clinical recommendations. (Crittenden, 2010).

 Table 3: CARE-index sensitivity score

Range:	n	(%)
Psychotherapy for parent		
0-2	2	(6.7)
Parenting intervention required		
3-4	2	(6.7)
Parental education		
5-6	5	(16.7)
Normally sensitive/non-		
clinical range		
7-21	21	(70)

The CARE-index data indicates that for 70% of mothers their sensitivity score was in the non-clinical range (i.e.7-21).

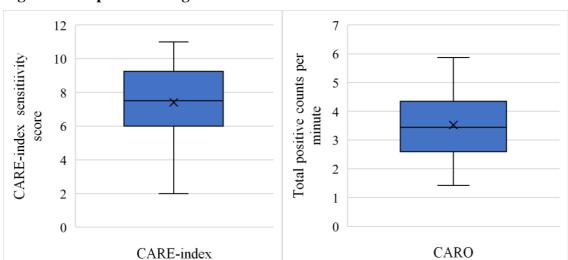
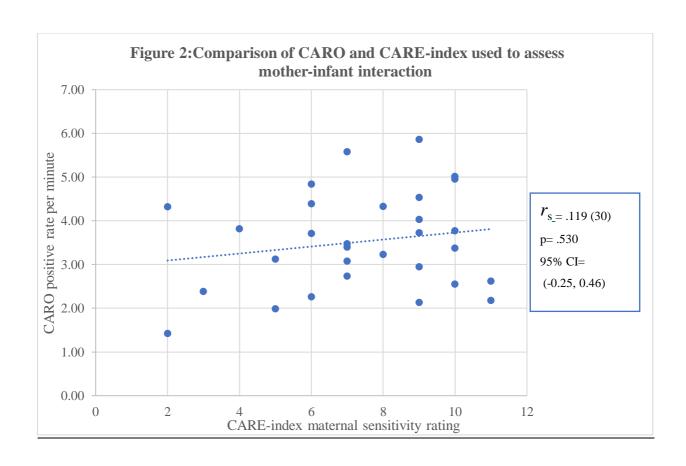


Figure 1: Boxplots showing distribution of mother-infant interaction scores

The mean number of positive interactions per minute, observed using CARO, was 3.52 (SD 1.11). Negative interactions were observed in 13 of the 30 participants with negative interactions per minute ranging from 0-1.58.

A scatterplot (Figure 2) is not suggestive of an association between the CARO and the CARE index variables and this was confirmed by the Spearman's rank correlation coefficient which was not significant (Figure 2) and by the confidence interval which contained zero. A further analysis was completed using only those with depression scores falling higher than the clinical cut-off for moderate-severe depression >10 (n=23). This correlation remained non-significant ( $r_s$  = .253, p = .244). These results therefore suggest that the null hypothesis (that CARO and the CARE-index are not measuring the same domain) should be retained.



# Association of depression with mother-infant interactions

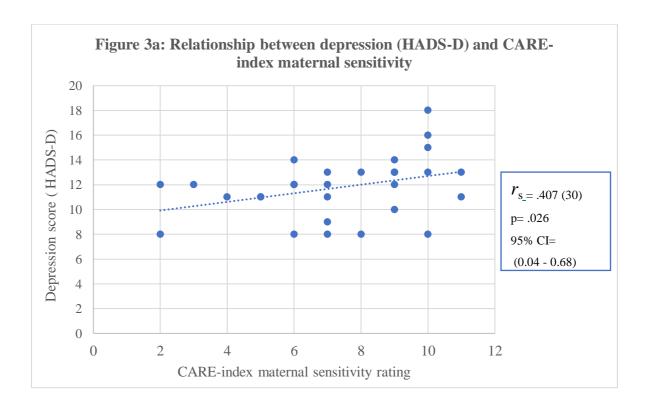
Participants with the highest depression scores were selected. Table 4 provides a breakdown of depression scores according to clinical cut-offs specified by the HADS scale (Bjellend et al., 2002). At the time of the recording most women in the sample scored in the moderate range for depression.

