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Perinatal Psychosocial Interventions

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Summary of the Major Research Project

Section A reviews and synthesises the current literature on perinatal psychosocial interventions. A systematic search identified 19 relevant studies that were critically evaluated and qualitatively synthesised. Interventions under investigation included home visitation, group work, and extended midwifery support. Randomised control trials, control trials, repeated measures trials (RCT) and qualitative studies were identified. Qualitative findings suggest perinatal psychosocial interventions improve women's feelings of satisfaction with care, social support, and their relationships with their babies and peers. Quantitative findings show women with increased psychosocial risk, but no mental health diagnosis, are likely to benefit from such interventions. Limitations of studies included high drop out rates, and large numbers of secondary analysis that increased the risk of bias; therefore results should be interpreted with caution.

Section B details the development of, and findings from, a pilot evaluation of an online training tool for student midwives. An online training tool was developed with the aim to better inform students of the impact of psychosocial factors on the attachment relationship between mother and baby, throughout the perinatal period. The tool was piloted through standardised quantitative measures and a qualitative feedback questionnaire. The initial pilot found training of this nature improved both knowledge and confidence of a sample of students and warrants further testing with a wider set of students.

Section C contains additional information and appendices.

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Section A: Perinatal Psychosocial Interventions: A Critical Review and Qualitative Synthesis of Current Research

Word Count: 8000 (plus 989)

Abstract

Background: psychological and social wellbeing is linked to a mother's ability to be responsive to her baby, and therefore has a bearing upon the infant's development. A number of different interventions are offered to mothers or pregnant women to improve their psychosocial wellbeing.

Objectives: to critique the evidence for perinatal psychosocial interventions for women.

Data sources: systematic searches of multiple electronic databases between 2000 and 2017 were undertaken using search terms.

Eligibly criteria: studies exploring the impact of psychosocial interventions on mother and/or infant outcomes during the perinatal period.

Appraisal and synthesis methods: quantitative studies were critically appraised using the consort (Schulz, Altman, & Moher, 2010) checklist. Qualitative studies were appraised using the Yardley (2000) guidelines.

Results: 19 papers were identified. 17 Studies were judged to be of moderate to high quality and two was judged to be of low quality. There were five group interventions, nine home visiting interventions and two clinic based interventions. Facilitators included psychologists, social workers, nurses and volunteers.

Conclusions: women qualitatively reported positive effects of intervention for social support, and better relationships. Quantitative findings were mixed; interventions often found small insignificant results. Significant results were limited to women with high numbers of psychosocial risk factors. Interventions facilitated by Midwives tended to

have successful results. Limitations include high attrition rates and many additional analyses performed increasing the risk of bias.

Implications: service providers should focus interventions on women who are likely to benefit most i.e. women with a number of risk factors but without a mental health diagnosis. Midwives should be encouraged to provide psychosocial interventions. Researchers should endeavour to understand the complicated web of factors that make up the mechanism of change in such interventions.

Keywords; Perinatal, Mothers, Intervention, Psychosocial, Review,

Introduction

Layout of review

Maternal psychosocial wellbeing significantly influences the development and wellbeing of children. A number of interventions exist, which aim to improve the psychosocial wellbeing of pregnant women and new mothers. This review first provides a background to the psychosocial approach and the impact of psychosocial resources on mothers and infants. The current political context is then highlighted. A systematic search is used to identify studies that are evidencing the use of psychosocial interventions. The individual interventions will be discussed and then compared with each other; similarities and differences will be highlighted and a methodological critique will be undertaken of the studies identified. The results will then be discussed in the context of the current evidence.

Whilst definitions of the perinatal period vary, this review defines it as the entire period of pregnancy and the first six weeks after birth (Fairbrother, Young, Janssen, Antony, & Tucker 2015). This definition also covers the average length of time that a midwife may have contact with a mother and her baby (Department of Health, 2010).

Both mothers-to-be and mothers will be referred to as 'mothers' throughout this review.

Defining 'Psychosocial'

The psychosocial approach looks at individuals in the context of psychological factors and the surrounding social environment that will impact their physical and mental wellness and their ability to function.

Psychosocial functioning describes the way in which a person is able to access and utilise psychological and social resources available to them (Sharan, 2012).

Examples of a mother's psychosocial resources include her mental health, her socio-economic status, accessibility of community and social support, presence of a supportive partner, financial stability, education, etc. (Sharan, 2012).

Predictably, psychosocial resources tend not to be sole entities that an individual possesses and which act in isolation; rather, there are significant correlations between them. For example, lack of education is linked to low socio-economic status (Tilak, 2002), which is in turn shown to be a risk factor for mental health difficulties (World Health Organisation, 2014).

Why do psychosocial resources matter for mothers and their babies?

It is widely recognised that infants thrive when their physical and emotional needs are met (Waldfogel, 2006). Infants with responsive mothers during the first year of life develop well physically, cognitively, and socio-emotionally (Lazinski, Shea, & Steiner, 2008, & Schore, 2001). In the longer term, there is evidence to suggest that these children go on to develop greater resilience to stress, form healthier relationships, have better school performance, and enjoy higher self-worth than children of unresponsive mothers (O'Connor, Heron, Golding, Beveridge, & Glover, 2002 & Karreman, & Vingerhoets, 2012).

For these physical and emotional needs to be met, parents (in particular the primary caregiver, which is often the mother) need to be responsive and attuned to their baby (Jonsson et al., 2001, & Puckering, McIntosh, Hickey, & Longford, 2010). It can be conceived, therefore, that the psychosocial resources available to a mother might be

directly linked to the development of their baby, and that this is mediated by the mother's mental health and, in turn, her accessible maternal responsiveness.

In other words, being in possession of good quality psychosocial resources is likely to mean that a mother is in a place of greater emotional, physical and social stability, which should improve her ability to be responsive and attuned to her baby.

Not only does the mother affect her baby, but the infant's functioning also influences the parent; i.e. a reciprocal relationship exists (Bowlby, 1969), and Bowlby defined this cyclical effect as an *attachment relationship*.

A securely attached infant feels confident that their mother is available to meet their needs. This bond of confidence enables them to use their mother as a safe base from which they are able explore the environment, secure in the knowledge that she will be available to be returned to in times of distress (Ainsworth, 1979; Main, & Cassidy, 1988; Fonagy, Gergely, & Target, 2007, & Van Ijzendoorn, Schuengel, & Bakermans-Kranenburg, 1999). An infant showing signs of a secure attachment is likely to help the mother in the development of her own identity as a parent. Thus, easing her anxiety; allowing her to become more responsive to both the child's immediate and longer-term needs and, therefore, decreasing the risk of any social and economic burden to both her own family and the wider community (Nelson, Kushlev, & Lyubomirsky, 2014; Seibold, 2004).

Secure attachment and good psychosocial functioning are predictors of future parenting capacity and, therefore, the risk of emotional deprivation being transmitted across generations is increased if a mother or infant is psychosocially vulnerable (Stein, Lu & Gelberg, 2000; Richards, Merrill & Baksh, 2011).

The notion of a reciprocal relationship has also been shown to extend to the bond between the mother and her unborn baby (Lumley, 1990; Glover & Capron,

2017). Attributing the unborn baby with characteristics, behaviours and feelings, as most mothers do, begins to identify the unborn baby as having their own distinct needs and personality separate from the mother. This is a key criterion in defining a secure attachment once the baby is born (Bowlby, 1969, & Doan & Zimmerman, 2003). Building a strong relationship between mother and baby during pregnancy i.e. prenatal attachment has been found to be a predictor of postnatal attachment (Brandon, Pitts, Denton, Stringer, & Evans, 2009, & Muller, 1996).

Political and policy context

The significance of psychosocial issues in perinatal mental health has percolated into official policy. The Healthy Child document (Department of Health, 2009) sets out Department of Health standards for providing preventive universal services to children and their families. The aim being to build strong parent–child attachment and positive parenting, which will in turn help to keep children healthy and safe. The programme also aims to ensure early intervention to address 'developmental delay, abnormalities and ill health, and concerns about safety' (Department of Health, 2009).

Government initiatives such as '1001 Critical Days' (Leadsom, Field, Burstow, & Lucas, 2013) have sought to increase awareness of the need for services for women throughout the perinatal period, and highlighting the importance of early intervention.

Within the vast array of psychosocial factors affecting outcomes, the effect of mental health has recently been a priority for researchers, policy makers, commissioners, and government (Department of Health, [DH] 2014). Mental health is often used as a proxy for the many variables under investigation within the 'umbrella' of the term psychosocial. Bauer, Parsonage, Knapp, Iemmi, and Adelaja, (2014)

suggest that, taken together, perinatal depression, anxiety and psychosis carry a total long-term cost to society of about £8.1 billion for each one-year cohort of births in the UK. This is equivalent to a cost of just under £10,000 for every single birth in the country (Bauer et al., 2014).

The Pan-London Care Pathway document (Green, Miele, & Protti, 2015) provides a clear structure for the care of women with mental health difficulties in the perinatal period. The document recommends different care options depending on the severity of the difficulties and where women are in their motherhood journeys. The pathways emphasise the impact of poor psychosocial resources on womens' mental health and the authors present a specific pathway to guide professionals in improving psychosocial functioning for this population of women (Green, Miele, & Protti, 2015).

Within statutory services, responsibility for perinatal psychosocial health falls mostly within the remit of the NHS, perhaps due to midwives being the front-line professionals with access to this population. Guidance from the Royal College of Psychiatrists (2012) highlighted the need for better perinatal mental healthcare, and the Royal College of Midwives (2014) reported that 48% of midwifery services did not have any specific midwifery posts for mental health. These reports prompted a government mandate in 2014 to improve perinatal mental healthcare; specifically by providing midwives with enough training to allow every woman that required it, access to a specialist mental health midwife (Royal College of Midwives, 2014). Targets set for specialist perinatal services by 2017 have yet to be officially reviewed. However, evidence suggests the majority of midwives still feel under-skilled, and overwhelmed when supporting vulnerable women with psychosocial difficulties, especially those with emerging mental health difficulties (Ashford, Ayers, & Olander, 2017; Brady, et al., 2017; McGlone, Hollins Martin, & Furber, 2016). In 2016, the Department of

Health proposed a new fund for perinatal community services with new targets being set for 2020 (Department of Health [DH], 2016).

Perinatal psychosocial models

Previously, parenting interventions had focused on improving attitudes and practice of parents, and infant behaviour (Barlow, Coren, and Stewart-Brown, 2002). Health interventions were often focussed on single physical risk factors such as smoking, physical health, and obesity etc. Evidence of the efficacy of these health interventions suggested they had limited success; (Bogaerts et al., 2013; Dodd et al., 2014) potentially due to the complex nature of psychosocial risk. Risk factors appear to be correlated with each other and therefore it is likely that women need holistic interventions that focus on multiple risk factors (Milgrom et al, 2011).

Perhaps as a result of the clear demand for more holistic services, models such as the 'Family Partnership Model' were commissioned. The Family Partnership Model is an approach based on a model of the 'helping process' to enable parents and families to overcome their difficulties, build strengths and resilience and fulfil their goals more effectively. This model is disseminated via training, research, consultancy and supervision. Positive impact of the model has been suggested for the developmental progress of children (e.g. Davis & Rushton, 1991; APIP, 1998), parent-child interaction (Barlow et al, 2007; Puura et al, 2005) and the psychological functioning of parents, families and children (e.g. Davis & Rushton, 1991 & Davis & Spurr, 1998).

Home Start is a UK charity that offers families with a child under five years of age support through the use of volunteers. Long term (10 year) follow of this model suggests improvement in feelings of competence, consistent and non-rejecting parenting behaviour, and internalizing and externalizing problem behaviours in children (Van Aar, Asscher, Zijlstra, Deković, & Hoffenaar, 2015).

The Solihull approach is a non-for-profit organisation that promotes positive parenting and emotional wellbeing through training and resources for practitioners working with children and families, online courses and face-to-face groups for parents. They also provide training for schools and resources for companies. The organisation runs a parenting group; 'Understanding Your Child's Behaviours' which aims to improve parents and carers understanding of the psychological processes behind child behaviour from 0-18 years of age, and therefore improve the capacity of parents to manage difficult behaviour (Johnson, & Wilson, 2012).

In 2003, the government committed to delivering 3,500 children's centres across the country by 2010. Sure Start children's centres were designed to deliver a place in every community that would provide integrated care and services for young children and their families, with a particular focus on closing the achievement gap for children from disadvantaged backgrounds.

Evidence of the efficacy of these centres is mixed, a relatively recent study suggested there were benefits for parents-child interactions and child behaviour but that the most disadvantaged 5% of families did not benefit from the centres (Rutter, 2006).

What is missing from the evidence?

There are now many interventions that aim to support mothers in a holistic way, for example: 'Mellow Babies' (Puckering, McIntosh, Hickey, & Longford, 2010), and 'Circle of Security' (Mercer, 2015). These Interventions work with mothers and children after the time period used by this review as the 'perinatal period'. Evidence of these interventions suggests small but insignificant improvements in outcomes (Mercer, 2015; Puckering, McIntosh, Hickey, & Longford, 2010).

Up to date reviews of interventions specifically targeting psychosocial health that *begin* in the perinatal period are lacking (Barlow, Coren, & Stewart-Brown, 2002 & Dennis & Doswell, 2005). It is well established that during this period i.e. pregnancy and the first six weeks post birth, women are likely to be in an emotionally, physically, and socially vulnerable position. This review aims to look at interventions that begin in this period to explore if supporting women in this time and beyond has positive outcomes for mothers and infants.

Qualitative studies provide data that can help to explore the mechanisms of change of an intervention (Bryman, 2006). These types of studies are not likely to be included in large-scale systematic reviews that tend to focus on the overall effect of randomised controlled trials (RCTs).

Rationale for the review

The critical nature of the relationship between a mother's psychosocial wellbeing, her ability to parent effectively and outcomes for mother, baby and the wider society has been established. Interventions to improve psychosocial functioning are taking place amid stretched community resources, underfunded services and professionals who report feeling under-skilled and overwhelmed by the task they face (Ridings, 2012). However, funding is increasing in perinatal care and the Department of Health has begun to fund NHS Trusts to develop and expand perinatal services, with aims to greatly improve the mental health arm of services by 2020 (Department of Health, 2014). As services expand, it is important that up-to-date information about the interventions currently being offered to this population is available. Having reliable evaluation of interventions will help to shape and determine the content of future interventions.

This will improve consistency of care across care services and sectors, it will also be cost effective in reducing duplication of work, and enable efficient allocation of the most appropriate care to women in need.

Scope of review

It is acknowledged that a variety of individuals (fathers, grandparents, foster families, adoptive families) take on care-giving roles. However, a birth mother is in the unique role of having carried her baby for forty weeks, and continues to be the most likely individual to provide the majority of care. This review therefore evaluates interventions targeted exclusively at birth mothers.

Whilst interventions exist that indirectly target the mother, by focusing on her partner or other family relationships for example, these are also excluded from the scope of this review.

The search strategy was restricted to studies published after 2000 to maximise the focus on recent and current interventions.

Overarching research question

A critical review of the extant research on perinatal psychosocial interventions and the examination of the effectiveness of such interventions for pregnant women or new mothers.

Research questions.

1. Which psychosocial interventions are being offered to women during the perinatal period?
2. What specific outcomes do these interventions target and are they effective?
3. Which theories and concepts underpin these interventions?
4. What are women's experiences of these interventions?

Method

Different methodologies were assessed for their ability to answer the research question proposed. Grant and Booth (2009) describe the purpose of a critical review to evaluate the strengths and weaknesses of the body of existing evidence around a specific topic. Therefore a critical review was used to analysis and synthesise material to understand the current body of evidence for psychosocial intervention for women in the perinatal period.

Eligibility criteria

All studies identified in the electronic search were screened for relevance to the overarching research question using the following criteria:

Inclusion criteria.

- Face to face interventions focussed on multiple psychosocial factors e.g. mental health, social support, social inequality, relationship issues.
- Interventions for women that begin in the perinatal period. Interventions that commence within the defined period but which continue to run beyond the perinatal end-point (as defined on page 9) have been included. Exclusion of these studies was considered but given the theoretical importance of the period immediately before and after birth, excluding studies information pertaining to effects accrued in this time period was deemed to be lacking in rigour.
- Studies using quantitative or qualitative outcome measures for babies and/or mothers.

Exclusion criteria.

- Studies that exclusively provide information on physical pregnancy outcomes such as pre-term birth.
- Interventions targeting specific populations of mothers for example; mothers with premature babies, addiction issues, or within prison populations, as these mothers are likely to need specific interventions.

As the review aims to be clinically relevant to women within the UK health and social care system, it was deemed that interventions taking place in developing countries were likely to be situated in a context that is widely different to the current healthcare system in the UK and, therefore, the applicability of these studies is likely to be minimal. These studies were therefore excluded.

Search strategy

Databases Psycinfo, Medline, Cinahl, and Embase were searched using the following search terms

- Psychosocial OR psycho social
- AND
- Intervention OR treatment OR Programme OR support
- AND
- Mother* OR mum*
- AND
- Pregnan* OR perinatal OR peri-natal OR prenatal OR pre-natal OR postnatal OR post-natal OR expect*

Additional search procedures. Reviews carried out in similar areas have discussed the difficulties with search strategies yielding relevant results. Barlow, Coren

and Stewart-Brown (2002) discuss difficulties with a filtered funneled search omitting many relevant papers and a wider search producing unmanageable data.

