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IBriS Study

Intervention Supporting Breastfeeding in Substance Dependency

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ABSTRACT

IBriS Study:
Intervention supporting Breastfeeding in Substance Dependency

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Degree of Doctor of Philosophy

Introduction: Breastfeeding offers the substance exposed mother and child potential short and long-term health benefits, with breast milk shown to alleviate the severity of Neonatal Abstinence Syndrome. Substance dependent women, however, have limited success establishing breastfeeding with physical, psychological and institutional factors cited as barriers. This study aimed to develop and test the feasibility of an evidence informed and theory based intervention to support continued breastfeeding for this group.

Methods: The research was a two-phase feasibility study. Phase 1 informed intervention development using a mixed methodology approach which included (a) a comprehensive systematic literature review of breastfeeding support for women from disadvantaged groups (b) expert advisory group recommendations and (c) 'think aloud' verbal protocols with opioid dependent women. Phase 2 underpinned the evidence with the theoretical constructs of behaviour change, prior to testing the acceptability and implementation fidelity of the intervention in a feasibility study with an embedded small-scale randomised controlled trial.

Results: Phase 1 identified the barriers to breastfeeding continuation as low maternal self-efficacy; neonatal feeding difficulties associated with withdrawal and unsupportive healthcare practices. Evidence and theory synthesis resulted in an integrated breastfeeding support model founded on practical, informational, psychological, person-centred and environmental components. Phase 2 demonstrated that the intervention was feasible to implement and acceptable to participants. The randomised

controlled trial reported higher rates of continued breastfeeding and a greater level of maternal confidence in breastfeeding ability in the intervention group compared to the control group. Breastfed infants were less likely to require pharmacological management and had corresponding shorter durations of hospitalisation than formula fed infants.

Conclusion: The research provided an original contribution to the development of a complex healthcare intervention which is meaningful to both existing research and clinical practice. The findings highlighted the potential of the intervention to support breastfeeding for the substance exposed mother and baby, which has wide ranging implications for the improved health and social equalities of this group.

Keywords

Feasibility study; healthcare intervention; substance use disorder; substance dependence; opioid dependence; Neonatal Abstinence Syndrome; breastfeeding support.

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CHAPTER 1
Introduction

1.0 Introduction

The thesis details the development process, and assessment of the feasibility, of an evidence informed and theory based intervention to support the continuation of breastfeeding for the substance exposed mother and baby.

This introductory chapter presents a brief overview of the study background and its context. The governance, research setting and local substance misuse services for pregnant women are described. This situates the study in its prevailing geographical, socio-cultural and clinical context. This is followed by a rationale for the choice of research topic in relation to policy, practice and contemporary evidence. The research purpose statement is forwarded and the chapter concludes by identifying the key research questions and research aim.

1.1 Overview of Research Context

Given the long-standing history of problem substance use in Scotland substantial investment has been made in recovery programmes (The Scottish Government 2008). The promotion of substitution medication services, a comprehensive package of harm reduction measures and prescription of methadone or buprenorphine, is at the forefront of these initiatives. This approach is considered a means of reducing the use of illicit substances, improving the general well-being of those addicted and tackling anti-social drug seeking behaviour (Amato *et al.* 2013).

Current national and international guidelines recommend the prescription of methadone for substance dependent women during pregnancy, as this is considered to optimise clinical outcomes for the mother and fetus compared to on-going illicit drug use (National Institute of Health and Care Excellence

(NICE) 2010; World Health Organisation (WHO) 2014). This policy is not without consequence, however, as methadone exposure in utero places the baby at risk of Neonatal Abstinence Syndrome (NAS) following birth. NAS is a self-limiting condition and supportive care initiatives, including breastfeeding, are encouraged to console the infant and alleviate the severity of the withdrawal process (Department of Health (DoH) 2007). Yet, the rate of successful breastfeeding establishment amongst substance dependent women is much lower than national averages with significant attrition in the initial postnatal period (Wachman *et al.* 2010; McAndrews *et al.* 2012). Several reasons have been forwarded for the premature discontinuation of breastfeeding amongst this population (Balain and Johnstone 2014). These include physical feeding difficulties inherent of NAS, low maternal self-efficacy and unsupportive health service practices. Yet, these are factors which should be modifiable with targeted interventions.

Pregnancy and motherhood are well documented as primary drivers for life style change, and are shown to be powerful motivators for women to abstain from illicit drug use (Ballard 2002; Chandler *et al.* 2014). Additionally, many women with a substance use disorder feel there is a need to prove their credentials for motherhood, both to themselves and to health and social care officials, with breastfeeding frequently equated as representational of a 'good mother' (Marshall *et al.* 2007; Fraser *et al.* 2007). Hence, for many women the intention and a strong desire to breastfeed is present, the challenges are considered as surmountable, yet a significant number are still unable to attain their goal.

Promoting and protecting breastfeeding is a priority public health objective due to the significant health, social and economic advantages it confers (The Scottish Government 2011). Infant feeding method is also a contributory factor in health and social equalities, with prolonged breastfeeding considered influential in reducing disparity. Alleviating the severity of NAS is a specific benefit of breastfeeding in relation to substance dependence. Therefore, there are substantial generic and distinct advantages of breastfeeding to improve the well-being of the substance exposed mother and infant, and combined with the poor breastfeeding rates achieved, highlights the urgent need for research activity in this area.

1.1.1 Definition of Addictive Substance Use and Dependence

Addictive substances constitute a wide range of agents including tobacco, alcohol, solvents, herbal products and prescription and illicit drugs (The Scottish Government 2008). Historically, controversy has surrounded the phenomenon of addictive substance use. It has been subject to varying descriptions arising from medical, legal and social perspectives and the terminology for the different situational contexts of use and users often intentionally chosen to convey judgemental or moralistic overtones, depending on underlying motivations (Jones and Fielder 2015). Acknowledging this, the rationale for, the definition of and the terms adopted to describe substance use in the current study are outlined below.

The Advisory Council on the Misuse of Drugs (ACMD) forwarded their definition of substance use as:

> *'any drug use which has serious negative consequences of a physical, psychological, social and interpersonal, financial or legal nature for users and those around them'* (ACMD 2003).

The ACMD further categorised problem drug use as frequent, may involve poly-pharmacy and produces the features of dependence. Drug dependence was classified by WHO (1994) as a combination of 3 or more pre-determined conditions occurring for a defined period of time. These included a strong desire to take the substance; impaired capacity to control drug use; withdrawal symptoms with non-use; tolerance of use; preoccupation with drug seeking behaviour and persistence of substance use despite adverse consequences. In 2014, WHO updated this to include dependence state or syndrome, defining this as a cluster of physiological, behavioural and cognitive phenomena where the use of a substance is attributed a much higher priority by the individual than other behaviours that once held greater value. WHO (2014) forwarded the concept of 'substance use disorders' to include both substance use and the co-existence of dependence syndrome.

These definitions coined by the ACMD (2003) and WHO (2014) have been adopted by the Scottish Government to underpin their understanding and description of substance use- inclusive of alcohol, tobacco and illicit and

prescribed drugs- in policy documents and to guide National Health Service (NHS) Scotland services (2008; 2011). Additionally, the use of a common lexicology of terms for those dealing with individuals and families affected by substance use is advised by professional bodies (Nursing and Midwifery Council (NMC) 2015; WHO 2014). Terminology which implies negative connotations or value judgements such as abuse, addict and addiction are discouraged and should be avoided. Recommended terms such as substance/drug use, substance use disorders, substance/drug misuse and substance/drug dependence are the preferred terms and should be promoted by health professionals.

The vocabulary used in this thesis follows NHS Scotland preferred terminology for those involved in substance/drug use and present with the signs of substance dependence. Substance exposure has been chosen to describe the circumstances of the feus/neonate. The term 'substance misuse services', is adopted to describe the specialist programmes available, inclusive of substitution medication services. The term opioid dependent is used for women engaged in opioid maintenance treatment (OMT), whether methadone of buprenorphine. Although it is accepted that poly-substance use occurs and may co-exist with OMT. This may include the concurrent prescription of other medication such as sedation, with benzodiazepine supplementation not uncommon, and the use of illicit substances cannot be excluded (Jones *et al.* 2012). Additionally, cigarette smoking/tobacco is highly prevalent amongst those who engage in other types of addictive substance use.

Therefore, substance use/dependence is adopted as a succinct description for the purpose of the thesis and research project. When reference is made to women who are engaged with OMT the use opioid dependent is favoured, acknowledging the above proviso.