Table 4 HADS-score at time of recorded interaction

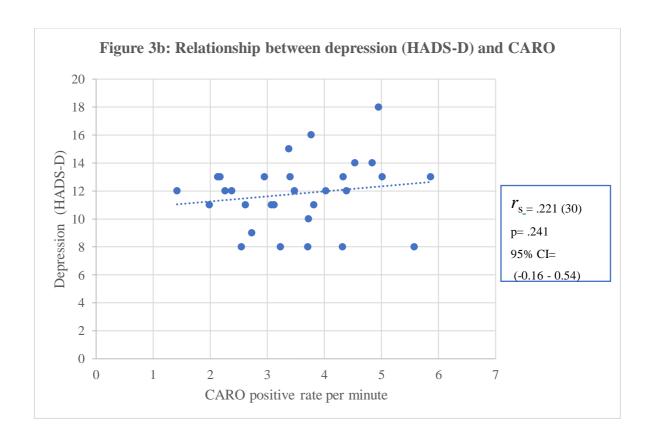
Range:	n (%)
Mild	
8-10	7 (23.3)
Moderate	
11-14	20 (66.7)
Severe	
15-21	3 (10)

Normality plots identified one score (18) that was 1.5 times greater than the interquartile range and therefore identified by SPSS as an outlier. However this was judged not to be a coding error and therefore was included in all subsequent analysis.

Figure 3a and the associated Spearman's rank order correlation is suggestive of a moderate, linear, positive relationship between depression and maternal sensitivity, as assessed by the CARE-index. In other words, higher depression scores were associated with higher levels of maternal sensitivity. However, the confidence interval narrowly missed containing zero (see figure 3a) limiting the degree to which these results can be considered conclusive.



Spearman's rank order correlations revealed a weak positive correlation between depression scores and the positive rate of interaction, as measured by CARO, which were not significant (Figure 3b).



Univariate analyses were performed to establish the relationship between both sociodemographic and clinical factors (which have a known association with parenting behaviours including maternal age, education, the three most common SNiPs criteria within the sample, maternal anxiety) and maternal sensitivity (see table 5). Anxiety was the only variable showing a trend towards statistical significance with the CARE-Index.

**Table 5**: Univariate Analysis between factors with a known association with

parenting behaviours			
Variable	Test Statistic		Significance
Maternal age			
CARE-index	$r_{\rm s} = .061$		p=.748
CARO	$r_{\rm s} = -2.63$		p=.160
Education			
CARE-Index	$X^2$ (7, n=29)= 6.211		p=.515
	0.211		
CARO	$X^2$ (7, n=29)=		p=.656
	6.211		
SNIPS			
Domestic Violence			
CARE-index	U = 87,	Z=-7.61	p= .447
CARO	U = 92,	Z = -538	p= .591
Homelessness			
CARE-index	U = 82.5,		p = .209
CARO	U = 91,	Z = -892	p= .373
Substance Misuse			
CARE-index	U = 82.5,	Z=-1.25	p = .209
CARO	U = 91,	Z=892	p= .373
Anxiety			
CARE-Index	$r_{\rm s} = .356$		p=.054
CARO	$r_{\rm s} = .193$		p=.306

 $r_s$  = Spearmans's rank order correlations,  $X^2$  = Kruskal Wallis, U= Mann-Whitney U

#### **Discussion**

This study investigates the concurrent validity of a newly developed tool of mother-infant interaction with the CARE-index. The results suggest that the rate of positive interactions measured by CARO is not concurrent with the maternal sensitivity scale of the CARE-index. The study also aimed to explore the relationship between depression and maternal sensitivity. A moderate positive association was demonstrated between depression and the CARE-Index maternal sensitivity variable but not for the CARO variable. Mothers who scored higher on depression were rated as being more sensitive on the CARE-index.