As an adjunct to searching the electronic databases, the reference lists of all relevant studies were also searched in order to identify potentially relevant citations that might have been missed in the electronic database search. A search of the Internet was performed using the Google platform to identify interventions that may have been missed in the academic search. Any interventions found in this way were then searched for on the Psycinfo database for relevant studies of their effectiveness. Many parenting groups aimed at mothers were identified in the Google search, however the majority of these interventions did not have an evidence base or, indeed record any specific intended or actual outcomes. Experts in the field of midwifery training and lead researchers of the identified interventions were also contacted in case they had material missed by the researcher. All papers obtained in this manner were subjected to screening for relevance, utilising the above inclusion and exclusion criteria. Unpublished dissertations were also included in the search strategy.

Quality appraisal

The literature acquired from the search was reviewed in turn, using the appropriate quality assessment described below.

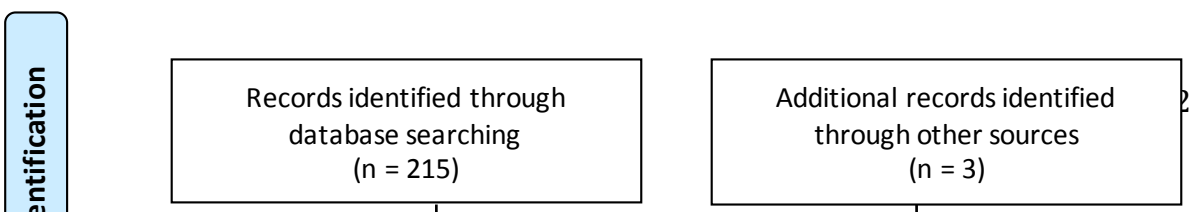
Randomised control trials. The Consort checklist (Schulz, Altman, & Moher, 2010) was used to discuss the quality of reporting of the RCTs presented in this review. Studies that include 1-12 items from the checklist were rated as 'low quality.' Studies that include 13-24 items from the checklist were rated as 'medium quality'. Studies that include 25-34 items from the checklist were rated as 'high quality.' (See appendix for Consort checklists).

Qualitative studies. Qualitative studies were addressed using the guidelines provided by Yardley (2000). These guidelines suggest four areas of evaluation for quality assessment: sensitivity to context, commitment and rigour, transparency and coherence, and impact and importance. Each of these criteria has been discussed descriptively.

Synthesis

Data were synthesised by comparing findings from all papers. The reviewer maintained an awareness of identifying both similarities and differences across the studies. Conclusions were drawn in terms of implications for research and practice.

PRISMA 2009 Flow Diagram



(Moher, Liberati, Tetzlaff, Altman, 2009).

Table one

Details of reviewed studies

Author /Date	Aims and hypothesis	Sample	Design and analysis	Outcomes measured	Key findings	Quality appraisal rating
Ammaniti et al., 2006	Analyse the efficacy of early intervention in enhancing the quality of mother–infant interaction in psychosocial risk and depressive risk mother–infant dyads.	36 women at risk of depression, 34 women with psychosocial risk and 40 women with low risk for both (n=110) Ages: 22-43	RCT, each risk group was split into intervention and controls	Mother-infant interaction, maternal representation, attachment	Impact on mother-infant interaction was found after six months of intervention	Medium
Birtwell, Hammond, & Puckering, 2013	To understand experiences of pregnancy and a group intervention for a group of vulnerable women	8 women, ages:17-37 between 14 and 40 weeks gestation, 5 already had children	IPA – exploring the sense that participants make of their experiences and the personal meaning of these experiences to the participants	Qualitative accounts of women's experiences	Key themes: A time of reflection, my body being taken over, pregnancy is an emotional rollercoaster, relationships are important and separating identities.	High

Breustedt & Puckering, 2013	To explore participants' experiences of taking part in Mellow Bumps	4 participants had completed the Mellow Bumps antenatal intervention within the last 18 months Ages: 19-38	IPA. The analytic process was guided by the sequences suggested by Barker et al (2002).	Women's phenomenological experience of the group	Key themes 1) Personal growth, 2) bonding.	High
Brugha et al., 2000	Hypothesis: intervention group women at increased risk of post-natal depression would be less likely to be depressed at 3 months postnatally compared to controls	209 first time mothers at risk of PND over the age of 16	Pragmatic RCT	PND, social support	No difference in outcomes between groups.	Medium
Cohen, Lisles, Williams, Brunsdon, Batstone, 2011	To evaluate the benefits of additional midwifery support for teenage mothers, particularly on the effect sizes that might be produced over a range of outcome measures.	164 women aged between 15 and 19	RCT; extended home visiting vs usual care. ITT	Self-esteem, social support, smoking, physical activity, accessing community resources	No significant differences between groups but women qualitatively benefitted and intervention group made better use of non- NHS services	High

Cupples et al., 2011	To determine the effect of a peer-mentoring programme	343 full time mothers living in socio-economically deprived areas aged between 16 and 30 with no recognised comorbid diagnosis	RCT. Peer mentor intervention vs usual care.	Mothers physical and mental wellbeing, infant development and growth	No significant differences between groups in primary outcomes, however mothers reported qualitative benefit of intervention and mentors gained skills and confidence	High
Darwin, McGowan, & Edozien, 2013	To consider how psychosocial assessment in the perinatal period may act as an intervention.	22 women, ages: 22-39. 77% white British 59% multiparous	QFA systematic stages that promote rigour: familiarisation, identification of a theoretical framework, indexing, charting, and mapping and interpretation	Reactivity of assessment and potential of assessment as intervention.	Assessment was found to provide intervention, depending on interviewer style, length of involvement, and discussion of risk origins. And coping strategies.	High
Dugravier et al., 2013	To evaluate the effectiveness of the program in terms of promoting infant mental health, reducing PND and promoting parenting skills.	440, first time mothers under the age of 26 (mean age 22.3)	RCT	Depression, quality of home environment and infant psychopathology at age 2	Impact of intervention on subgroup of women with high n of risk factors.	High

Elliott et al., 2000	To explore in an intervention can reduce the 3 month period prevalence of PND in mothers at risk of PND & an early pregnancy questionnaire can predict mothers at risk of PND	99 first and second time mothers	CT. women were allocated to groups based on expected date of delivery	Depression symptoms	Depression symptoms were reduced after intervention for first time mothers	Medium
Ickoviks et al., 2011	To examine the psychosocial impact of Centering pregnancy plus. Hypothesis: increased self-esteem and social support as well as decreased stress, social conflict and depression the biggest effect for high risk groups: younger age, African-Americans and those 'highest in stress'.	1047 women without any high risk physical risks i.e. diabetes	3 arm RCT; centring pregnancy, centring pregnancy plus (intervention), and usual care. ITT	Stress, social support, self-esteem, social conflict, depression	no overall differences in psychosocial function; yet, women with high number of risk factors reported significantly increased self-esteem, decreased stress and social conflict in the third trimester of pregnancy; social conflict and depression were significantly lower 1-year postpartum	High

Kemp et al., 2011	To investigate the impact of intervention on the health, development and well-being of the child, mother and family.	208 women under the age of 19 with at least one psychosocial risk factor	RCT, extended home visiting vs treatment as usual	Mother-infant interaction, quality of home environment and infant development	There were no overall group differences, some differences on specific items such as longer breastfeeding in the intervention group	High
MacArthur et al., 2002	To compare the effects of extended midwifery care on women's health with those of present care.	2064 women from 36 GP practices	Cluster RCT extended care vs usual care	General physical and mental health, and depression, and satisfaction with care.	Mental health scores were significantly improved for the intervention group. No differences for physical health	High
Miller, 2008	To investigate if the intervention increases reflective capacity of mothers?	21 first-time mothers aged between 15 and 25, with environmental, financial, and social stressors.	Mixed methods repeated measures design	Maternal reflective functioning		
Morrell, Spiby, Stewart, Walters, & Morgan, 2000	assess whether additional postnatal support provided by trained community postnatal support workers could have a positive effect on women's general	623 women that were 32 weeks gestation were allocated to intervention or control group	RCT. ITT	General health, PND, social support, breast feeding, user satisfaction	No difference in physical or mental health scores, or breastfeeding rates. Increased satisfaction for women	High

	health and cost savings to the NHS					
Olds, 2006	To summarise three RCT studies evidencing the impact of the NFP in Elmira, Memphis, and Denver.	Elmira: 400 primarily white women, Memphis: 1,138 primarily afro-Caribbean women. Denver:735 Hispanic women	Qualitative summary. Individual studies were RCTs; Extended home visit vs treatment as usual	Improve pregnancy outcomes, child's health and development and to improve maternal life	Improvements seen for parental care of the child and better infant emotional and language development; and the improvement of maternal life course compared to controls.	Low
Reid Glazener, Murray, & Taylor, 2002	To ascertain the effects of providing additional postnatal group support or self-help manuals on women's psychological and physical health	1000 first time mothers	Pragmatic RCT. ITT 2 × 2 factorial design.	Physical and mental health, social support and satisfaction	No differences were found for health or social support between groups. Women reported finding the packs useful	High
Robling et al., 2016	Aimed to establish the effectiveness of FNP when delivered in a broadly based, publicly funded, health-care setting.	823 first time mothers under 19.	RCT - pragmatic, open-label, individually randomised controlled trial; intervention vs usual care. ITT	biomarker-calibrated self-reported tobacco use by the mother at late pregnancy, birthweight of the baby, the proportion of women with a second pregnancy within 24 months post-partum, and emergency	No differences for primary outcomes were found between groups.	High

				attendances and hospital admissions for the child within 24 months post-partum.		
Sadler et al (2013)	To evaluate impact of minding the baby on mother and infant outcomes	105 mothers between 14-25 years old	RCT	Appointments attended, subsequent pregnancy, use of child protection services, attachment relationship	Significant impact of intervention on clinic attendance but no other domains	High
Sierau et al., 2016	Analysing the effects of an adapted version of the NFP program in Germany.	755 women who had at least one socio-economic risk factor and an additional psychosocial risk factor.	RCT, extended home visiting vs treatment as usual	Family environment, maternal competencies, and child development.	Positive treatment effects on parental self-efficacy, and marginally significant effects on social support, and knowledge on child rearing.	High

Results

Search Process

The initial search yielded 215 studies. Two further studies were found through a reference list search, and one was obtained by emailing experts in the field. 16 studies were removed due to duplication, 167 studies were then excluded after a title and abstract review. A full text review of 32 studies excluded 13 studies. At the time of submission one paper had not been obtained for full text review and was therefore excluded. Appendix 1 references excluded studies from the full text review. The PRISMA tool, in diagram 1 above, shows the pathway of the studies as they were subject to the selection criteria.

The full text review of the papers resulted in 19 papers being included in the final review. See Table 1 for details of included studies.

Studies are described in terms of aims and outcomes of intervention, and limitations of study design are discussed in methodological critiques. Finally, studies are compared and contrasted in the context of the initial research questions.

Group interventions (RCTs)

Preparing for Pregnancy A psychologist and health visitor ran 5 monthly antenatal group sessions from 24 weeks of pregnancy and six postnatal monthly sessions. Session themes included parental expectations of bringing the baby home, mental health, and abilities of the new born. The facilitators encouraged peer discussion and gradually reduced their input until the groups were mainly peer led.

Elliot et al (2000). The authors undertook a non – randomized controlled trial in the UK, where recruitment and allocation were determined by expected birth date. This study used a treatment-as-usual control group. A positive impact was found for subgroups of women who had some depressive symptoms, but did not meet criteria for a postnatal depression diagnosis. Limitations of this study included many post hoc analyses, which increases the changes of bias.

Support group and 'New Lives Magazine. This intervention consisted of a self-help manual and a support group. The manual provided supportive information and advice geared to new mothers and babies (mother's health, sleep and support needs, baby crying etc).

The groups were run for two hours on a weekly basis. Two midwives who had experience with group work facilitated the sessions. Content was dependant on the attendees; however, women were encouraged to talk about issues that related to their own health and wellbeing.

Reid et al (2002). The Scottish study investigated depression symptoms, mental and physical wellbeing and social support. The authors used a pragmatic randomised controlled trial and found no difference between the intervention and treatment as usual control groups, however qualitative feedback suggested women found the intervention useful. This study was limited by low uptake of intervention and therefore sample size.

Preparing for Parenthood (PFP). The Preparing for Parenthood programme (PFP) was a weekly 2 hour-long six-week prenatal class held for 6 weeks with a post-natal reunion session when the infants were approximately 8 weeks old. Nurses and occupational therapists delivered PFP through a manual; each session included practical

tips, psycho-education, role-plays, shared discussion about being a mother and caring for a baby etc.

Brugha et al (2000). A pragmatic randomized controlled trial in the UK found no quantitative differences between intervention or control group (routine antenatal care), however women reported enjoying the group and finding it beneficial. Limitations included high attrition rates, and a lack of training for facilitators.

Centering Pregnancy Plus. The Centering Pregnancy Plus groups ran from 18 weeks gestation to birth, weekly, for two hours, by a trained prenatal care provider (e.g. midwife) who delivered the intervention through a manual. Each group session comprised of a practical and social element; mothers were physically examined, psychoeducation was given, and supportive group discussion was facilitated.

Ickovics et al (2011). The study based in California, (USA) was an RCT with three arms; a treatment as usual control group, the original centering pregnancy intervention and the centering pregnancy plus option. They found no significant differences in psychosocial function between groups; however, a subgroup of women with high levels of psychosocial stress reported significantly increased self-esteem, decreased stress and social conflict in the third trimester of pregnancy and at one year follow-up, social conflict and depression were significantly lower compared to controls. Limitations were the number of secondary analyses undertaken and the risk of type one error.

Group interventions (qualitative studies)

Mellow Bumps. This was a six-week antenatal group that aimed to strengthen relationships between mothers and services, improve maternal wellbeing, reduce stress, and promote sensitive and responsive interactions with the baby in utero. Content of the sessions was predetermined and included education in infant development and practical exercises to encourage bonding with the baby based on attachment theory, behavioural strategies and psycho-education. The intervention placed a strong emphasis on engagement through providing transport, childcare and refreshments, two studies exploring the evidence for mellow bumps are included in this review:

Birtwell et al., (2015). An interpretative phenomenological analysis was used to collect and analyse data from eight women in the UK that had taken part in the intervention. Five overarching themes were extracted:

'A time of reflection'. Women felt able to reflect on the past and its relationship to the future, as well as pregnancy being an opportunity to do things differently.

'My body being different'. Women discussed the physical and emotional demands of their changing bodies, and the lack of control they felt they had over their bodies. The intervention was seen as a supportive environment to share anxieties regarding uncertainty of pregnancy and the labour process. The intervention was also described as helping women to prioritise their needs.

'Pregnancy is an emotional rollercoaster'. Women tended to report feeling more emotional during pregnancy and this left them feeling vulnerable, the group was seen as a safe space to explore these feelings and to access practical ways to feel more in control for example; the relaxation exercises.

'Relationships are important'. The Mellow Bumps intervention was reported to help relationship development with the baby, partners, and siblings. Women also reported some feelings of anxiety and guilt when thinking about the impact of their pregnancy on their other children.

'*Separating identities'*. The intervention was seen to be supportive as women journeyed through the process of taking on the identity of a mother, it was suggested that the group may help women to build healthy representations of themselves as mothers, despite adversities in their background.

Limitations of the study included a small sample size and combining data from a heterogeneous sample; i.e. women with different histories, ages, gestational ages etc. The sample all agreed to be interviewed and therefore could be viewed as self-selecting. Data obtained was subjective and limited to conscious narratives, there was also a lack of information regarding facilitators' backgrounds.

Breustedt and Puckering (2013). This UK study explored the views of four women, in relation to their experiences of the Mellow Bumps intervention, using in depth interviews. Transcripts were analysed using a phenomenological perspective. Two overall themes were found; the intervention was perceived as a time for personal growth and bonding.

'Personal growth'. Women discussed the intervention being non-judgemental and, therefore barriers to engagement were broken down. Women reported feeling able to address taboo subjects such as young motherhood and social disadvantage. Women reported feeling more socially connected as a result of the group, and this had an impact on mood and adjustment to motherhood.

'Bonding'. Women reported the group aided bonding with their babies and also with their peers, this then had an impact on the women's ability to adopt practical strategies and learn about infant development. Limitations of the study were the small number of participants and the subjective analytical process.

Individual interventions

Moments. This intervention took place in Northern Ireland. It was a peer mentor intervention where women received telephone calls and home visits fortnightly during pregnancy and monthly for the following year from their mentors. The content of the intervention was tailored to the needs of the mother. The Mentors were trained women of a similar social background and of a similar age with a young child.

Cupples et al (2011). A RCT was completed in Northern Ireland with a usual care control group. At one-year, infant psychomotor and mental development were assessed, however no differences were found between groups.

Women qualitatively valued advice given in the context of their mentor's personal experience of child rearing. Mentors also reported feeling skilled in health-related knowledge, and gaining new employment opportunities.