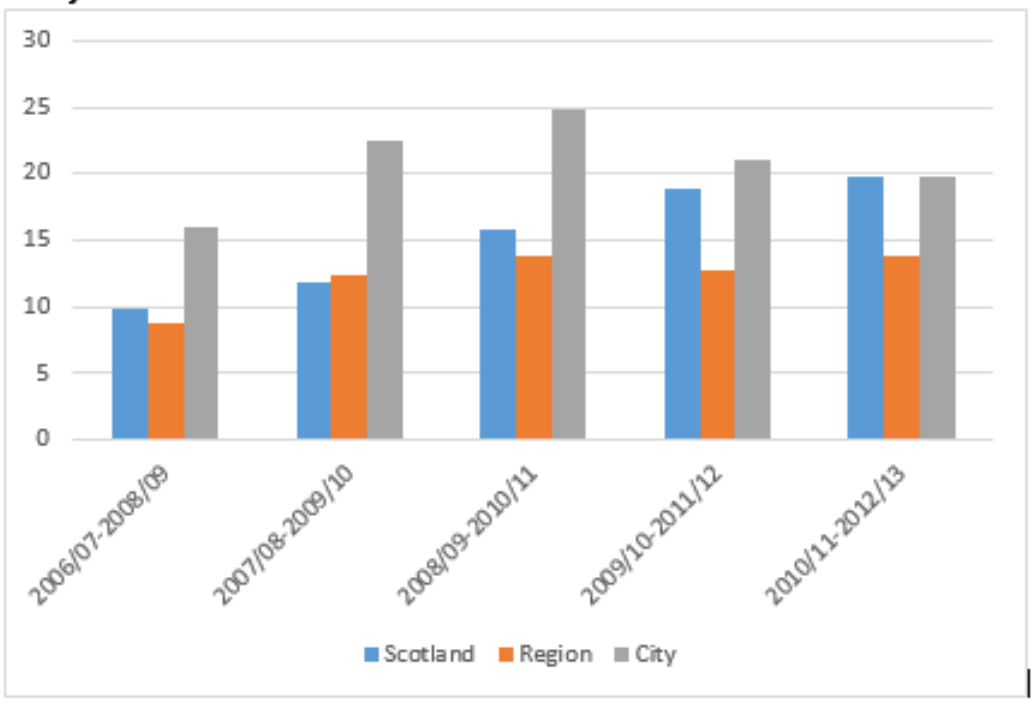
1.1.2 Research Setting: Geographic and Socio-Economic Status

The research was conducted in a tertiary level maternity hospital providing specialist midwifery, obstetric and neonatal services with estimated 5-5500 births per annum. The unit is situated in the North-East of Scotland serving a large geographical region with a population of approximately 500,000. Almost 50% of the population reside in a densely populated urban city and 50% in more remote and rural settings. The region has a diverse composition with sites of socio-economic deprivation situated alongside highly affluent areas. This has resulted from periods of economic expansion due to oil and gas exploration mingled with the decline of traditional industries.

1.1.3 Prevalence of Substance Dependence in Pregnancy

Figure 1 details the prevalence of substance dependence in pregnancy over 3 year aliquots countrywide, regionally and in the major city in which the research took place (Information Services Division (ISD) 2014). Within Scotland as a whole the number of pregnancies associated with maternal substance dependence is increasing annually, although the rise is marginal. The maternities recording drug misuse in the region and city mirror each other with an increasing trend from 2006 to a peak in 2011. Since that time, the rate has decreased in the city but this is not replicated in the region where rates are increasing after an initial decline. However, the documented statistics on illicit drug use are notoriously unreliable and depend on self-disclosure, assessment and recording techniques, which limits their usefulness. It does, however, give an indication of the minimum levels of drug dependency (Whittaker 2011).

Figure 1: Rate of Maternities Recording Drug Misuse 2006-2013 (per 1000 maternities)



1.1.4 Specialist Obstetric and Substance Misuse Services Clinic

It has been demonstrated that the provision of integrated and specialist care in substance dependence is cost effective and can improve birth outcomes, increase client satisfaction and address complex needs (Hepburn and Elliott 1997; Mitchell *et al.* 2003; Milligan *et al.* 2011). There has been substantial investment in the development of these services but access is variable and geographically challenging for some women (DoH 2007).

Within the local tertiary consultant unit there is a bi-weekly combined specialist obstetric and substance misuse service clinic. The clinic was established in 1997 to offer multidisciplinary care and advice to local pregnant drug users. Hall and van Teijlingen (2006) interviewed women attending the combined clinic to gain an understanding of their experiences of the service. They concluded that the attendees perceived the non-judgemental attitude of staff, continuity of staff, high level of support, reliable and drug specific information and the availability of multi-agency integrated care in one locale as the most important aspects of the service provided.

The clinic offers antenatal and postnatal midwifery care in conjunction with specialist drug services, thus enabling a comprehensive and corroborative assessment of the needs of the woman and baby. The multi-disciplinary team consists of an obstetrician; a community midwife; a community psychiatric nurse; a social worker and workers from a voluntary drugs service who provide counselling and social support. There is also the provision within the hospital to offer drug detoxification if requested. However only a minority of drug dependent women use this facility and it is more commonly accessed by those suffering from alcohol addiction.
The clinic has an average caseload of 60-80 women per annum although these figures have fluctuated with the decreased birth rate indicative of Scotland as a whole and with variations in patterns of drug use (Hall and van Teijlingen 2006). Following the confirmation of pregnancy, women engaged with addictive substance use, who live within the city boundaries, are referred to the substance misuse services clinic at the tertiary hospital to access consultant led obstetric care. The consultant pathway followed by this cohort recommends clinic attendance every 2 weeks for assessment of fetal and maternal well-being. This level of frequency is needed for increased vigilance of high-risk pregnancies and to titrate methadone dosage as maternal requirements change with the increased blood volumes associated with pregnancy. Daily methadone is prescribed for the overwhelming majority of pregnant women to stabilise their drug use, although there is an increasing use of buprenorphine. Once into the third trimester antenatal appointments may increase to weekly depending on individual needs. The clinic offers a postnatal and health visitor services until 8 weeks following the birth of the baby. This allows stabilisation of maternal methadone dose.
For substance dependent women who reside in rural areas there are peripheral hospitals within the health board jurisdiction which offer consultant obstetric reviews with the remainder of their antenatal care provided by their local GP. All women engaged with substance misuse services are advised to give birth in the consultant unit where specialist neonatal services are available if required. Cumulatively, within the consultant unit there are an estimated 100 births per annum of neonates exposed to addictive substances in utero (Black *et al.* 2013).

Given the researcher's base at the tertiary unit and established working relationships within the hospital, it was considered appropriate and advantageous to conduct the research in this area. The relative merits of recruiting potential participants for the feasibility study from the peripheral clinics during the antenatal period was considered. The disadvantages of increased resource expenditure and the unfamiliarity with the gatekeepers, however, outweighed the possible number of available recruits.

1.1.5 Neonatal Abstinence Syndrome and Infant Feeding Method

The incidence of NAS varies extensively between healthcare facilities and geographically (O'Grady *et al*. 2009). With differing hospital practices for NAS assessment and variability in the local awareness of substance dependence resulting in reported figures from 13% to 94% of infants requiring pharmacological treatment (Hudak and Tan 2012; Kaltenbach *et al.* 2012). In the local NHS region, initial recorded figures demonstrate an upward trend with the number of infants affected by NAS rising from 15 to 48 per year between 1998 - 2003 (Lloyd and Myerscough 2006). For the past decade these figures have plateaued with current rates approximately 45-52 cases annually (Clevermed 2015).

As the sub-set of substance dependent women who initiate breastfeeding is relatively small, figures are not available from national or local databases due to the risk of identification (personal correspondence). However, a review of the local situation suggests that there is a gradual increase in the number of substance dependent women initiating breastfeeding, although this figure is still considerably lower than average national breastfeeding rates. Additionally, the rate of breastfeeding discontinuation is significant, particularly in the first postnatal days when neonatal withdrawal symptoms are most pronounced. Whilst this overview results from personal correspondence (with specialist teams for substance misuse and infant feeding) and from local clinical observation, it is substantiated by published national and international literature (Welle-Strand *et al.* 2013; Balain and Johnstone 2014; Asti *et al.* 2015).

In summary, the prevalence of substance dependence is not diminishing and therefore, the number of infants born at risk of NAS will remain a healthcare,

social and economic issue for the foreseeable future. In respect of the current study, the local situation indicates lower than average breastfeeding rates exist amongst substance dependent women but are gradually increasing, a trend which is reflective of the national context.

1.2 Research Rationale

The rationale behind the research topic is discussed in relation to legislation and policy, statutory regulations governing Health Care Professionals (HCP), clinical practice and the existing evidence base. This gives an overview of the current situation regarding breastfeeding support in substance dependence, the implications of maintaining the status quo and the importance of continued research investment in this area.

1.2.1 Policy and Legislation

In the late 20th century, an increasing awareness of the health and social benefits of breastfeeding coupled with the emerging disadvantages of formula feeding focussed attention on the need to urgently address diminishing breastfeeding rates with WHO and United Nations Children's Fund (Unicef) collaborating to produce the Innocenti Declaration (Unicef 1990). This proposed a vision of an environment which enables mothers to make informed decisions about infant feeding methods through the provision of targeted interventions. The onus was placed on public bodies to gain an understanding of the determinants influencing infant feeding choices and to identify if these factors could be modified, and under which circumstances. Substantial research activity has concluded that inherent socio-cultural and economic demographics impact on breastfeeding initiation and prolongation and deemed these as modifiable with long-term investment and population wide promotional strategies (Renfrew *et al.* 2012a; Lagan *et al*. 2014). Following breastfeeding initiation, it is proposed that the type and quality of professional healthcare support available influences maternal decisions on the continuation and establishment of breastfeeding (Entwistle 2013). This is seen as a modifiable stage of the breastfeeding process with the availability of high quality and appropriate short-term interventions considered a means

of influencing maternal and infant feeding behaviour (Beake *et al*. 2012; Redshaw and Henderson 2012).