Possible explanations as to why no association was found between CARO and the CAREindex sensitivity scale come from differences between the constructs at the level of measurement, and differences with regards to the chosen observation scenario on which these tools are applied. First, the CARE-index requires a trained observer to apply a rating of sensitivity to several different pre-determined categories of behaviour, common of any interaction between a mother and an infant, which are summed to generate a score on the sensitivity scale, whereas CARO requires a trained observer to count behaviours categorised as being conducive to a sensitive interaction, in accordance with the rating tool on which it is based (MPOS). Where the CARE-index requires the observer to rate the degree of sensitivity shown in behaviours common of any interaction, CARO counts specific behaviours which indicate maternal sensitivity which are not necessarily common to all mother-infant dyads. The CARE-index has been shown to be highly correlated with attachment style, as demonstrated by the infant Strange Situation assessment (Svanberg et al., 2010). Therefore it is possible that the CARE-index reflects a more stable interaction style which is reflective of the attachment between mother and infant, whereas CARO is concerned with the counting of specific behaviours that indicate sensitivity, but that may or may not be present during an interaction. There are also key differences between how the measures score maternal insensitivity (see table 1) and as the concurrent validity of the measures was only assessed using positive rates of interaction, as opposed to negative rates, it is possible that the omission of these negative rates has contributed to the observed low correlation between the measures.

Second, the CARE-index assesses parent-infant interaction in a play-based scenario, whereas CARO is primarily designed to use a care-giving scenario in order that quality of interaction can be observed at a time when the parent is having to negotiate their own

agenda (as opposed to their child's). Videos were only coded in the most part for a play based scenario ideally suited to the CARE-index, not CARO, as it was considered a stronger study design if both tools were applied to the same interaction. The available literature does not suggest which scenario, (play or care-giving) is better able to demonstrate the presence or absence of sensitive interactions, only that these scenarios elicit different behaviours (Wilson et al., 2011). However, it is possible that a care-giving based scenario (more suited to CARO) may be more challenging for some mothers, giving rise to greater variability in behaviours counted (and therefore more variability in the rates per minute). The majority of scores for both the CARO and CARE-index variables fell into a narrow range and this is relevant as it reduced the likelihood of an accurate association being found. Furthermore, the validity of other observational tools has been found to be the highest in screening of the least sensitive interactions (Svanberg et al., 2013) and most scores for the CARE-index in this study fell within the normally sensitive/non-clinical range.

The positive association between maternal sensitivity (as rated by the CARE-index) and depression is somewhat surprising. Results of a recent meta-analysis show a significant small to moderate negative correlation between clinical levels of depression and maternal sensitivity from birth to twelve months (Bernard et al., 2018). Studies were excluded in the meta-analysis studies if sensitivity was only measured following a parenting intervention, as was the case for the current study; the videos used to assess sensitivity were taken following completion of a parenting programme for two thirds of the sample. The reason studies were excluded from the Bernard review on this basis, is that parenting programmes have shown to be effective at improving maternal sensitivity in those mothers with depression (MacBeth et al., 2015). It is possible that the success of the

parenting interventions has contributed to the large proportion of mothers scoring in the non-clinical range on the CARE-index, and that the selection of equal numbers of participants from each treatment arm has not been adequate to ensure a range of sensitivity scores required for the accurate calculation of associations between the variables.

The transmission pathway from poor maternal mental health to negative mother-infant interactions is complex, and most studies which have explored a link between depression and maternal sensitivity have been correlational (Bernard et al., 2018) and therefore, little can be said about the direction of this relationship. Furthermore, the magnitude of this association between maternal depression and maternal sensitivity is small with this association weakening in those with lower depression scores (Bernard et al., 2018). It is possible that other variables known to influence positive parenting (Thompson et al., 2014) are having an influence on the observed association between depression and maternal sensitivity, although these variables could not be identified by the current study. Maternal anxiety did show a trend towards significance. Prenatal anxiety has been found to be a predictor of parenting behaviours in a previous study but not in the expected direction. Higher levels of prenatal anxiety predicted an increase in positive parenting behaviours as measured using MPOS (Thompson et al., 2014).