Limitations of this study included high attrition rates, insufficiently sensitive outcome measures, and a lack of mentor fidelity checks.

Home visiting interventions (RCTs)

Community support workers. Support workers provided practical and emotional support; including helping the mother gain confidence in caring for her baby and reinforcing midwifery advice on infant feeding postnatally. All the women in the trial were offered postnatal care at home by community midwives, the intervention group were also offered 10 visits from a support worker for up to three hours per day in the first 28 postnatal days.

Morrell et al (2000) Results from this UK RCT indicated no differences in health outcomes between groups (intervention vs usual care control group), however women in the intervention arm reported higher satisfaction with care. The study also looked at any spending saved from providing the intervention; the intervention was not found to save money on NHS or social care resources. Limitations of the study include self-selecting participants and a lack of information regarding the specifics of the intervention

Miller Early Childhood Sustained Home Visiting Programme (MECSH). Women in this home visiting intervention received an average of 16.3 visits that lasted between 60 and 90 minutes. The intervention was delivered by a child health nurse and began at 26 weeks of pregnancy. The content of the visits was flexible and tailored to the specific needs of the mother, and after birth, the infant. As part of the intervention women were encouraged to access a 12 session parenting course, and community groups and activities. Goals of the intervention were to support women through the transition to motherhood, improve maternal and infant wellbeing, and establish access to community resources.

Kemp et al (2001). Authors studied mother-baby interaction in the Australian clinic using a standardized measure. They found no difference between intervention

and treatment as usual control groups. Limitations of this study were the small sample size which limited the power of analysis and a high drop-out rate of participants.

Extended Midwifery Intervention. Midwives extended their role with women for three months; interventions were tailored to women's needs for content and number of interactions. To ensure that specific needs could be identified, even if not spontaneously reported by the women or observed by the midwife, a symptom checklist was used at the first visit and needs were categorized into immediate or longer term.

MacArthur et al (2002). This UK RCT found mental health outcomes were improved in the intervention group compared to a usual care control group. However no physical health differences were found between groups, women in the intervention group were more likely to report care was 'better than expected' on a satisfaction scale. Limitations of the study included the midwives being volunteers and therefore generalizability needs to be made with caution, also, the design of the study (cluster randomization) lends itself to recruitment bias.

Social worker/psychologist home visitation. This intervention was carried out in Italy.

Women were visited at home from eight months of pregnancy, by social workers and psychologists, weekly for the first half of the intervention and then every two weeks. The aims of the intervention were to promote child development, improve parenting practices, and facilitate the parent infant relationship through facilitating mothers' potential. The intervention was based on attachment theory, developmental theory and early intervention theory and preventative models.

Ammaniti et al (2006). Researchers in Italy split their sample into 3 groups; women at risk of depression, women with psychosocial risk and women with low risk in both of these areas. Women in each group were randomly allocated to either the intervention or control arm of the study.

The study showed no overall difference in maternal representations between intervention and control group, however there were significant differences between groups in particular subscales, namely the 'representations of self and infant', 'maternal differentiation', 'maternal openness to change', and 'perception of child' subscales. Authors used semi-structured interviews and developed an observational scale to assess the attachment relationship between mother and infant. There was an effect of intervention found for mother-infant interaction at 6 and 12 months.

The main limitation of the study is the lack of intention to treat analysis; the study has a relatively high drop-out rate and therefore the risk of participant bias is increased.

Parenting skills and attachment in early childhood (CAPEDP). Women were visited at home by psychologists 14 times beginning at 20 weeks of pregnancy. The intervention was manualised and focussed on parenting skills, education about perinatal mental health, community resources and promoting quality attachment development.

Dugravier et al (2013). 440 women in France were randomly allocated into two groups. The intervention showed a positive impact on depressive symptoms in a subgroup of women that had some depressive symptoms but did not meet criteria for a postnatal depression diagnosis compared to a treatment as usual control group. The

main limitation of the study was the level of attrition (36.8%). Other limitations were lack of programme implementation fidelity, researcher bias due to data collector's knowledge of women that received home visitation and the use of self-report measures.

Nurse Family Partnership, Pro-Kind and Building Blocks. The USA Nurse Family Partnership programme (Olds, 2006) was adapted for the German population under the title 'pro-kind' (Sierau et al., 2016) and for the UK population under the title 'Building Blocks' (Robling et al., 2016) In the UK the intervention is generally known under the title 'Family-Nurse partnership'.

The intervention aimed to improve maternal prenatal health, family functioning, parenting competencies, and economic self-sufficiency. Midwives, family nurses, and social education workers visited mothers weekly for the first four weeks after intake and post birth, and then every two weeks and monthly for the final six months of the intervention for a total of 64 sessions. Session guidelines were provided however facilitators were encouraged to react flexibly to mothers' needs.

Olds (2006). This USA study was a qualitative review of three RCTs that had been previously carried out with different populations living in different contexts; Memphis, Denver and Elmira. Results from these trials indicated that the program had been successful in achieving two of its most important goals; the improvement of parental care of the child, and the improvement of maternal life course. The main limitation of this study was its design, the individual studies were not assessed for quality nor were any limitations discussed.

Sierau et al (2016). In this German study authors considered implementation theory, in addition to theories underpinning the original NFP programme. The

intervention group was compared to a wait list control group (n=755) and showed an effect on maternally reported child cognitive development, language development, and mental development in a specifically high risk sample of children. The authors used a range of self-report questionnaires to explore feelings of attachment, mother-child affectivity and mother-child responsiveness. The intervention group did report a small but significant increase in feelings of attachment but there was no difference found for mother-child affectivity and mother-child responsiveness. Limitations of this study included high drop-out rates, self-reported measures and no follow up data.

Robling et al (2016). Authors conducted a pragmatic trial in England. First-time mothers under the age of 19 were invited to join the study. When compared to a treatment as usual randomized controlled group authors found no differences for smoking cessation, birth weight, rates of second pregnancies, or emergency hospital visits for the infant. There were differences found for maternal self-efficacy, social support, and relationship quality, Limitations of this study were the large number of analyses carried out.

Minding the baby. This intervention offers young, first-time mums support to help them develop a positive relationship and secure bond with their baby. The intervention consists of weekly home visits starting in the 7th month of pregnancy and continuing until a child's 1st birthday. After that, visits are once every 2 weeks until the baby's 2nd birthday. The intervention aims to help mums to recognise and respond to their baby's feelings and needs (also called 'maternal reflective capacities'). The intervention is run by nurse practitioners, social workers or therapists. These practioners also give practical support on feeding tips, help with housing and financial advice. In

the UK the intervention is being endorsed by the NSPCC and is currently being trialed in Glasgow, Sheffield and York.

Miller, (2008)

This USA dissertation study measured the impact of intervention on mothers' reflective functioning ability. 21 first-time mothers between the ages of 15 and 25, all of whom were at high risk for parenting difficulties due to environmental, financial, and social stressor participated in the evaluation. Results suggested a significant impact of intervention.

Sadler et al (2013) intervention families in this USA study were more likely to be on track with immunisation schedules at 12 months, had lower rates of rapid subsequent childbearing, and were less likely to be referred to child protective services. In addition, mother-infant interactions were less likely to be disrupted at 4 months when mothers were teenagers, and all intervention infants were more likely to be securely attached and less likely to be disorganised in relation to attachment at 1 year of age. Finally, mothers' capacity to reflect on their own and their child's experience improved over the course of the intervention in the most high-risk mothers. Limitations include high levels of attrition.

Clinic interventions (RCT)

Extended midwifery support. This intervention was aimed at pregnant teenagers with aims to improve self-esteem, social support, physical activity and smoking status. Midwives targeted teenagers at usual clinic appointments and provided support and psycho-education. Women were encouraged to access community groups

and resources such as Sure Start. Information regarding peer support groups was provided and women were referred to specialist services if they required them.

Cohen et al (2016). Authors of this UK RCT reported small insignificant benefits for the intervention group in self-esteem, and physical activity compared to treatment as usual control group, women's qualitative accounts suggest they found the intervention helpful. Limitations of this study include small sample size, and lack of measurement of social support.

Clinic interventions (Qualitative)

Assessment as intervention. Darwin et al (2013). This UK study qualitatively analysed women's experiences of an in-depth interview assessment process carried out by researchers, the authors suggested that intervention could be provided through the assessment process. Women described feeling their experiences were validated, they felt listened to and were more motivated to access support compared to women that did not complete an in depth interview. Limitations include the lack of objective measures and the small sample size.

Methodological Critique

Studies were assessed for reporting quality using checklists described in the methods section. Results of the quality assessment are presented below using specific categories taken from the relevant quality assessment measure. Checklists for each study are in appendix 1 and the overall quality rating for each study is presented in table 1.

Randomised controlled trials/Controlled trial

Randomisation. 12 studies randomised their participants; all of the studies except Ickovics et al. (2011) compared intervention to a 'usual care' control group. Ickovicks et al. (2011) used three groups; a usual care control, the intervention under investigation (pregnancy care plus) and a previous version of the intervention as an active control group (centering pregnancy). Ammaniti et al. (2006) split their participants into three groups related to level of risk of depression. Each risk group was then randomly split into a control and intervention group. Elliot et al. (2000) did not randomise but instead assigned participants to group with respect to due date. Miller (2008) had one group and used a pre/post repeated measured design.

Blinding. It was not possible to blind participants or intervention facilitators to treatment arm in these studies. However, researchers were blinded to various degrees across the studies; i.e. data collectors were blinded (Cupples et al., 2011; Kemp et al., 2011; Sierau et al.,2016), and data analysers were blinded (Ammaniti et al., 2006; Cohen et al., 2011; Dugravier et al., 2013 Sierau et al.,2016). Morrell blinded all parties pre- allocation Brugha et al. (2000) and Ickovicks et al., 2011 did not disclose any blinding.

Participant drop out/Missing data. There were high numbers of drop out rate across all trials. Details of specific Reported participant drop-out rates are provided in appendix 3.

In order to limit bias from attrition two studies used a partial 'intention-to-treat' model for some analyses (Dugravier et al., 2013; Kemp et al., 2011). Seven studies used an intention to treat model on all analysis carried out (Brugha et al., 2000; Cupples et al., 2011; Elliot et al., 2000; Ickovicks et al., 2011; MacArthur et al., 2002; Morrell et al., 2000; Reid et al., 2002 & Robling et al., 2016). Three studies do not provide any information on steps taken to decrease risk of bias due to missing data (Ammaniti et al., 2006; Cohen et al., 2011; Sierau et al., 2016).

Qualitative studies (using Yardley criteria)

Sensitivity to context. Birtwell et al. (2013) and Breustedt and Puckering (2013) provided a review of the current literature on this topic. They discussed the implications of qualitative research and noted both its advantages and limitations, taking into account participants' perspectives and ethical issues. Darwin et al. (2013) discussed the current context of antenatal research and care. Ethical considerations were discussed and the rationale for the current study was given.

Commitment and rigour. Detailed descriptions of data collection were reported in all three studies, Themes extracted from data were presented by all studies. No studies provided coded transcripts. However, this was likely to be due to journal criteria for publication. Depth and breadth of analysis were summarised briefly by the studies. Limitations of methodology and selection were discussed by all studies (Birtwell et al., 2013; Breustedt & Puckering 2013, & Darwin et al. 2013).

Transparency and coherence. Both Birtwell et al. (2013) and Breustedt and Puckering (2013) were transparent in their reporting of methods for data collection and analysis. They discussed the theory of the methodology used (interpretative phenomenological analysis) in detail. Darwin et al. (2013) used a framework analysis and described the five systematic stages to promote rigour. All three studies provided quotes from transcripts to justify development of themes.

Impact and importance. All three studies provide research and clinical implications. In particular Birtwell et al. (2013) and Breustedt and Puckering (2013) discuss the impact of their studies on the current evidence for such interventions and the support for prenatal attachment theory. Darwin et al. (2013) discuss the importance of clinical assessment and advise caution of effects of assessment in research.

It was not possible to rate Olds (2006) study for quality of reporting due to the nature of the methodology.

Overall synthesis

Which psychosocial interventions are being offered to women during the perinatal period?

This review found 15 psychosocial interventions for women during the perinatal period. Interventions were carried out primarily in the UK; 'Community Support Workers', 'Mellow Bumps', 'Moments', 'Preparing for Parenthood', 'Preparing for Pregnancy', 'New Lives Support Group' Extended Midwifery', and a clinic based 'Extended Midwifery' intervention. 'Centring Pregnancy Plus', 'Nurse/family Partnership' (NFP) and 'Minding the Baby' are interventions from the USA currently on offer in the UK. NFP is also offered in Germany. The 'MESCH' intervention is available to women in Australia. There is an 'Extended Home Visitation' programme in Italy, and the 'CAPEDP' intervention in France.

Content of interventions focused on the emotional needs of the mother and baby (psychological resources) and environmental factors such as social support and access to community resources (social resources). Facilitators were midwives, health visitors, psychologists, support worker and volunteers. Eight interventions were delivered through extended home visiting; 'Moments', 'Community Support Workers', 'MESCH', 'Extended Midwifery', 'Social Worker/ Psychologist Home Visitation', 'CAPEDP', 'Nurse Family Partnership' and 'Minding the Baby'.

Five interventions were delivered through groups; 'Preparing for Pregnancy', 'Preparing for Parenthood', 'Centring Pregnancy Plus', 'Mellow Bumps' and the 'Support Group'.

Two interventions were delivered through clinics; 'Extended Midwifery Support', and 'Assessment as Intervention'.

What specific outcomes do these interventions measure and are they effective?

Interventions target psychosocial wellbeing; this encompasses many areas of the participants' life, and this is reflected in the extremely high number of outcome measures used in their evaluation. Table 1 gives an overview of the primary outcomes and results for each study.

Qualitative verse quantitative studies. There is a clear division in outcomes depending on the methods employed to examine interventions. All qualitative measures of women's experiences show women experience these interventions as positive, this is at odds with the quantitative results which, on the whole, have shown limited improvements of intervention.

One study looked at the cost effectiveness of their home visitation programme; they found no monetary value in the intervention i.e. it didn't save NHS or social care costs in other areas as predicted.

Potential active ingredients for change

Barriers to engagement. The Mellow Bumps intervention (Birtwell et al., 2013 & Breustedt & Puckering 2013) acknowledged barriers to engagement and made this a focus of their intervention by providing access to childcare and transport, this resulted in high levels of attendance, positive experiences of the intervention by women, in particular with respect to bonding with their babies and feeling supported socially.

Risk factors. 'Preparing for Pregnancy' (Elliot et al., 2000), 'Centring Pregnancy Plus' (Ickovicks et al., 2011) and the 'CAPEDP' trial (Dugravier et al., 2013) found interventions to be beneficial to a specific subgroup of women; those with a high number of psychosocial risk factors but no official mental health diagnosis.

Facilitators. The extended midwifery visit intervention (MacArthur et al., 2002) and clinic based midwifery intervention (Cohen et al., 2016) suggest positive outcomes for mental and physical health, and self-esteem. Women reported care was better than expected and that they found the intervention helpful.

Length of intervention. Ammaniti et al. (2006) measured outcomes at 3, 6 and 12 months; they found impact of intervention at 6 and 12 months, compared to the group interventions that showed limited, often non significant improvements. This is in line with the finding that the majority of interventions offered are extended home visiting.

The Nurse Family Partnership study by Olds (2006) shows positive impact of intervention but the review was not methodologically robust and the replication trials in Germany and the UK showed limited findings of secondary outcome measures (self-report feelings of attachment, maternal self- efficacy, social support, and relationship quality). These results need to be interpreting with caution.

Which theories and concepts underpin these interventions?

Pre and postnatal Attachment. All of the interventions were based on attachment theory. Activities such as learning to read babies cues, encouraging bonding and improving mental and physical wellbeing were facilitated to maximise the chances mothers would be able to be responsive to their babies and therefore facilitate the formation of a secure attachment.

Early intervention. These interventions are delivered at a time specifically to provide early intervention; based on the established idea that early intervention can help to

strengthen resilience, reduce risk factors; and therefore improve outcomes for infants, mothers and their communities.

Social learning principles. Interventions facilitated learning how to manage understand and manage infant behaviour

Self-efficacy theory (Bandura, 2003**)** Self-esteem will play a major role in how women approach the challenges that they will face in the coming months and years. Improving self esteem i.e. improving women's beliefs in their ability to successfully parent their baby is a major part of all of the interventions, this is facilitated through peer discussion, and also structured activities.

Human ecological systems theory (Bronfenbrenner, 1979). All of the interventions provide content that emphasises the environmental context the women is residing in; for example, the Mellow Bumps intervention includes a session out in the community; other interventions provide community resources and encourage mothers to access support through their communities.

What are women's experiences of these interventions?

Women have reported positive effects of interventions. The Mellow Bumps intervention was evaluated qualitatively and results suggest mothers found it beneficial, in particular as a time of reflection and growth, and a place to improve relationships. Darwin, et al (2013) suggested women felt listened to, validated and were more likely to access community support. Cohen et al (2011), Morell et al., (2000) and Reid et al (20012) found women had high satisfaction of care and they made better use of social supports, women reported feeling supportive when mentored by peers (Cupples, 2011).