The United Kingdom (UK) public bodies have instigated a framework of complementary strategies to address the challenge of increasing breastfeeding rates. To improve the quality of infant feeding provisions the Baby Friendly Initiative (BFI) was implemented extensively throughout National Health Service (NHS) facilities (Unicef 2009). In Scotland, a number of maternal and infant health nutritional directives concentrate on promoting sustained breastfeeding (The Scottish Government 2011). These include maternity protection legislation to facilitate breastfeeding in the public sphere and counter negative socio-cultural perspectives (The Scottish Government 2005). Many of these initiatives place particular emphasis on children considered socio-economically disadvantaged. This is particularly pertinent for infants born into or living in substance using households, as there is a strong association between social deprivation, poor health outcomes and substance use (Brown *et al.* 2010; ISD 2012).

Hence, breastfeeding is seen as a foundational part in the much broader context of addressing health and social equalities and its role is pivotal to long- term individual and national outcomes. Collectively, the substance exposed mother and baby are a priority group in relation to health and social policy, whilst recognising and addressing their distinct needs should be a primary objective for healthcare professionals

1.2.2 Statutory Regulation for Health Care Professionals

For the health care professional there is a requirement to achieve and maintain the professional standards defined by their regulatory body and to practice within the criteria set by their employing authority.

Nurses and midwives are bound by the professional standards set by the Nursing and Midwifery Council. The NMC code of conduct states that practitioners are accountable to deliver a standard of care commensurate with their position, are responsible for maintaining a relevant knowledge base and competency, and must accept liability for their own actions, omissions and attitudes (NMC 2015). Additionally, employing authorities specify criteria by which acceptable practice is measured and NHS Scotland

prioritise three quality ambitions; that HCP deliver care that is safe, effective and person-centred (The Scottish Government 2010). The onus is, therefore, on the professional to know what is, and how to deliver best practice in a given context, be aware of alternative treatments choices and facilitate clients to arrive at an informed decision (Polit and Beck 2013).

The provision of Evidence Based Practice (EBP) is considered the preferred and optimum approach to implement the highest quality of healthcare (Craig and Smyth 2012). EBP is the delivery of care based on the best available evidence or clinical expertise and integrated with patient values (Sackett *et al.* 1996). There are, however, major impediments to EBP such as the availability of, and what constitutes, best evidence and this varies significantly between medical disciplines and clinical conditions (Greenhalgh 2014). In the relatively young and specialist area of neonatology there is often a paucity of reliable or applicable evidence (Lissauer and Fanaroff 2011). The ethical and moral dimensions of recruiting and conducting research with this vulnerable group places further constraints on the situation. This has direct consequences on the depth of the evidence base in relation to the management of infants at risk of NAS. Consequently, the absence of robust evidence challenges the assessment of clinical efficacy of treatments and limits the advocacy of a person-centred approach for this cohort. Subsequently, there is an identified need for investment in ethically sensitive and clinically relevant research to explore the context of substance exposure in utero and the implications for the neonate.

1.2.3 Clinical Practice

Previous research confirms that breastfed substance exposed infants achieve better clinical outcomes than their formula fed counterparts (McQueen *et al*. 2011a; Welle-Strand 2013). With a substantial evidence base clarifying the safety profile of methadone in breastmilk, guidelines recommend that professionals encourage and promote the initiation and continuation of breastfeeding in substance dependence (DoH 2007; NICE 2010; WHO 2014). Hospital reviews by O'Grady *et al.* (2009) in the UK and Mehta *et al*. (2013) in the USA found that breastfeeding is not routinely or actively promoted for many substance dependent women. O'Grady *et al.* noting that only 81% of

UK hospitals encourage breastfeeding, 27% apply conditions and 7% actively discourage any breastfeeding amongst drug dependent women. Local contraindications based on drug history, compliance and viral status are all factors imposed on breastfeeding promotion and support. The presence of feeding difficulties resulting from neonatal withdrawal symptoms are also frequently associated with low breastfeeding continuation (Boxwell 2010; Maguire *et al.* 2015). Furthermore, several authors cite unhelpful institutional practices and the unsupportive attitudes of professionals towards these mothers as instrumental in high breastfeeding attrition rates (Pritham 2013; Roussos-Ross *et al.* 2015). Given the minority of women who successfully achieve the establishment of breastfeeding there is a clear disparity between recommendations and practice (Wachman *et al.* 2010).

1.2.4 Research Evidence

A preliminary, time limited, literature search was conducted to establish the status of the research base in relation to breastfeeding support in the context of substance dependence. Table 1 details the search terms and databases.

Table 1: Literature Search Strategy: Databases and Keywords

Databases	AMED- The Allied and Complementary Medicine Database
	CINAHL- Cumulative Index of Nursing and Allied Health Literature
	Cochrane Library
	Joanna Briggs Database of Systematic Reviews
	Internurse
	MEDLINE
	PsycARTICLES
	Sage Journals Online
Search Engines	Science Direct
	Web of Science
Internet sources	Google Scholar
	NICE
Repositories	Scottish Intercollegiate Guidance Network
	E-thesis online
	Open Air PhD Thesis repository (Robert Gordon University)
Keywords	Breastfeeding; Breast-feeding
	'Infant feeding'
	Support; Intervention
	Substance dependent
	NAS; Neonatal Abstinence Syndrome; Neonatal withdrawal; Neonatal Narcotic Syndrome
	Methadone; Buprenorphine

A comprehensive exploration was not the intention at this stage with the focus directed exclusively on breastfeeding support /infant feeding method and the implications of this for NAS. The literature was searched for evidence in the English language only, published up to June 2012.

The search strategy did not return any primary research on breastfeeding support, whether targeted or generic, for the substance exposed mother and baby. There were eight studies identified which discussed the association

between infant feeding method and the course of NAS. These included one case control study, two observational studies and five retrospective reviews of medical and nursing documents. The returned studies, their methods and findings, are listed in Table 2.

Table 2: Literature Overview: Study, Methods and Findings on Impact of Infant Feeding Method on Neonatal Abstinence Syndrome

Study Citation **Country of Origin**	**Study** **Aim/Objective**	**Study Design** **Participants**	**Key Findings/** **Recommendations**
Malpas and Darlow (1999) New Zealand *'Neonatal abstinence syndrome following abrupt cessation of breastfeeding.'*	To report on the observation of 2 substance exposed neonates.	Case report 2 infants	Infants appeared to develop neonatal abstinence syndrome after abrupt discontinuation of breastfeeding. Recommendations for controlled weaning.
Ballard (2002) New Zealand *'Treatment of neonatal abstinence syndrome with breast milk containing methadone.'*	To describe the management of infants with NAS.	Observational study 16 infants with NAS Treated with morphine (n=6) Treated with breast milk from methadone maintained mother (n=10)	The length of stay was shorter for the breastfeeding cohort compared to opiate treated infants.
Abdel-Latif *et al.* (2006) Australia *'Effects of breast milk on the severity and outcome of neonatal abstinence syndrome among infants of drug-dependent mothers.'*	To assess the effects of breast milk on the severity and outcome of neonatal abstinence syndrome.	Retrospective cohort study 190 substance dependent mother and infant pairs. Breastfed (n=85)	Breast milk intake was associated with reduced NAS severity, delayed onset of NAS, and decreased need for pharmacologic treatment. Duration of length of hospital stay was less in breastfed infants.

Jansson *et al.* (2008) United States of America (USA) *'Methadone maintenance and breastfeeding in the neonatal period.'*	Evaluation of concentrations of methadone in breast milk.	Matched case control study Methadone maintained, lactating women / infant dyad (n=8) Matched formula-feeding mother/infant dyad (n=8)	Fewer breastfed infants required pharmacological therapy for NAS but this was not statistically significantly. The authors recommend breastfeeding in methadone maintained women.
Dryden *et al.* (2009) UK *'Maternal methadone use in pregnancy: factors associated with the development of neonatal abstinence syndrome and implications for healthcare resources.'*	To investigate factors associated with the development of neonatal abstinence syndrome.	Retrospective case note review Four hundred and fifty singleton pregnancies of women prescribed substitute methadone. Breastfed (n=99) formula fed (n=351)	Breastfeeding was associated with reduced odds of requiring treatment for NAS. Pregnant drug-misusing women should be encouraged and supported to breastfeed.
Isemann *et al.* (2011) USA *'Maternal and neonatal factors impacting response to methadone therapy in infants treated for neonatal abstinence syndrome.'*	To identify maternal and neonatal factors that influence the response to methadone therapy for neonatal abstinence syndrome.	Retrospective review 128 infants that received pharmacotherapy for opiate withdrawal	Increased breast milk intake reduced length of stay with shorter durations of pharmacological treatment. 5% of infants experienced rebound withdrawal following reduction of breast milk intake.

McQueen *et al.* (2011a) Canada *'The impact of infant feeding method on neonatal abstinence scores of methadone-exposed infants.'*	To determine whether neonatal abstinence scores of infants exposed to methadone in utero differed by infant feeding method.	Retrospective chart review Twenty-eight infants with NAS. Breastfed (n=8) Combination fed (n=11) Formula fed (n=9).	Breastfed infant had decreased severity and duration of NAS; less pharmacological treatment compared to infants who were combination or formula fed. Women in methadone programmes should be encouraged and support to breastfeed.
Pritham *et al.* (2012) USA *'Opioid dependency in pregnancy and length of stay for neonatal abstinence syndrome.* '	To examine effect of substitution medication on neonatal outcomes, including length of stay for NAS.	Retrospective descriptive study Neonates of women maintained on methadone (n=136); breastfed (n=14); formula (n=96); combination fed (n=22). Neonates of women maintained on buprenorphine (n= 16); breastfed (n=3); formula (n=9); combination fed (n=4).	Length of stay was shorter in breastfed neonates than formula or combined feeding. The author recommends breastfeeding to shorten length of stay.