Maternal state of mind (not assessed in this study), is one such variable that has been shown to be a predictor (albeit weak, r=.20) of maternal sensitivity (Verhage et al., 2016). Flykt et al. (2010) found that maternal attachment state of mind moderated the association of depression and maternal sensitivity, with depression having no association with maternal sensitivity in those mothers who had a secure attachment style. This suggests

mothers who have had positive experiences of relationships and who make use of social support in times of distress are able to continue to be sensitive in their interactions with their infants even when experiencing depression.

#### **Strengths and Limitations**

This study had a number of important strengths: the use of a well-validated observational measure to assess concurrent validity, the naturalistic home setting for the assessment of mother-infant interactions, and a sample size that ensured the study was adequately powered to detect an association between the assessment tools.

There are also some important limitations. The mothers' experience of being videoed, and their participation in it, has been assessed in THRIVE but that data has not yet been reported. Although there is the assumption that observations were made in a naturalistic setting, from the mothers' perspective this has not yet been evaluated. The CARE-index was developed to differentiate high risk from low risk dyads and has a tendency to overestimate risk. As a result there is a recommendation that the interpretation of CARE-index scores is made on the basis of at least two observations (Crittenden, 2010). Only one observation of mother-infant interaction was available. It is possible that an average of several observations may have led to a more accurate representation of the sensitivity of the observed relationship. Videos were not rated by a second observer on the CARO measure therefore inter-rater reliability could not be assessed. It is not known whether the CARE-index had a second rater as the THRIVE trial is yet to be published. The choice of self-report tool to assess depression was not ideally suited to a perinatal population. The Edinburgh Postnatal Depression Scale (EPDS) would have been preferable as it

focuses less on the physical symptoms of depression which can be a normal part of postpartum recovery (Moraes et al., 2017). The study was powered based on the primary research question therefore it is not known whether the study was sufficiently powered to detect associations between depression and the variables used to assess maternal sensitivity.

# **Clinical Implications and Future Research**

With regards to the validity of CARO, future studies should ensure the sample is drawn from a population that have not received a targeted intervention to increase maternal sensitivity. Hopefully, this would widen the range of maternal sensitivity scores creating more of an opportunity to demonstrate an association between the assessment tools if one such exists. Future studies could apply both measures (CARE-index and CARO) to both types of interaction scenario (caregiving and a play), in order to explore the influence of the specific interaction scenario on the correlation found between the measures.

Future research should be directed at establishing how factors associated with less sensitive mother-infant relationships interact to transmit risk to the infant. Studies exploring links with maternal health and maternal sensitivity should include scales validated for use in a perinatal population. Routine assessment of the mother-infant relationship, in addition to that of solely screening for maternal mental health problems, should continue.

#### **Conclusion**

Few studies have investigated the validity of an observational measure of mother-infant interaction which is brief and simple enough to be used by non-specialist researchers in

a clinical setting (Svanberg et al., 2013). In this study, CARO did not show concurrent validity with a more established measure of mother-infant interaction. Future evaluation is needed to establish whether reliability can be reached between non-expert raters and to establish whether it is able to predict developmental outcomes for children.

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**MRP** Appendices

(Chapter 2)

# **Appendix 2.1. Publication Guidelines**

This is an extract of the guidelines for submission to the Infant Mental Health Journal

#### 1. Submission and Peer Review Process

Once the submission materials have been prepared in accordance with the Author Guidelines, manuscripts should be submitted online

at https://mc.manuscriptcentral.com/imhj

For help with article preparation, <u>Wiley Editing Services</u> offers expert help with English Language Editing, as well as translation, manuscript formatting, and figure preparation.