Discussion

Summary of results

The primary aim of this review was to critique the literature of psychosocial interventions for mothers during the perinatal period. Studies included in this review were carried out primarily in the UK, USA, France, Germany, Italy, and Australia. Content of studies focused on the emotional needs of the mother and baby (psychological resources) and environmental factors such as social support and access to community resources (social resources). Interventions were delivered through group work, extended home visiting and clinic intervention. Facilitators of these interventions were midwives, health visitors, psychologists, support worker and volunteers.

The methodological quality of the studies was moderate to high with the most frequently identified weaknesses being the high numbers of participant drop out in the quantitative studies, and increased risk of bias due to the large number of secondary outcome measures investigated by the studies.

Results from the studies are varied; it was often the secondary analysis that provided positive results. The results suggest a tentative link between positive outcomes and for women with high numbers of risk factors without specific diagnosis, interventions provided for a substantial period of time and interventions delivered by midwives.

Beckwith (2000) reported that women with too few or too many risk factors were likely to either not require an intervention or require a more specialist and focused intervention.

Other studies have reached similar inconclusive findings; a review investigating mind-body interventions found 'some but no strong evidence' for the effectiveness of interventions for the management of anxiety disorders during pregnancy (Marc et al.,

2009). Yonemtot, Doswell, Nagai and Mori (2017) reported that increasing the number of postnatal home visits may promote infant health and maternal satisfaction. They suggest more individualised care may improve outcomes for women in terms of physical and psychosocial health, although they are cautious with their conclusions due to the inconsistency between studies. In 2002 Barlow, Coren, and Stewart-Brown reviewed parenting groups for parents with children presenting with behavior difficulties. They found the groups had a significantly positive impact on maternal psychosocial wellbeing.

Limitations

Due to time and resource factors only one researcher carried out study selection and performed quality checks. Therefore, there is an increased risk of subjectivity in the studies included and excluded and in the quality ratings obtained.

This review has attempted to provide an inclusive overview of current interventions for women throughout the perinatal period. In order to achieve this, studies using different methodologies were included. The author was therefore not able to perform a meta-analysis and obtain an overall effect of intervention. Therefore, it is difficult to present a particularly reliable conclusion to the effectiveness of the interventions.

Theoretical implications

The interventions in this review assume that there is relationship between psychosocial risk factors, and outcomes for mother and infant. The rationale for the interventions is that decreasing the psychosocial risk will improve outcomes. However, the results of this review suggest the mechanism is more complicated than this. Results suggest that women with few risk factors tend to benefit less from intervention. Potentially as the impact of their difficulties can be buffered by some resources they already possess. Women with 'too many' risk factors also do not tend to benefit from such interventions. Generic interventions are likely to not be strong enough to arm the women with the resources they need. Active ingredients of interventions are yet to be established. Extended home visitation may provide one to one tailored psychoeducation and practical support and an intensive trusting relationship, but is likely to lack the social support and peer bonding that is accessed in group settings. However, groups can often lack the specificity that some women need to tackle their specific difficulties.

Clinical implications

This review provides evidence to support the use of psychosocial interventions to specific subsets of women. However, the improvements are small and it appears important that interventions are tailored to meet individual needs, personalities and social circumstances.

A general trend across studies showed interventions were of some benefit to women with high psychosocial risk when delivered over a substantial period of time, but not women with a postnatal depression diagnosis. This finding has implications for selection of women to generic intervention. Clinicians should endeavour to provide access to social support networks to vulnerable women but specific and tailored interventions for women with diagnosed mental health conditions.

The studies demonstrated the difficulties with participant retention. One of the interventions (Mellow Bumps) attempted to address this by providing access to transport and childcare. This appeared to improve retention. Interventions should attempt to include methods of supporting vulnerable women to participate in interventions.

Directions for future research

One of the main difficulties in the studies reviewed was the high number of outcomes analysed; the motivation for using a high number of outcome measures is likely to be linked to the wide range of areas that the intervention could potentially affect. Qualitative methodology may allow for more detailed exploration of the interwoven aspects of the interventions studied without the increased risk of bias.

Further research is needed to explore the specific mechanisms of the intervention that are causing the effect i.e. why the interventions appear to be effective for a certain subset of women.

It is likely that the role and characteristics of the facilitator impacts the effectiveness of the intervention. Further research in this area to explore the specific impact of facilitators is required.

The maximum time participants were followed up was 6 months. Therefore, findings are reporting relatively short-term outcomes only and future research should try to look at more long terms outcomes of interventions, especially with regards to infant development.

The majority of the measures used were self-report measures and therefore may be subjected to bias due to individual circumstances, societal expectations, and limited to conscious narratives. Future research could attempt to use more varied outcome measures such as detailed mother-infant observations, and data from health midwives and health visitors.

This review appeared to show a divide between studies that used qualitative verses quantitative measures. This requires further investigation; perhaps research in this area in the future could focus on mixed methodology to provide a more complete picture.

This review strongly suggests that the women report finding the interventions useful, however the strength of this argument is not evidenced by the standardized measures. Perhaps such interventions are not likely to reduce psychosocial risk in the short term, however the positive evaluation from women may lead to improvements later in their parenting journeys. This may have a long-term impact on the attachment relationship and therefore infant outcomes. The majority of the studies lack long-term follow up; this is likely due to many barriers with attrition and resource difficulties.

Conclusion

This review aimed to evaluate the evidence for psychosocial interventions delivered to women through the perinatal period. In particular, to understand the content of these interventions, the theoretical underpinnings and women's experiences. Results are tentative but suggest some benefit of interventions to a subset of vulnerable women who have a high number of risk factors but no mental health diagnosis. Individual interventions delivered by midwives are also likely to be of most benefit. Women's

experiences of the interventions were wholly positive, they feeling supported, building relationships with their babies (and others in the group, where applicable) and feeling satisfied with the care they have received.

Interventions focussed on improving the quality of parenting and increasing access to the community. The heterogeneous nature of the interventions makes it difficult to understand the mechanisms that effect change. Similar limitations were found across the studies, these included high drop-out rates and high numbers of analysis performed. Long-term effects of intervention were lacking and short-term effects were small and limited. Further research is needed to support their effectiveness.

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Major Research Project. Part B

The Development and Piloting of a Perinatal Attachment Based Online Teaching Module for Student Midwives

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Abstract

Objective: to develop and pilot an online training tool for student midwives. The aim of the training is to provide focused education and skill development on the attachment development between mother and infant, and the psychosocial factors that influence this relationship.

Design: mixed methods evaluation.

Participants; midwifery students in their first term of undergraduate midwifery training.

Intervention: an online training tool, accessible to students, offering teaching on the identification and assessment of the attachment relationship and the role of psychosocial resources on this relationship.

Measures: usefulness of the tool was measured by a knowledge questionnaire, a competency questionnaire, and a locus of control measure administered pre and post training. Qualitative feedback was gathered through a semi-structured questionnaire.

Results: 14 student midwives piloted the training tool. Knowledge and competence improved post training. Students qualitatively reported positive effects of training on their confidence in interacting and facilitating difficult discussions with vulnerable women. N o effect of locus of control was found.

Conclusion: Initial results from this pilot indicate the module is acceptable to students and increases knowledge and confidence. However, reliability of the measures is questionable and needs further revision and retesting. Further evaluation with large sample sizes across multiple sites is also required.

Keywords; Perinatal, intervention student midwives, online

Introduction

Defining psychosocial

The psychosocial approach acknowledges that an individual's physical and mental wellbeing, and therefore their ability to function successfully, is influenced by both psychological factors and the surrounding social environment (World Health Organisation, 2014).

Attachment relationship

Bowlby (1969) originally described attachment as being a two-way reciprocal relationship between mother and infant, in which both parties have specific needs fulfilled through the expression of mutually responsive behaviours.

Literature suggests that mothers who attribute characteristics, behaviours, and feelings to the unborn baby, begin to separate him or her in to their own distinct personality with an individual set of needs, and quite separate from the mother (Alhusen, 2008; Kim, et al., 2014) - a key criterion in defining a secure attachment for Bowlby (1969)

Being in possession of good quality psychosocial resources is likely to mean that a mother is in a place of greater emotional, physical and social stability, which should improve her ability to be responsive and attuned to her baby (Jonsson et al., 2001, & Puckering, McIntosh, Hickey, & Longford, 2010).

Emotional wellbeing of mother and baby

Pregnancy and the birthing period are times of significant life change requiring major psychological adjustment, and this period can promote significant anxiety and stress in mothers (Costa, Rippen, Dritsa, & Ring, 2003).

Poor emotional health through lack of adjustment can be conceived as being a risk factor for diminished relationships between mother and baby. It is likely that in cases where a range of physical, psychological or social disadvantages are faced by

mothers, they are less likely to possess the energy, time and resources required to engage in the necessary behaviour to foster and maintain a strong and stable, bi-directional, supportive, emotional attachment with their baby (Fonagy, Steele, & Steele, 1991; Kumar & Robson, 1984). Women experiencing such disadvantages are often described as having low psychosocial wellbeing.

The role of the midwife in facilitating the psychosocial wellbeing of mothers-to-be and new mothers

Traditionally new mothers may have relied on family, parents, and other members of the community to provide emotional and practical support throughout pregnancy and with a new-born baby (Bengtson, 2001). However, due to changes in societal structures, further living distances from families, and parents working until older ages, many new mothers find themselves relying heavily on midwives for emotional as well as practical support (Hunter, 2006).

This positions the midwife as a central figure in promoting the attachment relationship and identifying any psychosocial risks to the mother and baby's attachment very early in their relationship (Ross-Davie, Elliott, Sarkar, & Green, 2006).

Policy promoting psychosocial wellbeing.

The 'Midwifery 2020' publication specifically emphasised the importance of early bonding and attachment and highlighted the key role of the midwife in promoting this relationship (Department of Health [DH] 2010).

The High Quality Midwifery Care Review (Royal College of Midwives, 2014) stated that a more strategic approach was needed to involve midwives in working with psychosocial risk factors, in order to ensure the highest quality of care for mothers and

their babies. The review highlighted difficulties with resource constraints, service configurations, and the needs of the workforce as barriers to quality of care, especially for vulnerable women.

In 2014 a UK government mandate to improve perinatal mental healthcare was published with the aim of providing midwives with enough training to allow every woman that required it, access to a specialist mental health midwife by 2017 (Department of Health, 2014).

Midwives' experiences of providing care

Despite government pledges and targets to improve resources, midwives providing antenatal care consistently report increased expectations being placed on them by commissioners, and by women and their families (Pezaro, Clyne, Turner, Fulton, & Gerada, 2016 & Warwick, 2016). They also report experiencing particularly high levels of stress regarding a lack of skills and knowledge when caring for high-risk vulnerable women i.e. those with psychosocial vulnerabilities. This translates into them feeling less confident and unsafe when providing care for vulnerable women (Noonan, Doody, Jomeen, & Galvin, 2016).

The gap between policy and practice

In 2016, the World Health Organisation (WHO) published a document that highlighted the impact of perinatal mental health and the gap between policy and practice in this area. It suggested that a fundamental element in closing this gap related to the necessity of training of healthcare professionals. Further, it stated that this need was largely unmet in the UK and that professionals still 'lacked the

confidence and knowledge required for effective, woman-centred care' (Mahmood et al., 2016).

In July 2017, the Royal College of Midwives published a report summarising the narratives of over 6989 people affected by perinatal mental health. Results from the report indicated that, despite government initiatives and pledges of funding, the lack of perinatal mental health resources was a key factor in women not being supported.

Although there has not yet been a published evaluation of the pledge to give access to a specialist mental health midwife to every women that required by 2017; a House of Commons briefing paper published in August 2017 set out the government's mental health agenda for the coming five years, specifically, stating its intention to increase mental health support for pregnant women or new mothers. In order to make this a reality, the paper emphasised the need to train more healthcare professionals in the field of perinatal mental health (Parker & Powell, 2017). This report alongside the evidence discussed above suggests the original 2014 mandate is not likely to have been met.

Midwifery training

The Nursing and Midwifery council set standards for pre-registration midwifery education. The latest updates to the curriculum were published in 2009, (Nursing and Midwifery Council, 2009); these guidelines state midwives should be able to monitor and support women who have postnatal depression or other mental illnesses. They also

state the role of the midwife as enabling women to 'address issues of their social wellbeing.'

Despite curriculum standards clearly stating the need to midwives be competent in psychosocial issues, midwives are still reporting their training on mental health issues to be inadequate (Ross-Davie, Elliott, Sarkar and Green, 2014).

As recent as 2016, McGlone, Hollins Martin, and Furber found midwives reported no clear understanding of the purpose of routinely assessing mental health, feeling uncomfortable when women disclose mental health difficulties, a lack of knowledge of mental health issues and being unsure of how to refer to other agencies. The authors emphasise the need for pre registration training to prepare student midwives to effectively be able to identify pregnant women at risk.

Noonan, Doody, Jomeen, and Galvin (2017) recently reviewed the evidence on midwives perceptions and experiences of caring for women who experience perinatal mental health problems; they suggest the need for further training; that addresses knowledge, attitudes to perinatal mental health, communication and assessment skills.

E-learning

Traditional learning environments such as lecture theatre teaching have been, for some time now, accompanied by some form of e-learning (Bates, 2005). Educating using an online platform allows for access to a large number of students in a constant format (Johnson, Aragon, & Shaik, 2000).

For students, e-learning can be particularly effective for retention of information, as learners can revisit the material when necessary. Students can also be given the flexibility to choose the best time to undertake the teaching (Young, 2006). Being able to take breaks and learn in "bite-sized" chunks is known to help students that might otherwise struggle to stay focused for a longer period of time (e.g. Northrup, 2002).

E-learning also allows for different learning styles to be catered for; for example according to Kolb's learning module (1984), people naturally prefer one of four learning styles depending on social environment, educational experiences, and the basic cognitive structure of the individual. Styles include; 'Diverging' (information gathering, and ideas generation), 'assimilating' (concise and logical approach), 'converging' (doing and thinking) and 'accommodating' (doing and feeling).

Research shows that teaching via E-Learning takes a shorter length of time compared to classroom teaching on the same subject by up to 25-60% (Hall, 2001; Rosenberg 2001). Due to the individual nature of the learning, students are able to work through ideas and concepts they find easier quickly, and spend more time on areas they struggle with, compared to having to progress at the same rate as the rest of a class. This has been shown to lead to a 60% faster learning curve, compared to instructor-led training (Facts, Figures and Forces Behind e-Learning, 2000).

Current training and critique

An online search using the Google platform combined with information gained from supervisors and midwifery tutors at a London based university found four large- scale online training tools with a focus on perinatal mental health. An overview of the training tools, their authors, content, aims, pre requisites and intended audience are presented in table 2.

Table 2

Description of free training tool currently available in the area of perinatal mental health.

Name of training *Launch Date*	**Authors/organisers**	**Primary aims of course**	**Summary of content**	**Pre requisites**	**Intended audience**
Babies in Mind: Why the Parent's Mind Matters *July 2015*	The University of Warwick in association with 'future learn' accredited by The Association for Infant Mental Health	To answer the following questions… • How does a parent's mind influence the development of a baby before he or she is born? • What processes take place in the post-natal period that influence the baby's developing mind? • What can we do during pregnancy and the post-natal period to support parents who are experiencing difficulties?	• Social-emotional development of the baby from conception until aged two. • The impact of attachments and maternal stress on infant development.	No prior knowledge of infant or child development needed	This training was aimed at a generic audience; everyone who has an interest in promoting the wellbeing of their own baby, or the parents and babies they work with.

Maternal Mental Health *September 2015*	The Maternal and Child Health and Psychology teams at NHS Education for Scotland	To provide the background information on mental illness, medication and treatment issues during pregnancy and maternity care.	Two modules; • Information regarding mental illnesses and the importance of identifying risks in pregnancy, promotion of positive mental health, and information regarding prescribing in pregnancy and during breastfeeding. • Case examples	Experience of working with women and infants, experience of communicating with vulnerable women i.e. having a qualified level of skill set.	Qualified professionals
Perinatal Mental Health for Health Visitors	Institute of Health Visiting, funded by the Department of Health	To enable qualified health visitors to identify and treat postnatal depression, including making referrals to specialist counseling.	3 Modules; • Perinatal depression and other maternal mental health disorders, • How to recognize perinatal anxiety and depression • Interventions for perinatal anxiety, depression and related disorders	Experience of working with women and infants, experience of communicating with vulnerable women i.e. having a qualified level of skill set.	Qualified health visitors.

Perinatal Mental Health	Health Education England (HEE)	To raise awareness and understanding of mental health problems in the perinatal period.	• 2 introductory sessions, providing a broad overview of the topic and essential learning points for all health professionals. • 3 subsequent sessions focus on different stages in a mother's journey – the pregnancy, birth and the first year of a child's life.	No prior knowledge of perinatal psychiatry	Health care professionals that currently have work with women and/or infants from conception until one years of age.

Babies in Mind: Why the Parent's Mind Matters (July, 2015). The University of Warwick developed and released a free online training tool with a focus on the social-emotional development of the baby from conception until aged two. The training discussed the impact of attachments and maternal stress on infant development. This training was aimed at a generic audience.