Jansson *et al.* (2008) conducted a matched case control study assessing the bioavailability of methadone in breastmilk with a secondary observation comparing neonatal outcomes between eight breastfed infants and their formula fed counterparts. The findings demonstrated that fewer breastfed infants required pharmacological therapy, but this was not statistically significant. The authors accepted that a limitation of the study was the small number of participants (n=16) which can impact on the assessment of statistical significance.

The measured outcomes from the five retrospective reviews/studies of neonatal documentation were considered collectively. Overall, the authors concluded that breastfed infants demonstrate improved outcomes either in terms of shorter hospital duration, reduced need for pharmaceutical management or severity of withdrawal compared to formula fed infants. However, the heterogeneity of outcome measures and variability in the effect sizes limits speculation on the precise impact of breastfeeding compared to formula feeding. Additionally, a direct comparison between outcomes was restricted as the exact definition of breastfeeding, combination feeding or formula feeding was not clearly stated or not given by all the studies. The evidence generated by retrospective reviews is also constrained by the inherent weaknesses of this research method. There may be issues of confounding variables, self-selection of the respective cohort groups and different or arbitrary outcome measures (Creswell 2013). These factors can all affect the robustness of the evidence.

The literature search highlighted several key gaps in the existing evidence base. There was a paucity of prospective randomised trials within the methodological approaches used. Studies exploring the breastfeeding experience of substance dependent women, the facilitators and barriers, were poorly represented.

Further, research investigating ways in which to support substance dependent women meet their breastfeeding aims was conspicuous by its absence. Whilst this highlights the urgent need for robust research to address this gap, it also raises questions as to the reasons behind this deficit. The reluctance of the substance dependent community to engage with research is well-documented, and may be a contributory factor in this situation (Goode 2002; Taylor and Kearney 2005; Radcliffe 2011).

1.3 Purpose Statement

On consideration of the background and current status described the following purpose statement was formulated:

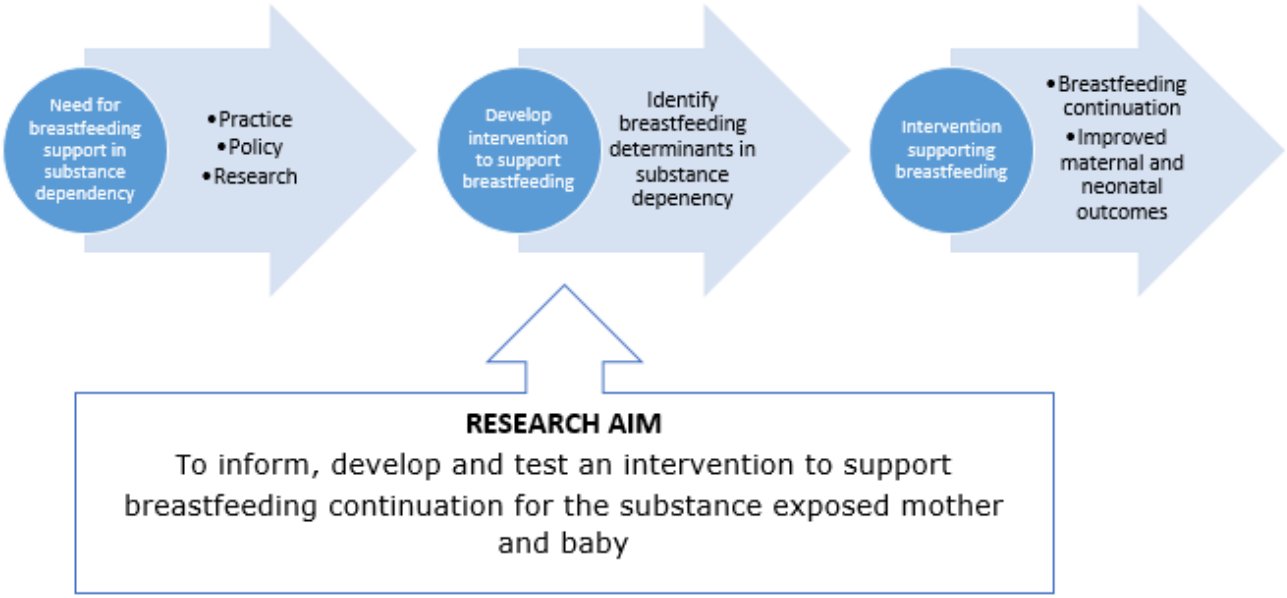
'The purpose of the research is to design and test the feasibility of an intervention to support breastfeeding amongst women who are substance dependent. It is proposed that a targeted intervention is a means of enabling the substance dependent mother and baby to continue breastfeeding during the period of neonatal withdrawal. The objective of supporting breastfeeding is to positively impact on short and long-term maternal and neonatal outcomes. The research aim is to be both meaningful for clinical practice and to contribute to the existing body of research knowledge.'

1.4 Conceptual Framework

The introduction of generic breastfeeding support interventions in the immediate postnatal period have shown positive results amongst the general population (Renfrew *et al.* 2012a). This demonstrates the potential for short-term initiatives to influence breastfeeding behaviour. The premise of this research is that an intervention informed by the factors influencing breastfeeding behaviour, within the context of substance dependence, should specifically target the particular challenges experienced by this cohort. The intervention would offer tailored support. This has the potential to enable the continuation of breastfeeding and may result in improved short and long-term maternal and neonatal health, social and psychological outcomes. The research aim, therefore, is to inform, develop and test an intervention which will support breastfeeding continuation for the substance exposed mother and baby.

Parahoo (2014) suggested that constructing a theoretical framework of a deductive relationship between variables can help conceptualise a research situation and enable identification of the key issues, research aims and objectives of a study. Figure 2 depicts the conceptual framework for the proposed study.

Figure 2: Conceptual Framework



1.5 Research Questions

The conceptualisation of the current clinical situation, context and research aim highlighted a number of key uncertainties of the study associated with the process, implementation and outcome of the intervention. The following research questions emerged:

PROCESS

- What are the key determinants of breastfeeding continuation in the context of substance use?
- What are the key components of a breastfeeding intervention in the context of substance use?
- Would substance dependent women be receptive to research participation?

IMPLEMENTATION

- Would a breastfeeding intervention be acceptable to substance dependent women?
- Would a breastfeeding support intervention be feasible to implement?

OUTCOME

- What is the efficacy of an intervention tailored to support breastfeeding continuation within the context of substance use?
- Would breastfeeding continuation affect the severity of NAS experienced by the substance exposed neonate?

1.6 Chapter Summary

This chapter introduced the research purpose and outlined the clinical context of the study. The rationale for the choice of topic was given in relation to government and healthcare policy, the current clinical situation and the identified gaps in the contemporaneous evidence base. This exposed the imperative nature for research specifically targeted at interventions to support the continuation of breastfeeding amongst the substance exposed mother and baby.

Concurrently, several key uncertainties emerged. These included the complexities of the phenomenon of breastfeeding support and of conducting research with the population group of substance exposed women and neonates which may present challenges for the ethical, sensitive and inclusive nature of the research design and conduct. Therefore, a wider understanding of the contextual issues informing the study was warranted. A comprehensive literature review was conducted to enable a greater appreciation of these factors and this is recounted in Chapter 2.

CHAPTER 2
Literature Review

2.0 Introduction

Reviewing the existing relevant literature is a key initial step in the research process and serves a variety of purposes. It situates the study within its wider context and enables an exploration of underpinning influences and contradictions. The work already completed is identified, highlighting what is known, what is currently under investigation and where gaps in the knowledge base exist. This information enables the direction of proposed studies to be determined and the research aims and objectives formulated. This chapter commences with a description of the literature review search strategy. The subsequent findings are divided into three sections. Section 1 details breastfeeding practice and support; Section 2 concerns the substance exposed mother and baby and Section 3 reports the development process for complex healthcare interventions. These topics were identified in Chapter 1 as integral and influential components of the research context. The chapter concludes with a review of the research questions forwarded in Chapter 1, how these have been informed by the literature review and the recommendations for intervention development based on these findings.

2.1 Search Strategy and Structure

The literature search was initially undertaken in February 2013 with the review continuously updated during the thesis. This adopted an expansive approach to capture the wider context of the historical and current status of the leading factors.

The search strategy consisted of a focussed search of online databases and search engines for qualitative and quantitative studies; government policy documents; drug agency recommendations and grey literature. Library databases were used to source textbooks and unpublished academic works. The literature was searched for evidence in the English language only. Table

3 details the key words and terms used and the databases, search engines and internet sites of professional bodies searched.