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Before you submit, you will need:

- Your manuscript: this can be a single file including text, figures, and tables, or separate files—whichever you prefer. All required sections should be contained in your manuscript, including abstract, introduction, methods, results, and conclusions. Figures and tables should have legends. References may be submitted in any style or format, as long as it is consistent throughout the manuscript. If the manuscript, figures or tables are difficult for you to read, they will also be difficult for the editors and reviewers. If your manuscript is difficult to read, the editorial office may send it back to you for revision.
- The title page of the manuscript, including statements relating to our ethics and integrity policies (see information on these policies below in Section 1):
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- funding statement
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# **Appendix 2.2 Study Protocol**



Name of Assessment: MRP Proposal

**Title:** The concurrent validity of the Child and Adult Relationship

Observation tool (CARO) for mothers with additional health and social care needs.

**Matriculation Number:** 

**Version number:** 6

**Word count:** 3214 including abstract and references

Maximum word count for proposal: 3000

#### **Abstract**

# **Background**

The importance of mother-infant interactions, especially in the first two years of a child's life, has been consistently linked to a wide variety of developmental outcomes for children. Depression is considered a risk factor for negative mother-infant interactions. Currently, most systems used to assess such interactions require extensive training and are time-consuming to score, and are therefore not a helpful aid to primary care mental health professionals wishing to monitor mother-infant relationships.

#### Aims

Our primary aim is to establish how the Child and Adult Relationship Observation tool (CARO), a simplified version of the Mellow Parenting Observation System (MPOS), corresponds with one other measure of mother-infant interaction of known predictive validity (CARE-index), in a population of mothers identified as having additional health and social care needs in pregnancy and who score highly on depression six months post-partum.

#### **Methods**

This study will use the data of 30 participants from the THRIVE trial. Ten of the highest scoring mothers on depression at follow-up (six months post-partum) from each of the three intervention arms, will be selected. The primary outcome of mother-infant interaction quality at follow-up on the THRIVE trial was measured using the CARE-Index scored from 3-5 minute videos. To achieve the present study's aims, the same videos will also be analysed using CARO, and concurrent validity with the CARE-Index will be evaluated using appropriate measures of association.

# **Applications**

It is hoped that this research will provide validation of a new clinically feasible tool being used to study mother-infant interactions in a non-specialist setting, and provide a platform for relationship interventions in the future.

#### Introduction

The importance of the mother-infant relationship, especially in the first two years of a child's life, has been consistently linked to a wide variety of developmental outcomes for children (Moss et al., 2011). One of the indicators of a secure adaptive relationship is the infant's ability to use their care-giver as a 'secure-base from which to explore' (Ainsworth, 1967, pp.447-448). Ainsworth (1963) suggests that the likelihood of an infant displaying adaptive behaviours is dependent on the mother's ability to respond sensitively to their needs, and there is increasing evidence to support this view (e.g. Moran et al., 2008).

Mental illness during the postnatal period is associated with an increase in negative interactions between mother and infant (Steadman et al., 2007). The relationship between poor maternal mental health and poor developmental outcomes for children is widely recognised (Goodman et al., 2011; Fraser et al., 2013) and there is a growing evidence base that mother-infant interactions are an important mediating factor of this relationship (Moss et al, 2011; Alink, et al., 2009). Of all the mental health diagnoses, the relationship between depression and the mother-infant relationship is the most widely studied. A meta-analysis of studies looking at the effects of post-partum depression on mother-infant interactions during the infant's first three months of life found that depressed mothers were more hostile to their infants, less engaged with their infants, exhibited less emotion and warmth, and had lower levels of play (Lovejoy et al., 2000).

The transmission pathway from poor maternal mental health to negative mother-infant interactions is complex and attachment theory is widely referenced in literature to explain this relationship. In accordance with attachment theory, childhood abuse affects how

mothers experience caregiving, influencing how they themselves parent. There is evidence to suggest that mothers who have experienced childhood trauma are more likely to engage in insensitive behaviours towards their infant such as being overly intrusive or unresponsive (Isabella & Belsky,1991). Depression can also have a more direct route to insensitive parenting, as it is thought that the symptoms commonly associated with depression, including a bias towards negative thinking and lack of emotional affect, may undermine the ability of the mother to engage with her infant. A few studies support this idea and have found that mothers with depression have a tendency to interpret their infant's behaviour more negatively than trained observers (Field et al., 1993)