Maternal Mental Health. The Maternal and Child Health and Psychology teams at NHS Education for Scotland (September, 2015) launched two e-learning modules on maternal mental health aimed at all health professionals. The training was focused upon women with diagnosable mental health conditions. The first module provided information regarding mental illnesses and the importance of identifying risks in pregnancy. It examined the promotion of positive mental health, and gave information regarding prescribing in pregnancy and during breastfeeding. The second module was an applied module that gave many case examples. This training took a minimum of four hours to complete. The training provided both theoretical knowledge and applied examples with links to further external resources. The training received positive reviews and has been described as exemplar template' (Mahmood et al., 2016).

Perinatal Mental Health. In 2016 Health Education England (HEE) launched five training modules on perinatal mental health aimed at qualified members of healthcare staff. The training features a wide range of mental health and psychosocial issues. Each module consists of at least 38 slides and a number of interactive resources. The course in total is expected to take a minimum of three hours to complete.

The training programmes aimed at qualified healthcare professionals assumed postgraduate academic ability level, a sound understanding and competence of communication style towards patients, and an awareness of how to access the relevant

community resources. The training aimed at a generic audience did not provide specific information on how to identify and intervene to improve psychosocial risk.

These training modules are not mandatory and are likely to be undertaken by professionals with a specialist interest in this area as part of their continued professional development. There is also a lack of evidence to demonstrate the effectiveness of such interventions on either health professionals' confidence and abilities or perinatal mental health.

Given government recommendations discussed above; it seems necessary that such educational content should be fully integrated into core professional curricula for midwives rather than optional continued professional development. What appears to be lacking from the tools available is an elementary online programme that guides a novice i.e. an undergraduate at the start of their careers, through the basics of attachment theory, its relevance to mothers in the perinatal period, the role of psychosocial wellbeing and some specific methods to assess, communicate and intervene with mother in need.

Rationale for an online training tool for student midwives

Despite standards set for midwifery students to be competent in the care of women with mental health difficulties, it is apparent from the evidence that training provided with the aim of fulfilling these competencies is likely to be insufficient (Mahmood et al., 2016; McGlone, Hollins Martin, & Furber, 2016 & Noonan, Doody, Jomeen, & Galvin, 2016).

Providing knowledge on attachment to midwifery students will help to establish and consolidate the importance of a psychological model as part of midwifery training,

and potentially help to embed the importance of perinatal attachment into their core clinical thinking from the start of their careers.

It is argued that an increase in knowledge and confidence will potentially enable newly-qualified students to help mothers develop their attunement and sensitivity to their baby, along with increasing their mental well-being and satisfaction in mothering. It is known that a healthy prenatal attachment predicts a healthy postnatal attachment (Brandon, Pitts, Denton, Stringer, & Evans, 2009, & Muller, 1996), and this is crucially important for the baby's on going social, emotional and cognitive development (Karreman, & Vingerhoets, 2012). This is particularly important for high-risk vulnerable women, for example those with mental health difficulties or who are socially isolated.

Possessing an adequately trained and confident workforce increases the likelihood of women receiving timely and effective help (McCauley, Elsom, Muir, Cochrane, & Lyneham, 2011). This in turn could decrease the emotional costs to women and their families and financial costs to health and social care, incurred through the development of insecure attachment relationships. Increasing midwifery knowledge and confidence in such areas may contribute to improving attachment in high-risk women and their babies (Lavender, & Chapple, 2004).

The role of the clinical psychologist

The Pan London Perinatal Mental Health Care Pathway suggests that the way forward for improved perinatal healthcare is for it to be resourced by a multi-disciplinary team that must include a clinical psychologist (Green, Miele, & Protti,

2015). Given that it is a key part of the role of a clinical psychologist to provide teaching to the wider healthcare disciplines (British Psychology Society, 2010), it seems entirely appropriate to utilise the knowledge and skills of a clinical psychologist to both design and deliver training of this nature.

Aim of research

This research will discuss the development an online training module for student midwives the aims of which are:

1) To deliver training in relevant psychological theory, relating to the attachment relationship between mothers and their babies throughout the perinatal period.
2) To highlight the impact of psychosocial wellbeing on the attachment relationship
3) To provide clear methods for students (and once qualified, midwives) to follow in order to successfully learn to assess and promote secure attachment, and signpost or refer vulnerable women to specialist services.

Research questions

1. Does an online training module improve midwifery students' knowledge on the impact of psychosocial wellbeing on the attachment relationship between mother and baby?
2. Does an online training module improve midwifery students' confidence in working with vulnerable women?
3. Do student midwives think the online teaching module is a useful tool in terms of both its content and mode of delivery?

Method

Use of a brief questionnaire (appendix 4) to assess the prior knowledge, and therefore needs, of student midwives in the area of attachment and psychosocial resources, prior to training delivery

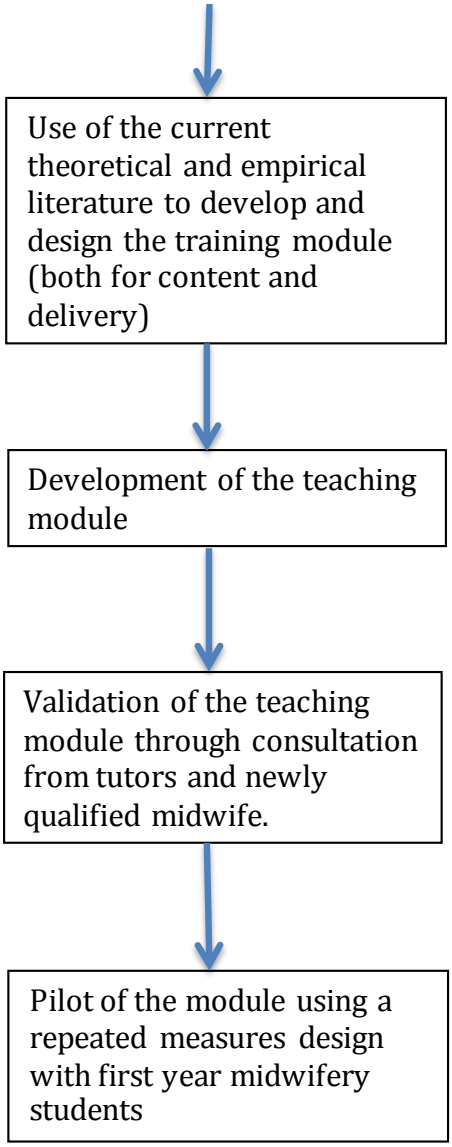


Diagram 1

A flow chart detailing the steps taken to develop and pilot the training tool

1. Use of a brief questionnaire (appendix 4) to assess the prior knowledge, and therefore needs, of student midwives in the area of attachment and psychosocial resources, prior to training delivery
2. Use of the current theoretical and empirical literature to develop and design the training module (both for content and delivery)
3. Development of the teaching module

4. Validation of the teaching module through consultation from tutors and newly qualified midwife.
5. Pilot of the module using a repeated measures design with first year midwifery students (with the teaching module as the independent variable and perceived confidence and knowledge as dependant variables).

Ethics

Ethical approval was obtained from Canterbury Christ Church University (see appendix 5). Midwifery departments at City University London and Canterbury Christ Church University were invited to take part in the study. The letter of formal ethics approval was provided to the main contact at each of the universities approached. Some of the material in the teaching module highlighted the adverse effects of an insecure attachment style; there were also references to mental ill health. These topics could be potentially distressing and affect the emotional wellbeing of the students. Therefore, links to resources that participants could access, for example, university counselling services and MIND were provided on the information sheet (appendix 6) and at the end of the teaching module. The researcher's email address was also given for participants to get further information or signposting, should they require it. Communication with the course tutors was maintained throughout, as it was important that tutors understood any issues arising from the teaching.

Data protection. During the study, electronic data was made anonymous, encrypted and stored on password protected computer and backed up on a password protected USB stick. Paper-based data was made anonymous and stored in a locked cabinet within the researcher's office. Following the study, data will be stored on a password protected CD at an office in Salomon's Centre for Applied Psychology, Canterbury

Christ Church University, in a locked cabinet for 10 years after which time it will be destroyed.

1) Brief questionnaire to assess the needs of student midwives in the area of attachment and psychosocial resources.

The theoretical rationale for an online training tool for student midwives has been established. In order to understand if current student midwives' views match the conclusions drawn from the literature a 16 item questionnaire was administered to a small sample of ten first year midwifery students on midwifery training programmes at both Universities (appendix 4). The year group was emailed and recruitment was voluntary. Questions focussed on knowledge and confidence in the area of perinatal attachment and mental health. The students were also asked about their preferred mode of delivery for teaching in this area.

Description of participants

9 female students and 1 male student completed the brief questionnaire; the average participant age was 19 (range between 18 and 44). All of the participants were in first term of their first year undergraduate degree in Midwifery. 9 students had completed A-levels prior to this course and one student had completed an access course. All of the participants were white British and 7 of them had previous employment in some form prior to starting this course.

Description of responses from the questionnaires

5 out of 10 participants were able to identify that 'attachment' is the relationship between caregiver and infant. 8 out of 10 participants were able to state one behaviour that caregiver and infant may display as a sign of a secure attachment. 2 participants

were not able state any behaviours and 4 participants were able to state two behaviours for both mother and infant.

4 participants were able to identify the type of attachment displayed in a vignette.

3 out of 10 participants were able to identify that signs of secure attachment were similar across all cultures. 9 out of 10 participants stated 'not sure' with respect to the stages of attachments throughout the first year. 9 out of 10 participants stated they felt midwives were in a good position to foster the attachment relationship.

All 10 participants stated a short-term consequence of insecure attachment e.g. difficulties breastfeeding. 8 out of 10 participants stated poor mental health as a factor contributing to insecure mental health. However, none of the 10 participants were able to give three contributing factors. 7 participants stated 'observation' as a method to assess the attachment relationship. 3 participants stated 'not sure.' All 10 participants were able to suggest a place to signpost vulnerable women for extra help. Places included 'mother and baby groups' and the General Practitioner (GP). All 10 participants were able to state at least one tip to help mothers bond with their babies; tips included 'skin to skin contact' and breastfeeding.

All 10 participants stated training in this topic would be 'very useful' and 8 participants stated an online training tool would be 'very useful.'

In summary it would appear that this small sample's knowledge of psychosocial issues, attachment and mental health is somewhat limited and in line with evidence that has been discussed thus far; i.e. that midwives lack the necessary knowledge and skills to promote psychosocial wellbeing and therefore maximise the chances of a secure attachment between mother and infant. This sample of students strongly encourage the need for online training in this area.

2) Use of the current theoretical and empirical literature to develop and design the training module (both for content and delivery)

A constructionist approach to delivery. Constructionist theory suggests people acquire knowledge through adapting and building on existing knowledge, beliefs, and past experiences, and progressing these areas through new experiences; i.e be able to apply their acquired knowledge to multiple situations (Driver, & Oldham, 1986; Duffy, T. M., & Jonassen, 1992). In particular; the notion that knowledge and experience are both required for learning is highlighted (Huang, 2002). This training tool aimed to deliver both knowledge and simulated experiences in order to facilitate learning. Throughout the training there was space to reflect on existing knowledge and experiences prior to accessing new knowledge and scenarios. Students were given multiple opportunities to apply and practice existing and newly acquired knowledge and to learn at their own pace.

Content of training. In order to extract the key teaching elements from the literature, a 'concept mapping' approach was used. Concept mapping is widely used to understand relationships between elements and to scope the literature of a specific area. It is also used in teaching as a lesson planning exercise (Kinchin, & Alias, 2005). Diagram 2 presents the final concept map and the associated key references obtained from a literature search of the topics. Table 3 below shows how the aims, extracted theoretical and practice content, and methods of evaluation are related.

The map represents two overarching themes; theory and practice. Theoretical content extracted included;

- Information regarding the founders of perinatal attachment theory; i.e. Bowlby, (1969) Ainsworth (1970) etc, and more recent leaders in the field,

for example, Fonagy, (1991, 2010)

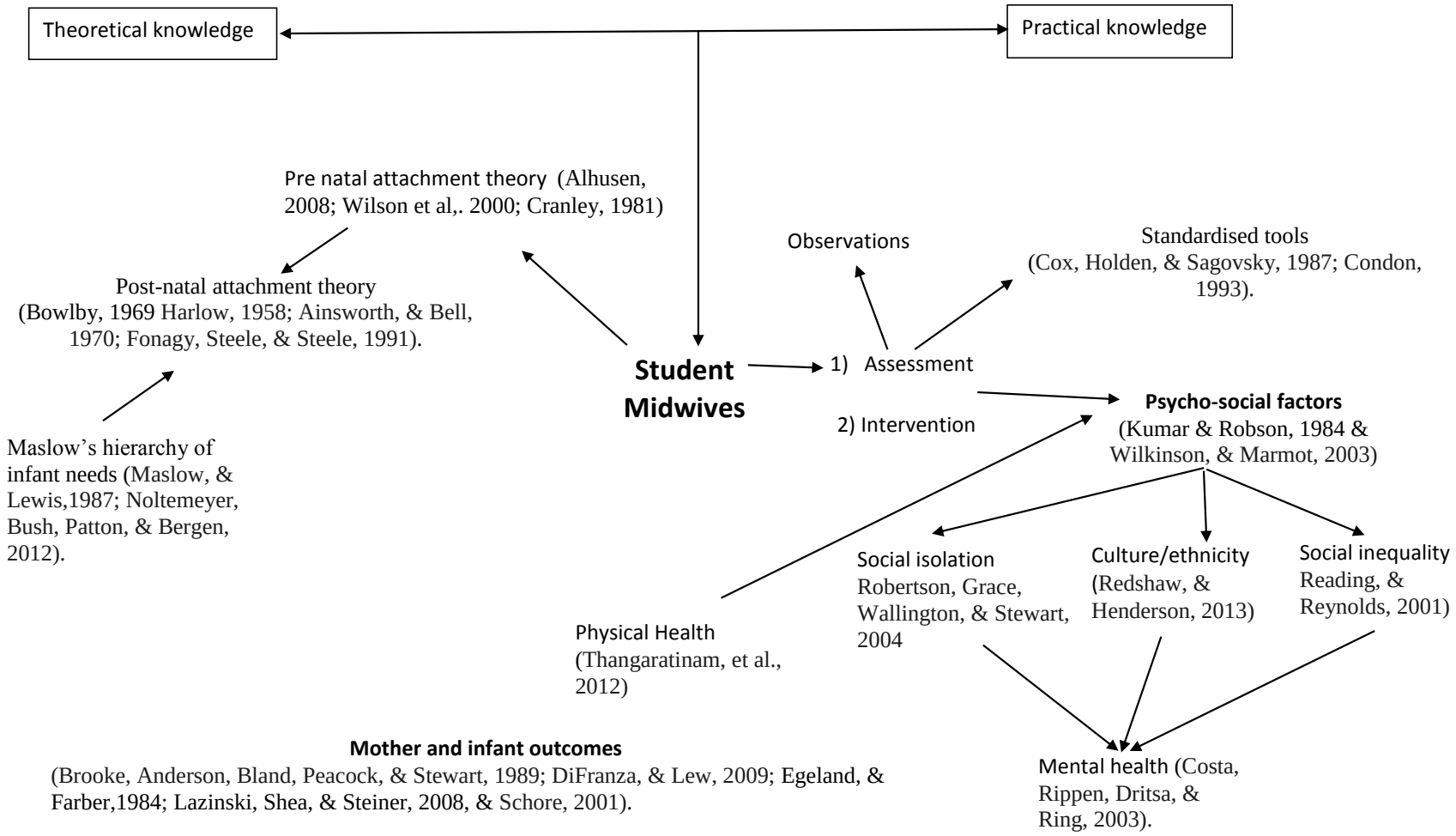
- A brief introduction to Maslow's hierarchy of needs and how it can be adapted to think about the needs of infants
- The existence of pre natal attachment
- The relationship between pre and post natal attachment
- Short and long term outcomes for mothers and infants

Content relating to practice of midwives included;

- Midwives role in assessing:
    - Psychosocial risk
        - Mental health
        - Cultural issues
        - Social inequality
    - The attachment relationship
- Midwives role in promoting the attachment relationship
- Information regarding signposting and referring to specialist services.

Diagram 2

Concept map for content of training



3. Development of the tool

A free e-learning platform: 'easy generator' was used to build the module.

Aims and objectives of module. The module aimed to use the extracted content from the literature to:

- Provide an overview of attachment theory in the perinatal period (unit one)
- Teach theory to practice links with respect to the relevance of attachment theory to psychosocial risk and vulnerable mothers (unit two)
- Provide knowledge on psychosocial factors that affect the attachment relationship (unit three)
- Teach skills to assess and identify women where the existence of psychosocial factors highlight the potential risk of the development of insecure mother-baby attachment relationships (unit four)
- Teach practical skills to foster the attachment between mother and baby throughout the perinatal period (unit 5)

Objectives: By the end of this module students should be able to:

1. Apply theory to practice with respect to the relevance of attachment theory, psychosocial risk and vulnerable mothers (unit one)
2. Identify and assess the differences between secure and insecure attachment styles (unit two)
3. Identify and assess the psychosocial risk factors to secure attachments (unit three)
4. Improve confidence in their ability to foster the attachment between mother and baby throughout the perinatal period (unit four)
5. Feel confident in knowing how and when to access further psychosocial support for the mother and baby, if necessary (unit four)

The content of each of the 7 units within the module was mapped to the key learning aim and objectives. The table below shows how the objectives, content, and outcomes are related.