Table 3: Literature Search Strategy- Databases and Key words

Database	AMED
	CINAHL
	Cochrane Library
Search Engines	Joanna Briggs Database of Systematic Reviews
	Internurse
	MEDLINE
Internet	PsycARTICLES
sources	Sage Journals Online
	Science Direct
	Web of Science
Repositories	Department Health
	E-thesis online
	Google Scholar
	NICE
	Open Air PhD Thesis repository (Robert Gordon University)
	The Scottish Government
	Scottish Intercollegiate Guidance Network
	WHO/Unicef
Keywords	Breastfeeding; Breast-feeding
	buprenorphine
Terms	'complex healthcare intervention'
Concepts	'healthcare intervention'
	'implementation studies'
	'infant feeding'
	methadone
	NAS; 'Neonatal Abstinence Syndrome'; 'neonatal withdrawal'; 'Neonatal Narcotic Syndrome'
	'substance addict*/depend*/misuse*
	support; intervention

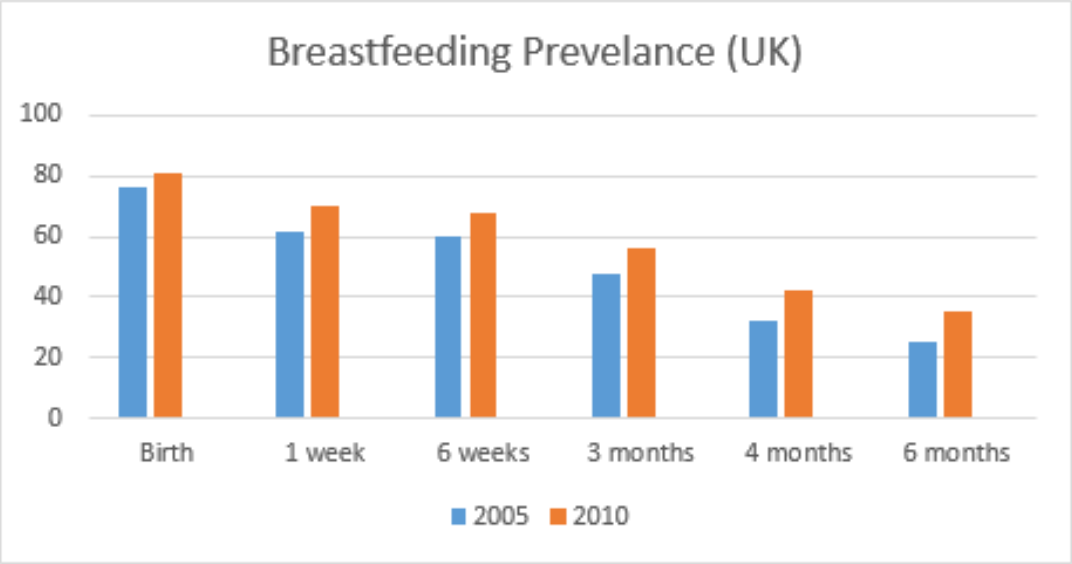
Key words listed included synonyms, alternate spellings and terms used in other countries and healthcare settings to describe the British equivalent. Due to the extensive body of literature available on breastfeeding the Boolean operators AND/OR were applied to combine with other search terms. This refined the search in relation to the relevance of the evidence returned and the quantity. Evidence was appraised for its relevance to the research aim and context of the study.

2.2 Section 1: Breastfeeding Practice and Support

Breastfeeding is the optimum and recommended method of infant nutrition. However, the predominance of breastfeeding as the infant feeding method of choice in the UK has been, and continues to be, significantly challenged. Historically, this was attributed to the advent of industrialisation, availability of formula milk and the medicalisation of maternity care (Faircloth 2010). The increased prevalence of formula feeding established this method as an easy, realistic alternative to breastfeeding with some social groups coming to regard bottle feeding as their accepted and cultural norm (Dungy *et al.* 2008; Brown *et al*. 2010). Latterly, combined media and social pressure stigmatising public breastfeeding has resulted in diminishing opportunities for vicarious experience. The sustained marginalisation of breastfeeding has seen an erosion of confidence amongst women in their ability to successfully nurture their infant thus perpetuating the decline of breastfeeding further (Lagen *et al.* 2014; MacVicar *et al.* 2015).

In response, substantial government investment, both financial and legislative, has been made in breastfeeding promotion and support in recent years. Figure 3 depicts the increasing prevalence of breastfeeding initiation and continuation in the UK, with the 2010 survey recording an initiation rate of 81% compared to 76% in 2005 (McAndrews *et al.* 2012).

Figure 3: Breastfeeding prevalence in UK, 2005-2010 (McAndrew et al. 2012)



Despite this improvement, set targets for breastfeeding initiation and duration are yet to be realised, and the UK still lags behind its European counterparts. Furthermore, significant attrition occurs in the initial postnatal period followed by a gradual decrease in breastfeeding rates over the first six months. Exclusive breastfeeding occurs for 69% of infants at birth, this falls to 46% at the end of the first week and only 23% of women continue to breastfeed at 6 weeks (McAndrews *et al.* 2012). High attrition rates suggest that whilst many women intend to breastfeed their attempt to establish lactation proves unachievable. Breastfeeding problems such as perceived insufficient milk supply; failure to satiate the infant; breast and nipple pain, latching difficulties and maternal preferences are all cited as reasons for this early discontinuation (Dykes and Flacking 2010). It appears that promotional programmes have positively influenced initiation rates but work to support the continuation and establishment of breastfeeding is still needed.

2.2.1 Implications of Infant Feeding Method

The adverse outcomes of limited breastfeeding and increased formula feeding are significant, not only to the individual mother and infant, but also the economic cost to society (Renfrew *et al.* 2012b). Breastfeeding confers extensive health and psychological benefits on both the woman and her child

(Ip *et al.* 2007; Quigley 2007; Horta and Victoria 2013). For women, breastfeeding may reduce breast and ovarian cancers, rheumatoid arthritis and result in a lower prevalence of post-menopausal osteoporosis (DoH 2009). Projected short-term health advantages for the infant include passive immunity, protection against infections such as gastric, respiratory, ear and urinary and a reduced incidence of sudden infant death syndrome (Hoddinott *et al.* 2008). The long-term health prognosis for breastfed babies suggest they are less likely to experience childhood leukaemia, eczema, asthma, diabetes mellitus, obesity, high cholesterol or type-2 diabetes in adulthood (Bartok and Ventura 2009; Chivers *et al.* 2010; Kramer *et al.* 2014; Greer *et al.* 2012). Additionally, Renfrew *et al.* (2012b) calculated that breastfeeding would reduce the financial burden on health service resources if there was a corresponding reduction in the incidence of four of the short and long-term morbidity and mortality states related to formula feeding.

2.2.2 Breastfeeding Support Practices

Recognition of the advantages of sustained breastfeeding at individual, societal and global levels has spearheaded its promotion in both developed and developing countries (Unicef 1991). The Baby Friendly Hospital Initiative (BFHI, subsequently BFI), was launched to globally promote, protect and support breastfeeding (Entwistle 2013). BFI recommends that infants are exclusively breastfed for the first six months of life, with breast milk contributing to their diet for at least two years. The programme endorses evidence based training to ensure equality of professional knowledge and standards. Its aim is to implement best practice in relation to infant feeding within maternity services.

The NHS introduced BFI in 1994 at a time when support for breastfeeding was considered to be poor with inconsistent information inherent within midwifery care (Entwistle *et al.* 2010; Dykes *et al.* 2012). The programme was seen as a foundation on which to rebuild both public and health service confidence in breastfeeding. Since its introduction, maternity facilities with BFI accreditation have achieved greater breastfeeding rates than non-BFI hospitals and universally demonstrate child health improvements (Kramer *et al.* 2001; Unicef 2009; Cleminson *et al.* 2014).

BFI accreditation is underpinned by implementing the 'Ten Steps to Successful Breastfeeding', fostering a culture of normality around breastfeeding and working in partnership with families to achieve best outcomes for mother and baby. The ten steps include staff education, facilitating skin-to-skin contact, rooming-in of mother and baby and avoiding supplementation with fluids other than breast milk. Table 4 details the ten steps to successful breastfeeding recommended by Unicef (2009).

Table 4: Unicef BFI Ten Steps to Successful Breastfeeding (Unicef UK 2009)

BFI Ten Steps to Successful Breastfeeding
• Have a written breastfeeding policy that is routinely communicated to all health care staff. • Train all health care staff in skills necessary to implement this policy. • Inform all pregnant women about the benefits and management of breastfeeding. • Help mothers initiate breastfeeding within one half-hour of birth. • Show mothers how to breastfeed and maintain lactation, even if they should be separated from their infants. • Give new-born infants no food or drink other than breast milk, unless medically indicated. • Practice rooming in - that is, allow mothers and infants to remain together 24 hours a day. • Encourage breastfeeding on demand. • Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants. • Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

A growing number of sources, however, challenge both the efficacy of the BFI programme and its implementation within the NHS (Bartington *et al.* 2006; Brand *et al.* 2011). Hoddinott *et al.* (2012a) suggested that the focus for some stakeholders is now to achieve and maintain BFI accreditation rather than fulfil its philosophy. Lagan *et al.* (2014) felt it constrains

practitioners, as they are reluctant to deviate from the set agenda thereby restricting their ability to collaborate with women to determine and meet their personal infant feeding aims. This was substantiated in a review by Redshaw and Henderson (2012) which reported that many women perceived BFI as task orientated and inflexible, with the authors concluding that the original principles of BFI have been distorted to a routinized healthcare mandate which does not best serve the aims of women, particularly those with additional needs. Indeed, there is increasing recognition that equitable breastfeeding support provisions, which address the distinct needs of some subsets of the population, are required in addition to the standardised strategies which are available to all (Unicef UK 2016). This has resonance for substance dependent women as this is a sub-population who experience additional and unique challenges to successful breastfeeding.