The prevalence rates of postpartum depression have been reported as being as high as 13% (Reck et al., 2008). Such prevalence rates highlight a need for universal postnatal screening to facilitate entry to effective treatment. Screening is usually facilitated by health visitors at various postnatal appointments. However, as previously outlined the relationship between maternal mental health and mother-infant interactions is complex, and evidence suggests that interventions that only target the mother's mental illness are not associated with an improvement in mother-infant interactions (Murray et al., 2003). It is therefore a priority that those who have a professional responsibility to assess and monitor the developing mother-infant relationship have a valid and reliable method to do so. Observer-led systems of analysing interaction involve time-consuming training and scoring, and are therefore not a practical option for many primary care professionals. Recent work has focused on simplifying one of the existing observational systems, the Mellow Parenting Observation System (MPOS; Puckering et al., 2014), to make it more applicable in a time-limited service context (Thompson et al., 2019). MPOS is used to analyse positive and negative parenting behaviours during one-to-one interactions at, for

example, mealtime or playtime. The Child and Adult Relationship Observation (CARO; Thompson et al., 2019) condenses the key dimensions of MPOS by placing limits on how each interaction can be coded. CARO has been shown to have good agreement with MPOS in relation to coding of behaviours (Thompson et al., 2019). Due to CARO's simplicity and brevity, it is hoped that it can be used by early years and non-specialist professionals to analyse behaviours in real time, thus guiding their overall assessment of parent-infant relationships.

#### Aim

We aim to establish how CARO compares with a more established measure of mother-infant interaction, the CARE-Index (Crittenden, 2004), for women identified as having additional health and social care needs in pregnancy and who score highly on depression six months post-partum.

#### The primary research question that will be addressed is:

Does CARO show concurrent validity with the CARE-Index for women who are recognised as having additional social needs in pregnancy and who have high depression scores six months postpartum?

# The secondary exploratory research question that will be addressed is:

Is depression (as measured using the depression scale (HADS-D) of the Hospital Anxiety and Depression Scale; (Bjelland et al, 2002)) associated with less sensitive mother-infant interactions as indicated by the CARE-Index and less positive interactions indicated by CARO?

#### **Hypotheses**

- 1. The correlation between the total number of positive interactions observed, using CARO and the CARE-index sensitivity scale, will be greater than 0.7 as we predict these scales are measuring the same domain.
- 2. The complex relationship between depression and mother-infant interactions, and the fact that some (but not all) mother-infant dyads will have received a targeted intervention, does not allow a reliable prediction to be made regarding the strength and direction of this relationship. However, evidence of a relationship will be explored.

#### **Plan of Investigation**

#### **Design**

This study will use a within-participants design to test the concurrent validity of CARO with the CARE-index six months post-partum.

#### **Participants**

The sample will be participants from the THRIVE study (Trial of healthy relationship initiatives for those with additional social and care needs during pregnancy). The details on the recruitment and procedure of the THRIVE trial can be found in Henderson et al., (2019). Participants in the THRIVE study were identified as being at social risk by the Special Needs in Pregnancy Protocol (SNiPS; Glasgow Child Protection Committee, 2008). The sample for the current study is ten mother-infant dyads from each of the three intervention arms in THRIVE.

#### **Inclusion and Exclusion Criteria**

The ten mother-infant dyads will be selected based on two conditions: Firstly, mother-infant dyads must have participated in a recorded episode of free play which has been coded using the CARE-Index sensitivity score. Secondly, those meeting the first condition with the highest depression scores, as assessed using the HADS-D, will be selected for inclusion. The inclusion and exclusion criteria from the THRIVE study which our sample is drawn from can be found in the THRIVE Protocol (Henderson et al., 2019).