Unit/number of objective	Objective	Summary of content	Learning activity	Assessment of objectives
1	Provide an overview of attachment theory	• Origins of attachment theory in an evolutionary context. • Work of Henry Harlow, John Bowlby and Mary Ainsworth. • How the attachment relationship is categorised by stage and style. • Key behaviours exhibited in each stage and/or style	• True/false multiple choice questions to consolidate learning after presentation of key facts. • Opportunity to produce own definition of attachment (based on information provided) before being given key definitions from the literature	• Multiple choice Questions (MCQ) Definition of attachment • MCQ on number of attachment stages
2	Understand the implications of attachment to mother and baby	• Application of attachment theory to parenting • The tasks involved in parenting • Maslow's hierarchy of needs and its relationship to parenting and secure attachment • Parenting and pregnancy • Role of midwives in supporting mothers with the attachment relationship	• Students are asked to list the tasks of a parent in order to foster a secure attachment	• True or false question on role of midwife • Open question on consequences of insecure attachment for mother and baby

3	Learn about the factors that may affect the attachment relationship	• Maternal, infant, social and environmental factors that may influence the attachment relationship	• Semi structured question on factors that might influence the attachment relationship.	• True or false Question on attachment in different cultures • Open question on factors affecting attachment
4	Learn how to assess the attachment relationship during pregnancy and postnatally	• Standardised assessment to identify risk to the attachment relationship • Observational methods to identify risk to the attachment relationship • Differences between assessment in pregnancy and assessment postpartum	• Students asked to list attachment behaviours that can be observed during assessment	• Give examples of behaviours exhibited by mother and baby • Question on how to assess relationship
5	Introduce students to the different intervention options available	• Skills students already have to help the attachment relationship • Interventions during pregnancy and postpartum • Midwife characteristics valued by mothers • When and where to access external help	• Students asked to list the skills midwifery students already possess • Students asked to predict the characteristics valued by mother	• Ask students to list any resources that may support mother and baby
6	Provide students with examples of how the theory	• Three vignettes are worked through with regards to	• Category matching task to consolidate learning	• 3 Short vignette questions asking student to identify attachment style, promote

	learnt so far can be applied in practice	assessment, intervention and signposting. • The vignettes explored social inequality, cultural differences, primary care mental health issues and severe and enduring mental issues.	regarding, assessment and intervention of attachment	secure attachment and understand when and how to access additional support.
7	Give students an opportunity to assess their learning	• Quiz	• Quiz	-

4. Validation of the teaching module through consultation from tutors and newly qualified midwife. The initial draft of the module was tested for information accuracy, relevance, ease of use, and user acceptability. This was achieved through eliciting feedback from six midwifery course staff (four from an urban university and two from a rural university) and one newly qualified midwife. Feedback was collected on anonymous feedback forms asking questions on content and structure of the module (see Appendix 7 for feedback questionnaire).

Amendments considering feedback. Suggested improvements made by tutor/newly qualified consultants were as follows:

- Add more information about the history and theory of attachment.
- Add a practice vignette that includes severe and enduring mental health issues as well as those focusing on more general mental health concerns such as anxiety or depression.
- Correct typographical errors.
- Embed video clips into unit pages.

4. Pilot of the module using a repeated measures design with first year midwifery students

Once the teaching module had been developed, the student participants were sent information via their University online e-learning platform. This was followed up with a face-to-face meeting with each year group to answer any questions and encourage participation.

Students were emailed the information (Appendix 6) and consent form (Appendix 8) along with the pre teaching questionnaires. (Knowledge: Appendix 4, generic confidence measure: Appendix 9) Demographic information on age, ethnicity, locality, and year and level of education was also collected before completion of the teaching module (Appendix 10)

Students were provided with the opportunity to discuss any questions or concerns with the researcher via email and also with the main liaison contact at the University. Once students returned the completed pre-teaching forms via email they were sent the link to the teaching module and the post teaching measures. Students were sent two reminders via email. No incentives were offered to complete the study. However, the relevance and usefulness of the teaching to their degree and professional careers was emphasised.

Recruitment of Participants

Eligibility criteria. All participants were students currently enrolled on a midwifery programme. There were no exclusion criteria. Participants were recruited from two universities, one in an urban setting, and the other in a rural setting. Both undergraduates and postgraduate diploma students, from all years, were invited to participate. All total number of 265 students were invited to attend.

Measures

Knowledge quiz. The knowledge questionnaire (see Appendix 4) was constructed using the material in the teaching as well as a number of online questionnaires used to evaluate student knowledge in this area, for example, the Victoria Survey for Midwives. Reliability and face validity of this survey has been shown through an evaluation by a group of experts (α=0.64) (McCauley, Elsom, Muir-Cochcrane, & Lyneham, 2011). The questions reflected the knowledge the students

were expected to gain during the teaching experience. The questions were split into theoretical knowledge and application of knowledge in their clinical environments. The questions required both qualitative responses and multiple-choice answers.

Per item confidence measure. Participants were asked to rank how confident they felt in answering each of the knowledge questions out of a score of 10. Assessing confidence in this way not only gives a more specific measure, it also allowed for detailed analysis of which areas the students were struggling with and which they felt comfortable with, allowing for detailed fine tuning of the teaching module (Thomas, & Macias-Moriarity, 2014)

These measures were administered before and after the completion of the teaching module.

Feedback questionnaire. A questionnaire was constructed to gain feedback from the students on their experience of the module. Nine questions asked for feedback on the content of the module, the process of completing the module i.e. length of time taken and ease of navigation, and the usefulness of the teaching package to their current stage in the midwifery profession. The items on this questionnaire were designed from the theories and recommendations for teaching discussed above.

Data analysis plan

The statistical package SPSS was used to explore reliability of measures and any significant differences in pre and post measures. Factor analysis was used to test if constructs were homogenous or multi-dimensional. Alpha reliability tests were carried out in order to test the internal consistency of the scales.

Paired t-tests were used to investigate differences between scores pre and post teaching. Demographic variables were accounted for using an ANOVA analysis. Due to the

divided literature on the quality of Likert data (Boone, & Boone, 2012) both parametric t-tests and non-parametric equivalents were used. The results were equivocal. Therefore, the parametric results are reported.

Results

Participant characteristics

85 students participated in the study giving a response rate of 32%. The average age range of participants was 20.1 years (SD= 3.7, range: 20-43)

79 (93%) participants were female. There were 62 (73%) students from the rural university and 23 (27%) from the urban university. 70 (82%) students had entered the programme through the undergraduate route and there were 15 (18%) postgraduates. 67 (79%) students lived in a small town 14 (16%) lived in an urban city and 4 (5%) lived in a rural setting. 66 (78%) students were white British, 5 (6%) students were other white British, 4(5%) were mixed race, white and Indian, 3 (4%) were Irish, 3(4%) were African, 3(4%) were Caribbean and 1(1%) was Indian.

13 of the 85 students who completed the initial questionnaires did not send back post training data. Two attempts were made to contact the students via email however no responses were gained. 72 sets of pre and post data were obtained.

Table 4

Table detailing overall differences for pre and post training outcomes.

Measure	n	Pre-training mean (SD)	Post training mean (SD)	Pre-post difference mean (SD)	t value	p value
Knowledge questionnaire	62	11.83 (1.12)	18.45 (3.30)	6.61(3.29)	t(84)=15.82	<0.01
Confidence in answering knowledge questions	60	4.11(1.54)	7.20(1.26)	3.08(1.49)	t(59)=16.05	<0.01
Confidence questionnaire	67	2.52(1.13)	4.16(1.86)	1.67(1.08)	t(66)=12.40	<0.01

Knowledge questionnaire

A paired samples t-test was conducted to evaluate the impact of the training on student' scores on the knowledge questionnaire. There was a significant increase in knowledge scores from pre training n=62 (M =11.83, SD = 1.12) to post training (M =

18.45, SD = 3.30), t(84) = 15.82, p < .001 (two-tailed). The mean increase in scores was 6.61 (SD= 3.29) with a 95% confidence interval ranging from 7.45 to 5.78. These results indicate the training improved students' knowledge on the topics covered in the training module. Internal consistency of the measure was evaluated using chronbach's alpha

Table 5

Knowledge subscales (internal consistency)

Scale	Number of items	Chronbachs alpha*
Theory	3	.62
Midwives role	5	.92
Mother/infant behaviours/outcomes	6	0.54

***C**ronbach's alpha value of .7 or above indicates an acceptable level of reliability (Devellis (2003)

Informal qualitative analysis of the data suggested technical knowledge about attachment was missing from the pre-teaching knowledge questionnaire for example, more than half of the students scored 0 on a question asking them to describe behaviours that demonstrated a secure attachment pattern. However, post-teaching participants were able to use more technical terms and gave many more specific answers.

Individual item confidence measure

Students were asked to rate each question on the knowledge questionnaire by how confident they felt in answering the question. Students were asked to score their confidence level out of 10. (1= not at all confident, 10= very confident). Overall scores were obtained by generating the mean average confidence score. A paired samples t-

test was used to evaluate the impact of the training on students' scores of confidence in answering the knowledge questionnaire. There was a significant increase in confidence scores from pre training (M=4.11, SD=1.54) to post training (M=7.20, SD=1.26), The mean increase was 3.08(SD=1.49), $t(59)=16.05$ $p < .001$ (two-tailed). These results indicate students felt more confidence in answering knowledge questions after completing the training module.

Generic confidence measure

Students were asked to rate their confidence with respect to working with vulnerable women. They were asked to fill out a 5 point likert scale. Overall confidence scores were obtained by generating a mean average score. A paired samples t-test was used to evaluate the impact of the training on students' scores of confidence when working with women There was a significant increase in confidence scores from pre training (M=2.52, SD=1.13) to post training (M=4.16, SD=1.86), The mean increase was 1.67, SD=1.08) $t(66)=12.40$ $p < .001$ (two-tailed). These results indicate students felt more confidence in working with vulnerable women after completing the training module. Internal consistency of the measure was evaluated using chronbach's alpha

Table 6

Confidence subscales (internal consistency)

Scale	Number of items	Chronbachs alpha*
Prenatal theory	4	.69
Post natal theory	4	.46
Prenatal practice	4	.74

Post natal practice	4	.52

Correlations

A significant correlation was found between knowledge and per item confidence $r(73) = .62$, $p<0.01$indicating as students became more knowledgeable their confidence in answering the specific question increased.

There was a significant correlation between knowledge and generic confidence $r(79) = 2.23$, $p=0.05$ indicating as knowledge increased students confidence with regards to performing their job also increased.

No significant correlation was found between the per item confidence measure and the generic confidence measure.

Acceptability/Feedback on module

Feedback was gathered from participants on a number of areas of the teaching module. The feedback questionnaires were not formally analysed. However, the following descriptive data was extracted.

No participants felt anything was missing from the module. Most participants felt the module was entirely relevant (n =64, 75%). The length of the module as a whole was deemed correct by the majority (n= 73, 88%) with individual units being described as 'useful'. This enabled some participants to undertake one unit at a time.

Navigation through the module was rated as very easy or easy by all of the participants. The majority of the participants felt the module was sufficiently interactive (n=56, 66%); however some commented that there were 'a number of pages that were not interactive'. All participants felt the module would be useful to other students 'I

think it would be easy enough to understand for those who haven't previously studied it'

There were a number of comments that the theory and historical background sections would more useful to those who had not studied any attachment previously, 'the practical examples were the most useful' 'the theory was not very useful as I already knew the basics'. Most participants felt the module was pitched at the correct level (n=59, 69%). However some reported that it was too easy (n=21, 25%) whilst (n=6, 7%) thought it was too complicated 'Other comments' on the module described the module as useful 'Having studied attachment at a level, this was a good recap', with a number adding that it would be useful 'to be able to download the module into a word or pdf format' for their future reference. Usefulness to midwifery practice was also commented on 'I feel inspired to help women with these ideas'.

Discussion

This research endeavoured to answer the question: does an online training module in the area of perinatal attachment, maternal psychosocial factors and mental health impact the knowledge and confidence of student midwives. In order to address this question a training module was developed using pedagogical models and empirical and theoretical literature on attachment. It was then piloted using a repeated measures

design with a sample of student midwives from two universities. Students were also asked to provide qualitative feedback on the module in order to understand their views on the module on terms of content and delivery.

Does an online training module improve midwifery students' knowledge on the impact of psychosocial wellbeing on the attachment relationship between mother and baby?

The teaching module improved a sample of students' knowledge significantly. Results indicated students' knowledge at baseline was higher on questions examining post natal attachment compared to pre-natal attachment. This difference carried across to the post teaching results where a bigger improvement in knowledge was seen in the prenatal questions.

These results support the evidence that education on attachment in the prenatal period is lagging behind post natal attachment education (Bellieni et al., 2007). It has been suggested that one reason for this difference may be due to the lack of empirical evidence of the pre-natal relationship in particular the difficulties of objectively measuring it (Brandon, Pitts, Denton, Stringer, & Evans, 2009 & Muller, 1993)

The data also suggested that the students already possessed a certain amount of knowledge about attachment; in particular post natal from the outset. This is contrary to the current literature base, which suggests midwives feel they have little or no knowledge or skills in working with the attachment relationship and vulnerable mothers (Ross-Davie, Elliott, Sarkar, & Green, 2006). One explanation for this difference in findings might be related to Maslow's learning theory, which discusses the process of learning from knowledge at the unconscious (Maslow, 1968) i.e. unconscious competence becoming conscious, through processes such as formalised teaching and

experiencing the practical application of theory. The teaching module may have been able to provide this opportunity.

Current literature suggests midwives lack confidence in working psychologically with women. One reason for this may be due to their lack of theoretical understanding of psychological issues, such as the attachment relationship. The results of this study suggest that students lacked technical knowledge and language with respect to the attachment relationship between mother and infant. Research suggests having an understanding of the theoretical basis and therefore having a specific language to contextualise the model, will make it more likely that knowledge is accessed and the intervention will be implemented. It will also be more likely to be correctly implemented due to the theory supporting and justifying the intervention.

Does an online training module improve midwifery students' confidence in working with vulnerable women?

The teaching module significantly improved students' confidence in answering specific questions centring on attachment theory throughout the perinatal period.

In line with the knowledge questionnaire, pre completion of the module students reported less confidence in prenatal attachment questions compared to post natal attachment. This difference in confidence between questions was not seen post teaching.

Prior to completion of the module the relationship between the confidence scores and the knowledge questions was poor, indicating students' difficulties in self-assessing. This supports the literature that suggests self-reported confidence assessments may add a level of assessment that could be useful to both students and

instructors, often indicating a misconception in learning where the confidence is not aligned to the knowledge score (Thomas, & Macias-Moriarity, 2014)

Ultimately, qualified midwives must be aware of their own competence to be able to make the best decisions for mothers, babies and their families. Poor alignment between knowledge and confidence could result in practitioners who do not use their knowledge when they should, due to a lack of confidence, or who make errors due to being overconfident (Dory Degryse Roex, & Vanpee, 2010).

The teaching improved generic confidence significantly. However, there was a poor relationship found between the per item confidence scores and the generic item scores. There are three potential explanations. The first is the internal consistency of the scale was low and a number of scales were extracted from the measure. This suggests the questionnaire may have been measuring a number of different concepts (Gliem, & Gliem, 2003). Secondly, the generic confidence questionnaires asked broad questions about the practice of midwifery. As the teaching was aimed at students, it is likely that the participants do not have much autonomy in the working environment at this stage in their careers. Therefore, although they felt confident 'in the classroom' it may have been difficult to generalise the teaching in an abstract manner. Thirdly, the post questionnaires were completed immediately after the teaching, therefore there was no opportunity to experience the teaching in a real life setting, for example on placement.

The results showed a relationship between knowledge and generic confidence. As knowledge improved so did confidence. This relationship is well established in the literature across most fields of research. For health care students, it has been suggested that formal teaching on theory and opportunity to apply theory in a safe and contained way, is likely to increase confidence (Blum, Borglund, & Parcells, 2010). An increase

in confidence in a theory and its application is likely to encourage students to provide an intervention and to provide it successfully (Leigh, 2008). This may be because having a theoretical basis provides a robust rationale for an intervention and, therefore, promotes confidence in the efficacy of the intervention (Payne et al., 2002).

Do student midwives think the online teaching module is a useful tool in terms of both its content and mode of delivery?

Response rate to the study was fairly low (32%), this contradicts the literature suggesting education in this area is lacking and wanted. However, the low response rate could be due to participation being voluntary with no incentives, at a time where students are undertaking a number of assessed pieces of work and also spending time on placements etc.

The feedback received on the module was very positive from both participants involved in the consultation process and from students that piloted the teaching.

There is potential of participation bias, therefore results should be interpreted with caution. As participation was voluntary, it is possible that that students with a particular interest in this area would have chosen to participate, also only students who completed the module provided feedback. Therefore, data was potentially missing from participants who may have chosen not to finish the module or had other negative comments about it.