In addition to BFI, there is an extensive body of research discussing other methods of breastfeeding support with several systematic reviews assessing the efficacy of these. Renfrew *et al.* (2012a) reviewed 52 studies exploring breastfeeding support for healthy mothers with healthy term babies. The meta-analysis reported that all forms of extra support produced an increase in duration of partial and exclusive breastfeeding at 6 months (RR 0.91, 95% CI 0.85 to 0.96) and had a positive impact on breastfeeding continuation at 4 to 6 weeks (RR 0.74, 95% CI 0.61 to 0.89). Support was considered more likely to be successful when delivered face-to-face rather than by telephone and there was no discernable difference in perceived effectiveness if provided by professionals, lay supporters or a mix of both. However, it was not possible to determine the effectiveness of individual support components, the most appropriate method of delivery or the most conducive setting. The authors noted several limitations of the reviewed studies including the lack of a comprehensive description of the intervention and/or the comparator/routine care. Furthermore, very few studies reported the theoretical basis, and subsequently an explanation of the change mechanism, of the support elements. A noted disadvantage of all studies was an absence of maternal perception of the acceptability of the support and how this impacted on their opinion of its efficacy. The authors made several recommendations based on their findings. They suggested that proactive and scheduled contact would be more likely to lead to prolonged breastfeeding

rather than reactive support once the mother had encountered problems and requested assistance. It was concluded that breastfeeding support tailored to the individualised needs of the setting and the population group should maximise efficacy.

A comprehensive assessment of the impact of interventions on breastfeeding initiation, exclusivity and continuation was conducted by Sinha *et al.* (2015). This reviewed 195 studies and compared the efficacy of the support components and whether the setting influenced breastfeeding outcomes. This study reiterated the findings of Renfrew and colleagues, that a combination of strategies was more effective than single components, particularly when used concurrently. This was also reflective of the setting where interventions were more successful if breastfeeding support was delivered in a continuum beginning in hospital and followed up in the community. Hannula *et al.* (2008) conducted a systematic review of 36 studies of professional breastfeeding support interventions. This review included the general breastfeeding population and women from disadvantaged groups. The findings suggested that a combination of strategies were more effective than single elements and that practical methods of support, including BFI, were more successful if accompanied by encouragement and positive reassurance. The authors supported the opinion forwarded by Renfrew and colleagues that it was difficult to determine the actual effectiveness of individual support elements. The review highlighted the importance of considering maternal emotions, attitudes and beliefs and the need to incorporate psychological aspects of support in addition to practical strategies. It was recommended that women would benefit from support tailored to their particular needs and from the promotion of practices which empowered and enabled mothers to develop self-efficacy. The authors also forwarded the opinion that vulnerable women, such as low income or teenage, required additional assistance compared to the general breastfeeding population.

Schmied *at al.* (2011) conducted a metasynthesis of 31 studies exploring maternal perceptions and experiences of breastfeeding support. The findings reported that women responded positively to practices if they considered a genuine relationship existed with the supporter and subsequently they were more likely to view the encounter as facilitative.

Contrastingly, when the mother described feeling disconnected from the supporter she was more likely to perceive advice as ineffectual, discouraging and counterproductive. The authors recommended that continuity of care-giver, person-centred care and the establishment of a trusting relationship could enhance maternal perceptions of support. McInnes and Chambers (2008) conducted a qualitative review exploring maternal and practitioner opinion of the efficacy of breastfeeding support. This reported that HCP associated ineffectual practices with a lack of time to provide adequate breastfeeding assistance or emotional support. In contrast, some women felt that it was the quality of the interaction which influenced the outcome rather than the duration, with the establishment of a trusting and facilitative relationship considered the underpinning component of a supportive encounter. The authors concluded that health services provisions in the UK are lacking which results in these unsatisfactory outcomes. This work underlines the importance of gaining an awareness of the needs and perspectives of the target audience and the possible disparities and contradictions between opinions when dealing with a multi-factorial and personal experience such as breastfeeding.

The systematic reviews collectively substantiate the independent finding that women who report feeling supported demonstrate improved breastfeeding outcomes compared to those who perceive themselves as being unsupported. Additionally, a combination of intervention strategies is more effective than single components and a flexible approach receptive to the changing needs and goals of families should be practiced. It would appear, however, that despite the substantive body of research there is no definitive answer as to the most effective breastfeeding support strategy or intervention components. All the studies concluded that individualised strategies addressing the particular needs of the mother were beneficial and should be promoted. Continuity of care-giver and the establishment of a facilitative relationship was also considered a foundational part of supportive practice. An important finding identified by Hannula was the need for additional breastfeeding assistance for vulnerable women. This highlights the importance of acknowledging the distinct needs of groups and tailoring support packages accordingly. This has implications for the current study as the substance exposed mother and baby are considered as clinically and

socially vulnerable. This endorses the need for a targeted intervention to overcome the infant feeding challenges faced by this group and is reflective of the recommendations to promote person-centred breastfeeding assistance. A finding of the systematic reviews was the importance of complementing practical strategies with psychological support in the form of encouragement, reassurance and capacity building. Currently, psychosocial support is not included in the BFI ten steps to successful breastfeeding. Maternal confidence in ability has been identified as a modifiable variable of breastfeeding behaviour with women who possess high levels of self-confidence more likely to initiate and maintain breastfeeding than women with low self-confidence (Thulier and Mercer 2009; Otsuka *et al.* 2014). Several studies have considered the psychosocial aspects of breastfeeding promotion and support in relation to theories of behaviour change with the extensive use of Social Cognition Theories (Dennis 1999; McMillan *et al.* 2009b; Lawton *et al.* 2012; De Jager 2013). Social cognitive determinants are frequently associated with health behaviour models due to their cause and effect properties and receptiveness to behaviour change techniques (Bandura 1998; Connor and Norman 2005).

2.2.3 Breastfeeding Support and Theoretical Models of Behaviour

Social Cognition Theory (SCT) and its predecessor Social Learning Theory (SLT) are psychological models of behaviour based on the work of Bandura (Bandura 1977; Bandura 1986; Bandura 1991). SLT integrated behavioural and cognition theories of learning to provide a comprehensive model of learning experience. This challenged the previous historical view that reinforcement, classic conditioning and operant conditioning governed behaviour (Maio and Haddock 2009). SCT advanced the idea that learned behaviour occurs through observation of others within a social context and the predominant influencing factors are personal cognition, behaviour and the environment. These concepts interplay in a triadic reciprocal relationship to shape the learned behaviour (Bandura 1991). Within this triadic relationship there are stages of learned behaviour which SCT hypothesises as learning by vicarious observation and modelling. Vicarious observation is defined as observing the behaviour of others and modelling is observing the

behaviour of others and the consequences of their actions within the prevailing socio-cultural environment. The theory expands upon this to describe a four-step process in which observational learning occurs. The initial step is 'Attention' where the individual selects a behaviour to emulate. Step 2 is 'Retention' where a behaviour and its consequences are observed and retained. This step involves the cognitive processes of converting the observation to a symbolic representation to be accessed in the future. The third step involves 'Production' when the behaviour is replicated and feedback received, with the type of feedback modifying or reinforcing the behaviour. The final step is 'Motivation', as the individual will only repeat the behaviour if the response met their objective. An important distinction of SCT is that learning can occur without an actual or observed change in behaviour as step 4, 'Motivation', is not acted upon. Therefore, an individual can learn from the observation of others but choose not to demonstrate that learning (Maio and Haddock 2009). This brings the influence of personal agency to behaviour choice.

SCT provides a framework to understand the determinants influencing behaviour. From this work various other models of behaviour have been postulated which focus on particular conditions or aspects of decision-making (Bowling 2014). The predominant SCT theories used to explain, predict and support breastfeeding are the Theory of Planned Behaviour (TPB) and Self-Efficacy Theory (SET).

2.2.3.1 Theory of Planned Behaviour

The Theory of Planned Behaviour is a predictive model of deliberate, planned behaviour. This proposes that the predictor of behaviour is the intention to engage in that behaviour and that intention is bound by motivation (Ajzen and Fishbein 1980; Ajzen 1991; Fishbein and Ajzen 2011).

TPB forwards that whilst the primary determinant of behaviour is intention, three theoretical constructs predict the intent to follow a defined course of behaviour. The first construct is the individual's attitude towards the behaviour and the second construct relates to subjective norms, which are the perceived pressures to engage in the activity. The final construct is that of perceived behavioural control, which is the degree of control and

capability the individual feels they have to perform and sustain the behaviour. Each of the three theoretical constructs are divided further into two components. Table 5 details TPB constructs and definitions.

Table 5: Theory of Planned Behaviour Construct (Ajzen and Fishbein 1980)

Theoretical Construct	Definition	Components	Definition
Attitude	Attitude towards the behaviour	Affective attitude	Emotional consequences of engaging in the behaviour
		Instrumental attitude	Value attributed to the behaviour.
Subjective Norms	Perceived pressures to engage in the activity	Descriptive norms	How the individual perceives what 'important others' do in the given circumstances.
		Injunctive norm	Approval of 'important others' gained through adopting the behaviour change.
Perceived Behavioural Control	Perceived degree of control and capability to perform and sustain the behaviour	Perceived control	Degree of environmental control to engage in the behaviour.
		Self-efficacy	Level of confidence in capability to perform the target behaviour.