#### Measures

#### Maternal depression

The depression subscale of the Hospital Anxiety and Depression Scale (HADS-D; Zigmond and Snaith, 1983) will be used to measure symptoms of depression. The HADS-D is a 7 item self-report questionnaire. Items include "I still enjoy the things I used to enjoy". Participants rate items on a Likert scale between 0 and 3 in accordance with how they have been feeling in the last seven days. There is reverse coding of three items. The possible range of scores is 0-21, with higher scores indicating a higher degree of symptom severity. A cut-off of score of 8/21 is considered the optimal balance between sensitivity and specificity (Bjelland et al., 2002). The HADS has been shown to be a reliable and valid measure of assessing depression in primary care settings (Bjelland et al., 2002)

#### Quality of mother-child interaction

A single three to five minute video recorded session of mothers playing with their babies has already been analysed using the CARE index, and for the present study will be analysed using CARO.

#### CARE-index

The procedure for the CARE-index (Crittenden, 2004) consists of coding of 3-5 minutes of mother-infant interaction during unstructured play. The coding system is based on seven aspects of interaction behaviour: Facial Expression, Verbal Expression, Position and Body Contact, Affection, Turn–Taking, Contingencies, Control and Choice of Activity. The adult and the infant are separately evaluated on each of the aspects, and the scoring of each item contributes to one of seven scales; three adult scales and four infant scales. The three adult scales are sensitivity, unresponsiveness and control. The four infant scales (birth to 15 months of age) are cooperativeness, difficultness, compulsivity and passivity. On the adult scale, sensitivity is defined in play as "any pattern of behaviour that pleases the infant and increases the infant's comfort and attentiveness and reduces its distress and disengagement" (Crittenden, 2004, p. 3). The score ranges between 0-14 with 14 being outstandingly sensitive. The CARE-index has been shown to be a valid measure of assessing mother-infant interaction in high risk populations, such as mothers with psychiatric disorders (Kemppinen et al., 2006b).

#### **CARO**

The procedure for CARO (Thompson et al., 2019) requires coding 3-5 mins of one-to-one interactions such as mealtime or playtime. The coding system for CARO consists of counting positive or negative parenting behaviours across three domains: Co-operation, Autonomy and Responsiveness. There is a limit of one positive and/or one negative code per 10 second segment of interaction. This provides rates of positive and negative interaction per minute overall, and per each of the three dimensions.

#### **Recruitment Procedures**

Permissions will be sought from the study's Chief Investigator to access an anonymised study data subset, associated with the study's aims, from the main THRIVE dataset.

#### **Procedure**

Ten mother-infant dyads will be selected from each of the three intervention arms used in THRIVE in line with this study's inclusion criteria. Contained within this dataset is a measure of mother-infant interaction (CARE-index sensitivity score) taken at 6 months post-partum by researchers who were reliability trained, blind to intervention and independent of the study's main researchers. The Chief Investigator (and academic supervisor) on the current study will be responsible for coding the same videos that were used to derive the CARE-Index Score using CARO, and is sufficiently trained to the point of being reliable to do so. These ratings will be added to the existing THRIVE dataset by the Principle Investigator (student) and the data will be analysed in line with the study hypotheses. Any missing data will have been managed by researchers on the THRIVE trial.

#### **Data Analysis**

Appropriate descriptive statistics will be used to describe the demographic profile of the sample, to ensure it is representative of the wider population from which it is drawn. Normality of the distribution of scores will be assessed using normality plots. Assuming that data is not normally distributed, the concurrent validity of CARO with the CARE-Index will be assessed by means of a Spearman's correlational analysis. Spearman's rho  $(r_s)$  correlation of  $\pm$  0.7 is representative of a strong correlation (Dancey & Reidy, 2007). Similar methods will be used for the study's secondary research questions.