Implications

This initial pilot suggests that teaching midwives about the theory of attachment and its practical application may improve midwives knowledge and self-reported confidence in working with mothers using this model. Delivering online teaching in a

structured and time limited way, at an early stage of midwives careers, supports the call for a 'strategic way' to embed the midwifery profession in the area of public health. In particular with respect to improving psychosocial risk to women through the perinatal period (Royal College of Midwives, 2014).

This research was an initial pilot of a newly developed training module. The next stage with respect to the module would be to modify it in line with feedback gained. The module would then need to be evaluated with a larger student population to see if the positive effects of this study are generalised. It may also be of benefit to compare the impact of this training module with others such as the modules launched by Health Education England.

If results from a larger evaluation are positive it may be possible for universities to begin to roll out the programme their students.

It was beyond the scope of this study to explore the implications of such teaching in a clinical setting. This is an area for future research; it would be important to understand if the training had an impact on students' confidence once they had begun to deliver care to vulnerable women.

The impact of the training on the quality of care delivered to vulnerable women would also be an important area to evaluate.

Confidence and knowledge have also been linked to job satisfaction. In the current climate for under resourced NHS services and staff feeling the pressure to take on more roles (McInnes, & McIntosh, 2012) it would be useful to explore if providing training at this early stage helps to improve job satisfaction and decrease burnout.

There is currently discordance between policy commitments to improve perinatal wellbeing and the confidence of midwives to deliver this care. This study suggests training does improve knowledge and confidence. Within services qualified

staff are under immersive time and service pressures and it is likely that there is lack of time to complete other free online trainings in this area. Therefore services, in particular maternity services should attempt to provide training in consistent and accessible way to maximise the confidence and skill level of already qualified staff.

The role of Clinical Psychologists as educators is well established but often occurs in an informal manner. Using the research and clinical skills of clinical psychologists in developing training in areas such as perinatal mental health and attachment is likely to be an economical use of NHS resources as there is the potential to reach a very large proportion of the workforce.

Conclusion

The aim of this project was to develop and pilot a standardized online teaching module for student midwives on the importance of the attachment relationship between mother and baby within the perinatal period. This teaching module has received good feedback and, with some minor adaptations to content and design, is potentially ready to be piloted again to a larger number of students on broader range of teaching programmes. The research aimed to explore the effect of the module on midwifery student knowledge and confidence. Initial results from this pilot suggest that the module did improve performance on both variables. However, reliable of the measures

is questionable and need further revision and retesting. Further evaluation with large sample sizes across multiple sites is also required. Early intervention for women and their babies throughout the perinatal period has been shown to have long-term benefits for individuals, families and communities. Having a knowledgeable and confident workforce is likely to promote the attachment relationship and increase the changes of positive outcomes.

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Section C

Appendices

Appendix 1

Consort checklists

CONSORT 2010 checklist of information to include when reporting a randomised trial*

A prevention and promotion intervention program in the field of mother-infant relationship (Ammaniti et al., 2006)

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Not reported
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Not structured
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	71-74
	2b	Specific objectives or hypotheses	73
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	74
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not reported
Participants	4a	Eligibility criteria for participants	74-75
	4b	Settings and locations where the data were collected	74-75
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	78
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	76/7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not reported
Sample size	7a	How sample size was determined	Not reported

	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Not reported
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Not reported
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Not reported
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Not reported
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Not reported
	11b	If relevant, description of the similarity of interventions	Not applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	80
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	79-81
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	74
	13b	For each group, losses and exclusions after randomisation, together with reasons	74
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Not reported
	14b	Why the trial ended or was stopped	Not reported
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	76
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	78-81
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	78-81
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	78-81
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	82

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	82-84
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	82-84
Other information			
Registration	23	Registration number and name of trial registry	Not reported
Protocol	24	Where the full trial protocol can be accessed, if available	Not reported
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Not reported

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Exploratory study to explore provision of additional midwifery support to teenage mothers

(Cohen et al., 2011)

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Not reported
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	632/633
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Not reported
	2b	Specific objectives or hypotheses	632/633
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	632/633
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not reported
Participants	4a	Eligibility criteria for participants	632/633
	4b	Settings and locations where the data were collected	632/633
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	633
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	633/634
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not reported
Sample size	7a	How sample size was determined	Not reported
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not reported
Randomisation:			

Sequence generation	8a	Method used to generate the random allocation sequence	634
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	634
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	634
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	634
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	634
	11b	If relevant, description of the similarity of interventions	633
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	634
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	635
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	635
	13b	For each group, losses and exclusions after randomisation, together with reasons	635
Recruitment	14a	Dates defining the periods of recruitment and follow-up	634
	14b	Why the trial ended or was stopped	Not reported
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	635
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	635
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	636
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	636
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Not reported
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	637
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	636/7

Other information			
Registration	23	Registration number and name of trial registry	Not reported
Protocol	24	Where the full trial protocol can be accessed, if available	Not reported
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	637

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Psychosocial and psychological interventions for preventing postpartum depression
Dennis &Doswell 2013

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1/2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3/4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	101
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4/5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6/7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	7

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	11
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	13
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	12-19
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	11/12

Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	12-19
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	20
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	21
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	22
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	102

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Impact of a manualised multifocal perinatal home visiting program. CAPEDP trial (Dugravier et al., 2013)

Section/Topic	Item No	Checklist item	Reported o page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable
Participants	4a	Eligibility criteria for participants	3
	4b	Settings and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not reported
Sample size	7a	How sample size was determined	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not reported
Randomisation:			
	8a	Method used to generate the random allocation sequence	3

Sequence generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Not reported
	11b	If relevant, description of the similarity of interventions	not reported
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	4
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	4
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	5
	13b	For each group, losses and exclusions after randomisation, together with reasons	5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Not reported
	14b	Why the trial ended or was stopped	Not reported
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	5
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	8
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	8
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8

Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	9
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Not reported

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Promoting mental health after childbirth: controlled trial

(Elliot et al., 2000)

Section/Topic	Item No	Checklist item	Reported o page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Not randomise
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	223/4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	224/5
	2b	Specific objectives or hypotheses	226
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	226
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not reported
Participants	4a	Eligibility criteria for participants	228
	4b	Settings and locations where the data were collected	Not reported
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	226/7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	227/8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not reported
Sample size	7a	How sample size was determined	Not reported
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not reported
Randomisation:			
	8a	Method used to generate the random allocation sequence	not randomise

Sequence generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	not randomise
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	not randomise
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	not randomise
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	not randomise
	11b	If relevant, description of the similarity of interventions	not randomise
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	230
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	230
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	229
	13b	For each group, losses and exclusions after randomisation, together with reasons	228
Recruitment	14a	Dates defining the periods of recruitment and follow-up	227
	14b	Why the trial ended or was stopped	Not reported
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	No table but te
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	229
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	237-5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	237-5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	232-5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Not reported
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	237
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	237/8

Other information			
Registration	23	Registration number and name of trial registry	Not reported
Protocol	24	Where the full trial protocol can be accessed, if available	Not reported
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	239

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Child and family outcomes of a long-term nurse home visitation programme: RCT (Kemp et al., 2011)

Section/Topic	Item No	Checklist item	Reported o page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1
	2b	Specific objectives or hypotheses	1
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not reported
Participants	4a	Eligibility criteria for participants	1
	4b	Settings and locations where the data were collected	1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not reported
Sample size	7a	How sample size was determined	Not reported
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not reported
Randomisation:			
	8a	Method used to generate the random allocation sequence	3

Sequence generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Not done
	11b	If relevant, description of the similarity of interventions	not reported
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	4
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	4
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	3
	13b	For each group, losses and exclusions after randomisation, together with reasons	4
Recruitment	14a	Dates defining the periods of recruitment and follow-up	3
	14b	Why the trial ended or was stopped	3
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	4
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	5/6
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	5/6
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	6
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	6
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	7

Other information			
Registration	23	Registration number and name of trial registry	7
Protocol	24	Where the full trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	7

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Robling et al., 2016)

Section/Topic	Item No	Checklist item	Reported o page No
Title and abstract			
	1a	Identification as a randomised trial in the title	146
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	146
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	146/7
	2b	Specific objectives or hypotheses	147
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	147/8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not reported
Participants	4a	Eligibility criteria for participants	148
	4b	Settings and locations where the data were collected	148
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	148
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	147
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not reported
Sample size	7a	How sample size was determined	Not reported
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not reported
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	148
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	148

Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	148
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Not reported
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Not reported
	11b	If relevant, description of the similarity of interventions	149
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	149
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	149
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	149
	13b	For each group, losses and exclusions after randomisation, together with reasons	147
Recruitment	14a	Dates defining the periods of recruitment and follow-up	147
	14b	Why the trial ended or was stopped	Not reported
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	151
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	150
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	150
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	151
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	152
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	152
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	152
Other information			

Registration	23	Registration number and name of trial registry	147
Protocol	24	Where the full trial protocol can be accessed, if available	147
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	154

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Effects of home visitation on maternal competencies, family environment and child development

(Sierau et al., 2016)

Section/Topic	Item No	Checklist item	Reported o page No
Title and abstract			
	1a	Identification as a randomised trial in the title	40
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	40
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	40/41
	2b	Specific objectives or hypotheses	41
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	41
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not reported
Participants	4a	Eligibility criteria for participants	41
	4b	Settings and locations where the data were collected	41
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	43
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	43
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not reported
Sample size	7a	How sample size was determined	Not reported
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not reported
Randomisation:			

Sequence generation	8a	Method used to generate the random allocation sequence	41
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	41
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	41
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Not reported
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	43
	11b	If relevant, description of the similarity of interventions	43
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	45
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	43
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	43
	13b	For each group, losses and exclusions after randomisation, together with reasons	43
Recruitment	14a	Dates defining the periods of recruitment and follow-up	41
	14b	Why the trial ended or was stopped	Not reported
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	43
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	44
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	44
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	44
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	49
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	47-9
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	47-9

Other information			
Registration	23	Registration number and name of trial registry	Not reported
Protocol	24	Where the full trial protocol can be accessed, if available	Not reported
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	50

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix 2

Excluded References:

Khan, S. (2011). *Baby Steps: A Bonding Program for Adolescent Mothers and Their Infants* (Doctoral dissertation, Chicago School of Professional Psychology).
Exclusion reason: no full text available

Atif, Najia, Krishna, Revathi N, Sikander, Siham, Lazarus, Anisha, Nisar, Anum, Ahmad, Ikhlaq, et al. (2017). Mother-to-mother therapy in India and Pakistan: Adaptation and feasibility evaluation of the peer-delivered Thinking Healthy Programme. BMC Psychiatry, 17, doi:10.1186/s12888-017-1244-z
Exclusion reason: *children over one*

DeSocio, Janiece E, Holland, Margaret L, Kitzman, Harriet J & Cole, Robert E. (2013). The influence of social-developmental context and nurse visitation intervention on self-agency change in unmarried adolescent mothers. Research in Nursing & Health, 36, 158-170. doi:10.1002/nur.21525
Exclusion reason: secondary analysis of outcomes not directly linked to intervention

Evans, Emily C & Bullock, Linda F. C. (2017). Supporting rural women during pregnancy: Baby BEEP nurses. MCN: The American Journal of Maternal/Child Nursing, 42, 50-55. doi:10.1097/NMC.0000000000000305
Exclusion reason: Outcomes were linked to telenursing not psychosocial intervention

Hok, V, Hoisnard, G, Simon-Vernier, E, Hauchecorne, A, Thomas, A, Menard, C, et al. (2011). Psychologists at home: Practices, models and issues of a preventive intervention. Pratiques Psychologiques, 17, 119-135. doi:10.1016/j.prps.2010.11.005
Exclusion reason: No outcome measures

Howell, Elizabeth A, Bodnar-Deren, Susan, Balbierz, Amy, Loudon, Holly, Mora, Pablo A, Zlotnick, Caron, et al. (2014). An intervention to reduce postpartum depressive symptoms: A randomized controlled trial. Archives of Women's Mental Health, 17, 57-63. doi:10.1007/s00737-013-0381-8
Exclusion reason: No psychosocial intervention

Meghea, C. I, Li, B, Zhu, Q, Raffo, J. E, Lindsay, J. K, Moore, J. S, et al. (2013). Infant health effects of a nurse-community health worker home visitation programme: A randomized controlled trial. Child: Care, Health and Development, 39, 27-35. doi:10.1111/j.1365-2214.2012.01370.x
Exclusion reason: No psychosocial intervention

Mucka, Lilia E, Dayton, Carolyn J, Lawler, Jamie, Kirk, Rosalind, Alfafara, Emily, Schuster, Melisa m, et al. (2017). Mixed-methods evaluation of participant recruitment and retention in the mom power parenting intervention program. Infant Mental Health Journal, No Pagination Specified. doi:10.1002/imhj.21652

Exclusion reason: No psychosocial outcomes

Shorey, Shefaly, Chan, Wai-Chi Sally, Chong, Yap Seng & He, Hong-Gu. (2015). A randomized controlled trial of the effectiveness of a postnatal psychoeducation programme on outcomes of primiparas: Study protocol. Journal of Advanced Nursing, 71, 193-203. doi:10.1111/jan.12461

Exclusion reason: intervention was purely educational

Sidor, Anna, Kunz, Elisabeth, Eickhorst, Andreas & Cierpka, Manfred. (2016). The effects of the early prevention program "Keiner fallt durchs Netz" (KfdN) ["Nobody Slips Through the net"] in the German state of Saarland. A longitudinal study using a quasi-experimental control-group design. Zeitschrift fur Entwicklungspsychologie und Padagogische Psychologie, 48, 1-13. doi:10.1026/0049-8637/a000139

Exclusion reason: Intervention aimed at whole family

Tissier, J, Bouchouchi, A, Glaude, C, Legge, A, Desir, S, Greacen, T, et al. (2011). A perinatal mental health promotion intervention. Pratiques Psychologiques, 17, 107-117. doi:10.1016/j.prps.2010.11.006

Exclusion reason: No psychosocial intervention

Weis, Karen L & Elmore, Kelly O. (2017). Military prenatal intervention models. Thiam, Melinda A. New York, NY, US: Routledge/Taylor & Francis Group, US; pp. 151-165. Retrieved from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=psyc13&NEWS=N&AN=2017-14598-009.

Exclusion reason: No psychosocial intervention

Barilla, Dora; Marshak, Helen Hopp; Anderson, S. Eric; Hopp, Joyce W. (2010) Can psychosocial support reduce newborn admissions? MCN: *The American Journal of Maternal/Child Nursing*. 35(1), 33-39.

Exclusion reason: No psychosocial outcome measures

Appendix 3

Levels of attrition for studies

Study	n	Mean Age (range)	Ethnicity	Drop-out rate %
Ammaniti et al., 2006	111	32.5 (22-43)	Not reported	17.2% during the first 3 months of the program.
Birtwell, et al., 2013;	8	26 (17-37)	5x white Scottish, 2x white British 1x mixed white/black Caribbean.	n/a
Breustedt & Puckering, 2013	4	28 (19-38)	3 x White Scottish. 1 x black African	n/a
Cohen, et al., 2011	164	17.5 (Not reported)	Not reported	21.3%
Darwin et al., 2013	22	31.7 (26-39)	White British (77%)	n/a
Dugravier et al., 2013	440	22.3 (not reported)	57.8% French citizenship 52.1% first generation immigrants	20%
Elliott et al., 2000	373	Not reported	Not reported	Not reported
Kemp et al., 2011	208	27.7 (15-45)	Country of birth Australia: 51% Overseas (31 different countries worldwide) 49%	26%
Robling et al., 2016	1645	17.9 (16.9-18.80	88% white, 5% mixed race, 2% Asian 4%	19.3%

	black, other	1%

Appendix 4

Pre teaching knowledge questionnaire

1. *People understand attachment in different ways. According to your current understanding attachment is (please circle the correct response)*

    a. The way parents speak to children
    b. The relationship between child and caregiver
    c. The parenting style of the primary caregiver

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

2. *Give two examples of behaviours you might expect to see from an infant that has a good attachment to his or her mother*

    .....

    .....

    .....

    .....

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

3. *Give two examples of behaviours you might expect to see from a mother that has a good attachment to her baby*

    .....

    .....

    .....

    .....

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

4. *Is each of the following statements true or false?*
    a. What could be considered 'good attachment' is different in different cultures
       Answer:
    b. The concept of attachment has been shown to exist in all cultures
       Answer:
    c. Attachment occurs during pregnancy for mother and unborn baby
       Answer:
    d. Attachment between mother and baby only begins when the baby has been born
       Answer:

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

5. *In the first year of life, how many stages of the attachment relationship are there? (Please circle the correct response)*
    a. One
    b. Four
    c. Six

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

6. *Is the following statement true or false?*
   Midwives are in a good position to foster the attachment relationship between mother and baby
   Answer:

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

7. *Give two consequences of an insecure attachment during the pregnancy, for birth outcomes*

   ……

   ……

   ……

   ……

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

8. *Give two consequences of in insecure attachment post partum for the baby*

……

……

……

……

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

9. *Give two consequences of in insecure attachment post partum for the mother*

……

……

……

……

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

10. *Give three factors that may negatively affect the development of a secure attachment between mother and baby*

……

……

……

……

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

11. *Can you think of one way to assess the attachment relationship between mother and baby?*

……

……

……

……

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

12. *Can you give any examples of places or people you may signpost women to in order to access extra help?*

……

……

……

……

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

13. *You see a baby with her mother in a home visit. The baby is fretful, squirming in the mother's arms and is turning away from its mother. The mother ignores the baby but bounces her vigorously up and down on her lap. Would you describe the baby's behaviour as*

a. Anxious
b. Avoidant
c. Secure

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

14. *You have been invited to give a talk to the local mother-and-baby group. What top three tips might you give the mothers about how they could form a strong mother-child attachment relationship?*

……

……

……

……

On a scale of 1-10 (10 being the highest) how competent did you feel in answering this question? __

Appendix 5
Ethics approval

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APPENDIX 6
Doctorate in Clinical psychology Major Research Project.