Within breastfeeding literature, authors have used the TPB to assess the importance of intention and its theoretical constructs as a predictor and variable in the initiation and maintenance of breastfeeding. Swanson and Power (2005) found that subjective norms such as the views of significant others were strongly associated with breastfeeding decisions and stressed the importance of HCP presenting positive views of breastfeeding to the women in their care. However, this study may have overestimated the significance of subjective norms due to sampling limitations when measuring attitudes at different time points of the maternal breastfeeding journey.

Lawton *et al.* (2012) examined initiation and continuation of breastfeeding and found that intention was the best predictor of initiation but that affective attitudes were associated with breastfeeding behaviour at 6 months. This study followed previous work by Lawton and colleagues (2007; 2009) exploring the predictors of health promotion or health risk behaviours which also proposed that affective attitude was a significantly more powerful predictor of behaviour than instrumental attitude. The authors concluded that affective attitudes and specifically the emotional outcome of actions had a direct impact on the decision to engage in health-related behaviours. They recommended that interventions could target the emotional consequences of actions and omissions as a means of supporting behaviour change and maintenance. Assessing the theoretical constructs of TPB, Armitage and Connor (2001) noted that perceived behavioural control and self-efficacy were both useful predictors of intention and behaviour. They concluded that this implied that individuals form intentions that they are firstly, confident they can achieve and secondly, that they undertake a prior evaluation of external conditions and the degree of control they have over these. McMillan and colleagues (2008; 2009a/b) carried out a series of research programmes using the constructs of TPB to predict breastfeeding initiation amongst women from disadvantaged groups and found it offered good predictive value and could be used for the selection of groups who would be the target of interventions. This finding was strengthened by a systematic review of 24 studies of the use of TPB in empirical research, which concluded that the theory is most useful to gain an understanding of behaviour to enable identification of groups who may benefit from behavioural interventions, rather than guiding intervention development (Hardeman *et al.* 2002). Indeed, Hardeman proposed further that there was insufficient available evidence to draw robust conclusions about the usefulness of this theory for intervention development.

Systematic reviews evaluating the efficacy of TPB in relation to studies undertaken in the general population suggests that it can be a predictor of intention and behaviour. However, the actual strength of the association is open to speculation due to the unreliability of self-reported outcome measures used by many studies. Armitage and Connor (2001) reviewed 185 published studies and concluded that the TPB and its constructs accounted

for 39% of the variance in intention and 27% of variance in behaviour. McEachan *et al.* (2011) updated these findings in their meta-analysis of 237 studies and determined that TPB accounted for 19% of variance in health-related behaviour with intention the strongest predictive factor. These findings complement work by Webb and Sheeran (2006) who reviewed experimental studies of intention-behaviour association and found that a medium-to-strong intention only resulted in a small-to-medium change. This was expanded upon by Hagger and Luszczynska (2014) who highlighted the existence of an intention-behaviour gap and warned that there are limitations of accepting intention as a reliable predictor of future behaviour. The authors speculated that whilst there was a demonstrated correlation between intention and behaviour, the possibility of a third or more causal inferences could not be ruled out.

Collectively, TPB has demonstrated efficacy as a predictive model of breastfeeding intention but its usefulness in developing support interventions is unsubstantiated. Additionally, its utility and validity to predict behaviour is currently being challenged in contemporaneous literature (Sniehotta *et al.* 2014; Ajzen 2015; Armitage 2015; Conners 2015). Nevertheless, empirical evidence suggests that its associated theoretical constructs may be open to influence with positive reinforcement of intention acting on social norms and facilitating capacity building may enhance behaviour continuation. The impact of affective attitudes, and the emotional consequences of behaviour, is of relevance in breastfeeding support.

2.2.3.2 Self-Efficacy Theory

Self-efficacy is implicated as a theoretical construct in several models of behaviour and was reconceptualised by Bandura as an independent theory (Bandura 1986; 1993; 1997). SET proposes that it is an individual's perception of their capability to achieve the desired behaviour that dictates whether they engage in a course of action. High self-efficacy levels increase belief in capability whilst low self-efficacy levels result in a diminished perception of ability (Dennis 1999). Self-efficacy is informed by four theoretical constructs; performance ability, vicarious experience, verbal

persuasion and psychological/physiological status. These are detailed and defined in Table 6.

Table 6: Self Efficacy Theory Constructs

Theoretical Construct	Definition
Performance ability	Mastery of a particular task.
Vicarious experience	Observing others succeed or fail at the chosen behaviour.
Verbal persuasion	Direct positive or negative encouragement. This is bounded by the significance attributed to the persuader.
Psychological/Physiological status	Physical and emotional response to the situation.

Self-efficacy is considered a modifiable variable of infant feeding decisions and is responsive to external conditions such as the quality of health services practices and the opinions and actions of significant others (Dennis 1999; Hoddinott *et al.* 2013). Self-efficacy, as a measure of maternal confidence in breastfeeding ability, has been researched extensively both as a predictive tool and as a framework to guide evaluation and development of interventions (Dennis and Faux 1999; Nichols *et al*. 2009). Noel-Weiss *et al.* (2006) delivered a self-efficacy workshop and found an increased percentage of the intervention group breastfeeding at 4 and 8 weeks compared to the control group, although this was not statistically significant. The authors surmised that the small sample size (n=110) may have impacted on statistical analysis but considered that the results had clinical implications for incorporating self-efficacy principles into practice. These findings were replicated by McQueen *et al.* (2011b) who assessed breastfeeding outcomes amongst 251 women and again the results were not statistically significant but the percentage of women breastfeeding at 4 and 8 weeks was greater amongst those with high self-efficacy levels. Additionally,

high self-efficacy was associated with increased breastfeeding exclusivity and slower rate of discontinuation. Otsuka *et al.* (2014) and Koskinen *at al.* (2014) considered the impact of health service practices on maternal self-efficacy levels and the resulting breastfeeding outcomes. Both research groups found that maternal confidence was diminished if hospital practitioners or policies were unsupportive of breastfeeding and under these circumstances self-efficacy promotional strategies did not result in improved breastfeeding rates. Schmeid *et al.* (2011) and Demitras (2012) surmised that women felt supported by practitioners who facilitated breastfeeding expertise and offered positive reinforcement thereby bolstering maternal belief in their breastfeeding ability and correspondingly their self-efficacy levels. This was endorsed by a review of maternity care undertaken by Redshaw and Henderson (2012), where women who considered that their breastfeeding ability was undermined by health service practices felt disempowered and demotivated and were more likely to introduce formula feeding. Entwistle *et al.* (2010) conducted qualitative interviews to explore maternal confidence and this concurred with the quantitative reports than low self-efficacy results in poorer breastfeeding rates. The research indicated that practices to facilitate maternal breastfeeding skill, the provision of positive reassurance and encouragement and examples of successful breastfeeding amongst peer groups may all enhance maternal self-efficacy. Additionally, practitioner awareness and timely resolution of maternal stressors such as pain, fatigue and anxiety may limit the adverse effects of physiological factors on self-efficacy levels.

A recurrent limitation of all the studies, however, was the self-selection of the research participants, which may imply that these are women who are naturally more motivated and, therefore, more likely to persevere with breastfeeding. Whilst this does enhance the internal validity of the studies it casts doubt on the generalisability of self-efficacy interventions to impact on the confidence levels of less committed women. Although statistical significance was not achieved in several of the studies, the clinical significance of the findings must be taken into consideration. Collectively, improved breastfeeding outcomes were noted amongst women with high self-efficacy levels and the importance of promoting a conducive environment to support and sustain this is indicated. In respect of informing

intervention development, SET offers explicit identification of theoretical constructs and proposes the mechanism of behaviour change (Bandura 2004). This can enable development and delivery of targeted support when there is an understanding of the behaviour determinants involved.

2.3 Section 2: The Substance Exposed Mother and Baby

The prevalence of substance dependence in pregnancy is difficult to calculate. This is reflective of the subversive nature of illicit drug use amongst young women and inconsistencies when diagnosing NAS (Dryden *et al.* 2009). Sources in the UK and USA estimate the use of illegal substances in pregnancy as ranging between 4.5% and 16% (Kassim and Greenough 2006; Substance Abuse and Mental Health Services Administration 2014). The current methods of confirming the presence of substance use in pregnancy are self-reporting or compulsory biological specimens, both of which have limitations. Self-reporting provides comprehensive information on the substance type, timing and frequency but is dependent on maternal veracity and accuracy of recall. Biological testing confirms recent drug use but is constrained by the sampling method, type and timing of screening and drug detection policies (Behnke *et al*. 2013). Subsequently, it is felt that the incidence of substance use in pregnancy is most likely grossly underreported and underestimated (ISD 2012).