#### **Justification of sample size**

There is no basis in which to estimate sample size for our primary aim using previously reported correlations, as CARO is a newly developed tool and its concurrent validity with other tools has never been previously investigated. Additionally, there is no explicit basis for estimating sample size in validation studies (Antoine et al., 2014). However, using a sample of 30 mothers/infant dyads, the study will have 90% power to show a correlation of 0.55, or 80% power to show a correlation of 0.5. Sample size estimates have been provided by SAS v9.3 and were calculated by Nicola Greenlaw, Consultant Biostatistician, University of Glasgow. The study has been powered based solely on the study's primary research question. The reason for choosing ten participants from each of the three intervention arms (post-intervention), is due to the prediction that this will provide a range of mother-infant interactions scores, thus enabling CARO's validity to be tested in as wide a range of scores as possible, given the study population.

# **Settings and Equipment**

An encrypted NHS laptop is required to conduct the analysis.

#### **Health and Safety Issues**

#### Researcher/Participant Safety Issues

As this study involves analysis of a secondary data set, there are no foreseen risks to either the researcher or the participant.

#### **Ethical Issues**

Ethical approval for the THRIVE study was obtained from the NHS West of Scotland Research Ethics Service Reference GN12KH589.

#### **Data Management Plan**

For the current study the Principle Investigator will be provided with an anonymised dataset and data will be limited to what is necessary to answer the study's research questions. Data will be stored on secure, password protected, university network and storage facilities. The study's Chief Investigator is a co-investigator on the THRIVE trial and so is named on the research governance documentation and therefore already has the necessary permissions to view the play/caregiving videos. Data will be managed in accordance with confidentiality agreements stipulated by the Chief Investigator on THRIVE.

#### **Financial Issues**

Anticipated costs include only those associated with stationery.

# **Proposed Timetable**

Dates	Principle tasks
Data Request	April 2020
Data Analysis and write up	May -July 2020
Submission of report	31st July 2020
Viva	3 <sup>rd</sup> /4 <sup>th</sup> September 2020

# **Practical Applications**

It is hoped that this research will provide validation of a new tool with practical application being used to study mother-infant interactions in a non-specialist setting and provide a platform for relationship interventions in the future.

# **Sponsor**

THRIVE was sponsored by NHS Greater Glasgow and Clyde. Further sponsorship is not required for the current study.

# Plan for dissemination of the results

The results will be analysed and submitted to the University of Glasgow as part of my qualification as a Clinical Psychologist. The plan is for dissemination via: publication in a scientific journal, conference presentations and via the THRIVE website.

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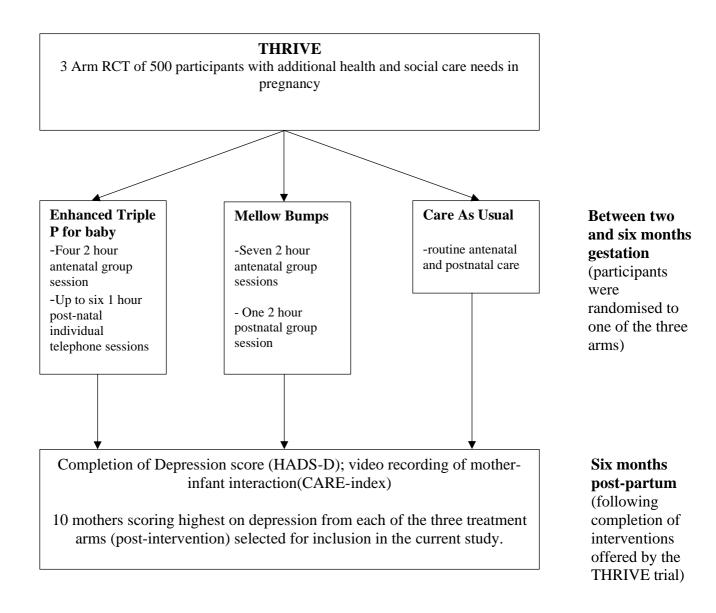
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# Appendix 2.3 Timeline of both randomisation of participants on the THRIVE Trial and extraction of data for current study



**Abbreviations**: THRIVE, Trial of healthy relationship initiatives for the very early years; RCT, Randomised Controlled Trial; HADS-D, Hospital Anxiety Depression Scale-Depression Subscale