INFORMATION SHEET FOR PARTICIPANTS

The development and pilot of an online teaching module for student midwives, to improve their knowledge and perceived competence of attachment issues in the perinatal period.

You are being invited to be involved in this research study. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully. If you have any further questions or concerns please contact the researcher using the contact details below. Please take time to decide whether or not you wish to take part.
Thank you for reading this information sheet.

Who is doing this research and why?

The main researcher of this project is currently undertaking a Doctorate in Clinical Psychology at Canterbury Christ Church University. Students of the course are required to submit a Major Research Project and this study is being undertaken to fulfill that requirement.

What is the purpose of the study?

The purpose of this study is to explore if teaching student midwives about attachment increases

a) Their knowledge on the attachment relationship.

b) Their perceived competence in promoting a healthy attachment, and in providing psychological care to pregnant women. In particular vulnerable women who may have difficulties that could effect the attachment between them as a mother and their unborn baby.

Why have I been chosen?

Targeted and timely support focused on improving the quality of the attachment between mother and unborn baby, may help to produce better outcomes for mother and baby. This support is most likely to come from midwives, as their contact with pregnant women means that they are well placed to detect early difficulties in the emotional relationship between mother and unborn baby. Providing you with this teaching during your study of midwifery will hopefully give you a theoretical understanding as well as practical knowledge to help develop your skills and understanding around the importance of the attachment relationship between a mother and her unborn baby. The teaching will be a blend of theory as well as practical tips and advice to help you become skilled and confident practitioners.

What will participation involve?

Participation will involve completing a teaching module that you can access through a link provided in your own time. The module will work through theory and practical tips to help you develop skills and increase your knowledge. The module does not need to be finished in one sitting and you can save your work and come back to it at a later date. The module will last approximately 90 mins and will involve reading some information as well as watching videos and taking part in quizzes to test your knowledge.

Exactly what information will I be providing?

1. Scores from a pre teaching set of questionnaires. These scores will determine your baseline knowledge and competence levels. Baseline information is required in order to see if the teaching has changed your knowledge or competence levels.
2. Scores from post teaching questionnaires. These scores when combined with the pre scores will allow the researcher to see if the teaching has change your knowledge and/competence levels.

Flow chart of process of participation:

3. Feedback data. There will be a questionnaire asking for feedback on the teaching module and how you found the process as a whole. This will be made anonymous and is collected in order to allow the researcher to make changes to improve the teaching.
4. Demographic data. Demographic data will be collected in order to explore if there are any specific characteristics that generate a bigger or smaller change in scores. For example, is there a bigger change in females compared to males?

This teaching will not directly affect any of your university results or degree outcome. However it is likely to help you gain an understanding of attachment and feel more competent to work with vulnerable women.

As this is purely a research study you are free to withdraw your consent at anytime. You are under no obligation to finish the teaching. If you wish your data to be removed at any point please contact the researcher on the contact details below.

Some of the material in the teaching package will highlight the effects of a difficult attachment style; there will also be references to mental ill health. These topics could be potentially distressing. If at any stage you feel you need to speak to somebody about these topics please contact your university counselling service or alternatively you can speak to MIND who are a registered charity that support people that may be distressed. You can access MIND at http://www.mind.org.uk or call them on 0300 123 3393 or text them on 86463. The researcher is also available to discuss and questions or concerns via email XXXXXXXXX or XXXXXXXXXX . Please also feel free to contact your personal tutor.

During the study all data will be made anonymous, encrypted and stored on password protected computer and backed up on a password protected USB stick. After the study data will be stored on a password protected CD at an office in Salomon's Centre for Applied Psychology, Canterbury Christ Church University, in a locked cabinet for 10 years after the study is completed, after which time it will be destroyed.

The results of the study will be published in a journal and you will be able to have access to a summary of the project. Please specify on the consent form which mode of information you would prefer to receive the summary i.e. email/post.

Please note that:

- You can decide to stop participation in the research at any point
- You need not answer questions that you do not wish to
- Your name will be removed from the information and anonymised. It will not be possible to identify anyone from my reports on this study.

It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw during the study or any time up until April 2016 and without giving a reason. If you withdraw from the study all data will be withdrawn and destroyed.
If you do decide to take part please retain this information sheet and sign the consent form and fill in the questionnaires that are below.

Please email this document back to the researcher. You will then receive an email with a link to the teaching.

Thank you

Appendix 7

Feedback questionnaire

Please complete the questionnaire below. The aim of this form is to get your feedback on the teaching module in order to improve it for future teaching. To students. Your answers will be made anonymous. This feedback is greatly appreciated.

1. Is there anything you feel is missing from the module? (Please circle a choice)

   Yes No

Comments:

_____
_____
_____
_____
_____
_____

2. Is there anything in the module you feel is not relevant? (Please circle a choice)

   Yes No

Comments:

_____
_____
_____
_____
_____
_____

3. What do you think about the length of the module?

Too long Just right Could be longer

Comments:

_____
_____
_____
_____
_____
_____

4. How easy was it to navigate through the module? (Please circle a choice)

   Very easy easy difficult very difficult

Comments:

_____
_____
_____
_____
_____
_____

5. Do you feel the teaching module was interactive enough? (Please circle a choice)

Yes No

Comments:

_____
_____
_____
_____
_____
_____

6. Do you feel the content of the teaching module will be useful to students? (Please circle a choice)

Yes No

Comments:

_____
_____
_____
_____
_____
_____

7. Do you think the content of the teaching module was pitched at the correct level? (Please circle a choice)

Too basic Correct level Too complicated

Comments:

_____
_____
_____
_____
_____

8. What were your overall impressions of the teaching module?

Comments:

_____
_____
_____
_____
_____
_____

9. Any other comments:

_____
_____
_____
_____
_____
_____

Appendix one

Appendix 8

Consent form

CONSENT FORM for students completing teaching module

Title of Project: The development of an online teaching module for student midwives, to improve their knowledge and perceived competence of attachment issues in the perinatal period.

Name of Researcher: **Jenna Vyas**

Please initial all boxes

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my degree being affected. ☐

3. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent.	Date	Signature

Appendix 9

Confidence measure

Competence Questionnaire

Please read the following statements and rate how much you agree on a scale from Strongly agree (1) to Strongly disagree (5). Please read the questions within the context of your practice on clinical placements.

The term 'competence' means ***"having the necessary ability, knowledge, or skill to do something successfully"***

	Strongly agree	**Agree**	**Neither agree nor disagree**	**Disagree**	**Strongly disagree**
1. I feel competent in my knowledge on the theory of attachment	1	2	3	4	5
2. I feel competent in my knowledge of the factors that can affect the attachment relationship between mother and **unborn** baby	1	2	3	4	5
3. I feel competent in my knowledge of the factors that can affect the attachment relationship between mother and **new born** baby	1	2	3	4	5
4. I do not feel competent in thinking about how attachment affects my clinical work	1	2	3	4	5
5. I feel able to assess attachment between mother and **unborn** baby	1	2	3	4	5
6. I feel able to assess attachment between mother and **new born** baby	1	2	3	4	5

7. I do not feel competent in my knowledge to intervene to promote a secure attachment between mother and **unborn** baby	1	2	3	4	5
8. I feel competent in my knowledge to intervene to promote a secure attachment between mother and **new born** baby	1	2	3	4	5
9. I am worried about working with women with mental health difficulties	1	2	3	4	5
10. I am concerned about providing emotional care to women	1	2	3	4	5
11. I feel competent in my knowledge of the mother's needs and expectations of a midwife	1	2	3	4	5
12. I feel competent in accessing external resources for the mother and baby	1	2	3	4	5
13. I do not feel it is the role of the midwife to encourage the attachment relationship	1	2	3	4	5
14. I feel competent to educate women about the attachment relationship in an appropriate and relevant manner	1	2	3	4	5
15. I feel competent in my knowledge and skills from obstetrics, neonatology, the social sciences, public health and ethics to deliver high quality, culturally relevant, appropriate care for women, newborns, and childbearing families	1	2	3	4	5

16. I do not feel competent to deliver high quality, culturally sensitive health education and services to all in the community in order to promote healthy family life, planned pregnancies and positive parenting	1	2	3	4	5
17. I feel competent to provide high quality antenatal care to maximize health during pregnancy and including early detection and treatment or referral of selected complications	1	2	3	4	5
18. I feel competent to provide high quality, culturally sensitive care during labour, conduct a clean and safe birth and handle selected emergency situations to maximize the health of women and their newborns.	1	2	3	4	5
19. I do not feel competent to provide comprehensive, high quality, culturally sensitive postpartum care for women.	1	2	3	4	5
20. I feel competent to provide high quality, comprehensive care for the essentially healthy infant from birth to two months of age.	1	2	3	4	5

Appendix 10

Demographic information

Demographic questionnaire.

Please fill out the following questionnaire by highlighting the most relevant response. This information will help the researcher to determine any specific characteristics that may influence the effect of the teaching module. For more information please see the information sheet provided.

Q1. What is your age?

- 18-24 years old
- 25-34 years old
- 35-44 years old
- 45-54 years old
- 55-64 years old
- 65-74 years old
- 75 years or older

Q2. What is your gender?

- Female
- Male
- Transgender

Q3. Which university do you study at?

……..

Q4. Which entry point are you study at

- Undergraduate
- Postgraduate

Highest level of education

- A levels
- Undergraduate degree
- Post graduate degree
- Other ……

Previous profession

- Yes. (Please state previous profession) ……
- No. Directly from education

Q4. Where do you live?

a) Countryside
b) Small town
c) Urban city

Q5. What is your ethnicity?

White

- English/Welsh/Scottish/Northern Irish/British
- Irish
- Gypsy or Irish Traveller
- Any other White background, please describe

Mixed/Multiple ethnic groups

- White and Black Caribbean
- White and Black African
- White and Asian
- Any other Mixed/Multiple ethnic background, please describe

Asian/Asian British

- Indian
- Pakistani
- Bangladeshi
- Chinese
- Any other Asian background, please describe

Black/ African/Caribbean/Black British

- African
- Caribbean
- Any other Black/African/Caribbean background, please describe

Other ethnic group

- Arab
- Any other ethnic group, please describe

Appendix 11

Journal of submission author notes

The British Journal of Midwifery (BJM) welcomes unsolicited articles on various midwifery issues. The journal **publishes original research, literature reviews and clinical case studies.** All articles submitted to BJM are subject to double-blind peer review. Following acceptance for publication, MA Healthcare will hold exclusive rights to articles. The journal is indexed on CINAHL.

Articles should be approximately 3000 words, although this can be exceeded in special cases when agreed in advance with the editor. All manuscripts should be submitted online here. Articles should be **double-spaced** and **pages should be numbered. All tables and figures should be included and numbered**.

If you have any queries relating to potential articles, please contact the Editor on 0207 501 6777 or bjm@markallengroup.com

SUBMISSIONS

1.Your article should **be submitted online** at www.edmgr.com/bjm

2.Articles should be typed **double-spaced** (and referenced), preferably in Microsoft Word. If you are not using Microsoft Word, please save the document as an ASCII or text file.

3.For purposes of confidentiality, **author identification should not appear anywhere in the article**.

4.You will **receive proofs for correction before publication**.

MA Healthcare Ltd, publishers of BJM, will hold copyright of all articles published in BJM.

ARTICLES

Title page

The title page, which must be submitted as a separate file from the main manuscript, should carry only the title of article. Author details will be entered during submission.

Abstract

An abstract of between **100 and 150 words** must be submitted giving a brief outline of the content of the article, including major findings.

Headings

Relevant **subheadings should be used** to structure the article.

Conclusions

Your conclusions should be **succinct and logically ordered.** Identify gaps in present knowledge and suggest future initiatives.

Key phrases

You must supply 4–6 full sentences that adequately summarize the major themes of your article.

Tables and figures

Figures (illustrations, graphs, bar charts and photographs) and tables (information listed in a boxed off row-and-column format) are **popular with readers and are encouraged**:

1.Please clearly indicate the number of the figure or table in the text of the article and also on the figure/table.

2.In the case of illustrative figures, our artists can transform rough drawings

you provide into finished artwork. Graphs, bar charts etc must have all percentages/numbers clearly marked on them, as our artists also redraw these.
3.Photographs and slides can be supplied in hard copy or electronically. If supplied electronically, please ensure that the images are high-resolution. It is preferable that they each be sent separately (i.e. not embedded in a Word document or Powerpoint presentation).
4. If you are sending photographs or slides, please indicate the locations of any arrows or labels on an an accompanying illustration. Also indicate the detail you particularly want to illustrate and the degree of cropping that can be made.
5.You must have written consent to publish photographs of patients and/or their conditions. Please indicate that such consent has been obtained in your submission.
6.Please ensure that permission has been granted to use them. If they are from another publication, seek the original publisher's permission.

REFERENCES
The Harvard system must be used. Provide full details of the original source of the material used (do not use 'cited in…'):
In the text
1.For one or two authors, give surnames plus the year of publication:
As Black and White (1987) have shown...
As already reported (Black and White, 1987)...
2.For three or more authors print the first author's name followed by et al:
As Black et al (1987) have shown...
3.When several references are cited simultaneously, the order should be chronological:
Ross, 1990; James, 1997; Levi, 1998
In the reference list
1.Arrange references alphabetically by first author's name.
2.Print the names and initials of all authors for references with six or less authors:
Black B, Green G (1965)...
Black B, White W (1963)...
Black B, White W, Green G, Brown B, Tan T (1973)...
Black B, Green G, Tan T (1974)...
Black B, Abel C, Tan T (1975)...
The last three references in the above list are in chronological order as they are cited in the text as 'Black et al'. For seven or more authors print the first three and add 'et al'–these references are arranged chronological order.
3.The sequence for a journal article is: author(s) (year) Title. Journal (abbreviated as in PubMed) volume(issue): first–last page numbers. For example:
Smith B, Abel CH (1987) Sexual hypersensitivity. Br J Hosp Med 33(1): 40–6
4.The sequence, layout and punctuation for books are:
Personal author:
Ellis H (1980) Lecture Notes on Psychiatry. 5th edn. Blackwell, Oxford
Editor:
Scott H, Brown B, eds (1973) Histocompatability Testing. Vol 5. Raven Press,

New York: 418–19
Chapter in Book:
Samuels B (1979) Pulmonary complications of AIDS. In: Rand A, Long B, eds. Management of AIDS. Butterworths, London: 387-–95
5.Articles that have been submitted for publication but not yet accepted are not acceptable as references. They should be cited in the text as 'unpublished observations' (XY Smith, unpublished observations, with or without a date). Similarly, 'personal communication' should be inserted in the text in parentheses.
6.Articles that have been accepted for publication but not yet published may be included in the reference list: Abel HL (1988) Endometriosis. Br J Hosp Med (in press)

Abbreviations and units

Abbreviations are acceptable as long as they are **defined at first mention**. **SI units should be used**, except for measurement of blood pressure (mmHg) and haemoglobin (g/dl).

Conflict of interest

It is the journal's editorial policy to **ask authors to declare any conflict of interest**, including any possible interest, financial or otherwise, that may embarrass the author or the journal if revealed at a later date. If you believe that applies to you, please provide a statement when prompted during the submission process.

Ethical approval

If your article involves the use of human subjects, you need to ensure that the article **contains a statement that all procedures were performed in compliance with relevant laws and institutional guidelines and that the appropriate institutional committee(s) has/ve approved them.**

Appendix 12

End of study notification letter to ethics panel/participant summary

Dear chair/participants,

I am please to inform you that my study is now complete.

The rationale of the study was that early intervention for women and their babies throughout the perinatal period has been shown to have long-term benefits for individuals, families and communities. Having a knowledgeable and confident workforce is likely to promote the attachment relationship and increase the changes of positive outcomes.

The aims of the research were to develop and pilot a teaching module for student midwives. It was hope that teaching on the attachment relationship between mother and baby throughout the perinatal period would improve students' knowledge and confidence in the area.

This teaching module has received good feedback and, with some minor adaptations to content and design, is potentially ready to be piloted again to a larger number of students on broader range of teaching programmes. The research aimed to explore the effect of teaching on midwifery student knowledge and confidence. Initial results from this pilot suggest that the module did improve performance on both variables. However, reliable of the measures is questionable and need further revision and retesting. Further evaluation with large sample sizes across multiple sites is also required. The study also explored the relationship of work locus of control with knowledge and confidence, there were no relationships found with work locus of control and knowledge or confidence.

Many thanks
Jenna Vyas-Lee