2.3.1 Management of Substance Dependence in Pregnancy

For women who seek treatment for their drug use, either before or during pregnancy, the current UK management is to offer a substitution medication programme of opioid maintenance therapy accompanied by harm reduction measures (NICE 2010; WHO 2014). The basis of this programme is to replace the use of an illicit drug of unknown composition with an alternative 'pure' therapy at a stable dose given under medical supervision (Greig *et al.* 2012). Enrolment on a programme provides pregnant women with access to obstetric care, detection and prevention of blood borne viruses, advice on nutrition and socio-economic interventions. The most commonly prescribed

substitution medication is methadone, with the use of opioid antagonist buprenorphine gradually increasing. Methadone and buprenorphine are long-acting drugs, which keep blood concentrations within a narrow range so that recipients experience minimal intoxication or withdrawal. A steady concentration of opiate in the placental blood flow prevents the adverse effects of repeated fetal withdrawal such as early demise and preterm labour (Boxwell 2010).

Following the initial introduction of methadone during pregnancy, its use was associated with a reduced incidence of intra-uterine growth restriction, fetal distress and premature birth when compared to illicit heroin use (Zelson *et al.* 1973; Jones and Fielder 2015). However, there was a limited understanding of the potential neonatal consequences (Gray *et al.* 2010). There is now a well-established and recognised relationship between methadone use in pregnancy and NAS. Cleary *et al*. (2010) systematically reviewed 67 studies and concluded that there was an increased incidence of neonatal withdrawal in infants exposed to methadone compared to illicit drug use, although the difference was not statistically significant and the association varied with methadone dose. Additionally, confounding factors such as concurrent illicit drug use or continued presence of alcohol or nicotine complicated the reliability of the findings. There were also limitations in the review process, with substantial heterogeneity across the papers and the impact of inherent biases associated with observational studies.

Buprenorphine has a much smaller research base due to its shorter duration of availability but some studies suggest that it reduces the severity of NAS compared to methadone, although the presence of confounding variables compromises the reliability of these findings (Bakstad *et al.* 2009; Jones *et al.* 2010; Lacroix *et al.* 2011). A recent Cochrane review found few differences in either maternal or neonatal outcomes in a comparison of methadone, buprenorphine or oral slow-release morphine maintenance during pregnancy (Amato *et al.* 2013). The incidence of NAS did not differ significantly between groups, although improved birth weight was seen in the buprenorphine group in two trials. The participant numbers, however, were small and therefore may not be sufficient to draw robust conclusions.

The use of substitution medication remains a controversial topic. Methadone or buprenorphine are not without consequences, with the use of these drugs

linked to physical and psychological problems for the mother (McLemore *et al.* 2013). Further, the improvement in fetal outcomes in comparison to illicit heroin use must be weighed against the increased incidence of NAS and its consequences (Behnke *et al.* 2013; Jones 2013). However, at present, a methadone substitution programme is regarded as the most effective and generally most acceptable treatment for drug dependency during pregnancy in the UK (NICE 2010).

2.3.2 Neonatal Abstinence Syndrome

Neonatal Abstinence Syndrome occurs as the direct consequence of the prolonged exposure of the fetus, via placental transmission, to maternal use of addictive substances during pregnancy. Passive addiction occurs in the fetus, and following the abrupt discontinuation of the substance at birth, the neonate experiences withdrawal symptoms. NAS is a self-limiting condition and is indicative of a dysregulation of neuro-behaviour and maladaptation (Boxwell 2010). Historically, NAS referred to the withdrawal process from in-utero exposure to opioids, either prescribed or illicit. In today's society, it can be associated with other psychoactive substances such as benzodiazepines, cocaine, nicotine and antidepressants (Hall *et al.* 2014). Abstinence syndrome can occur at birth or up to several weeks of age depending on the type and combination of drug exposure, the timing of the last dose and a complex interplay between maternal-placental-neonatal metabolic processes (Lissauer and Fanaroff 2011). Contemporary research concentrates on identifying factors which may have a synergic effect with methadone to explain the variation of severity of NAS. Dryden *et al.* (2009) studied a cohort of 444 infants and found a strong positive association in the increase of withdrawal symptoms with concurrent benzodiazepine use. A report by Jansson *et al.* (2011) strengthens these findings as they found that 83% of infants exposed to poly-drug use required pharmacological treatment for NAS compared to 42% of those withdrawing from methadone only. Jansson and Velez (2011) proposed that the interplay between genetic, epigenetic and environmental factors may all contribute to NAS pathophysiology with substitution medication being only one component. Fielder *et al.* (2015) postulated further that NAS incidence and severity are

independent of maternal methadone dose and that genetic variability could be the determining factor.

The speculative nature of much of the literature on NAS underpins the lack of clarity regarding this condition. The most accurate description of this current situation is that the underlying mechanisms of the display of NAS are multifactorial and unique to the individual mother and infant dyad (McLemore *et al.* 2013). This accounts for the variability seen in the pathophysiology, prevalence and severity of NAS. It also contributes to the challenge of accurate assessment of the neonate at risk and determining optimum management.

2.3.2.1 Pathophysiology of Neonatal Abstinence Syndrome

The pathophysiology of NAS includes central nervous system irritability such as exaggerated primitive reflex, hyper or hypotonicity, uncoordinated movements and jitteriness (Boxwell 2010). Infants may display an immature behavioural capacity and be unable to modulate between sleep and alert states resulting in disorganisation when awake and a labile sleep pattern (Jansson *et al.* 2010; 2011). There can be dysregulation of the autonomic nervous system manifesting as cyanotic episodes, mottling, sweating, sneezing and yawning. In the most severe cases, seizure activity can occur (Lui *et al.* 2008). Respiratory signs include tachypnoea and respiratory distress. Poor motor control combined with autonomic stressors can lead to an inadequate feeding ability due to an uncoordinated suck/swallow reflex, incorrect positioning of the tongue, regurgitation and excessive intake of air when swallowing. Gastro-intestinal symptoms include feeding intolerance, emesis and loose stools (Gomella 2009). The infant presents with a high-pitched cry and can be inconsolable despite attempts to pacify (Murphy-Oikonen *et al.* 2010).

The majority of adverse effects of NAS will present in the newborn period but there are potential long-term issues. These include impaired vision, as immature visual reflexes and nystagmus are common amongst substance-exposed infants (MacTier 2012; Spiteri Cornish *et al.* 2013; McGlone *et al.* 2014). There is an inconclusive body of evidence regarding neurodevelopment due to the confounding influence of environmental factors on social maturity and cognitive ability (Lloyd and Myercough 2006; McGlone

and MacTier 2015). Logan *et al.* (2013) noted deficiencies in the regulation and quality of movements in opioid exposed infants and abnormal levels of excitability during the first year of life. Hunt *et al.* (2008) systematically reviewed the available literature and despite the heterogeneity of the studies and low retention rates, concluded that the outcome for this group was not reassuring and the children could not be considered as having 'normal development'.

2.3.2.2 Prevalence and Assessment of Neonatal Abstinence Syndrome

Globally, the reported incidence of NAS varies extensively with estimates ranging from 13% to 94% of affected infants requiring pharmacological treatment for withdrawal symptoms (Hudak and Tan 2012; Kaltenbach *et al.* 2012). Speculation for this deviation includes lack of awareness of the condition, particularly in areas where drug use is less common, the validity or lack of assessment tools and the presence of maternal and neonatal confounding factors (O'Grady *et al.* 2009; MacTier 2012).

Statistics from Scotland recorded 1.97% (3338) of all births, as an aggregate of three years between 2010/13, as affected by maternal addictive substance use, giving an estimated 1113 infants annually at risk of NAS (ISD 2014). Within the local geographical area, approximately 100 births per annum are to mothers with a substance use disorder (Black *et al.* 2013). The local tertiary unit carried out an audit between 1998 and 2003, which demonstrated an upward trend from 15 to 48 infants affected by NAS per annum (Lloyd and Myercough 2006). The current figures show a treatment rate for NAS of between 45-51 cases annually, which has been stable for the past decade.

An assessment of the severity of NAS symptoms and a guide for management is made using numerical scoring systems. There is not a uniform or universally accepted assessment method but the most commonly adopted scale is the Finnegan Neonatal Scoring System (FS), either in its modified form or an in-house abbreviated version (Finnegan *et al.* 1975; WHO 2014). Although other scoring systems are available, the FS was the method in operation in the local area during the research study and therefore it is the focus of the discussion. FS consists of 31 weighted items each

scoring from one to eight and assessment occurs 4 – 8 hourly. Three consecutive scores of equal to or greater than eight, or three scores equal to or greater than 24 is indicative of severe NAS and requires pharmaceutical management. It is a complex and time-consuming system and is open to individual interpretation with excessive variability seen between operators (Asti *et al.* 2015). Pharmacological therapy commences once the FS reaches the predetermined level, and the system is then used to titrate the medication.

2.3.3 Management of Neonatal Abstinence Syndrome

NAS management is based on supportive measures to pacify the infant, and this is supplemented with pharmaceutical therapy if there is excessive neurological disruption (Gomella 2009; WHO 2014). Pharmacological measures allow the process of controlled withdrawal but results in prolonged hospitalisation with the potential of long-term adverse health and cognitive consequences (Hunt *et al.* 2008; Osborn *et al.* 2010a/b).

2.3.3.1 Supportive Management: Consolation Therapies

Supportive management includes consolation measures and the reduction of external stimuli such as excessive light, noise, temperature and handling (Gomella 2009). Care-givers need to be responsive to the infant's cues and functional maturation and modify the supportive measure as appropriate (Hudak and Tan 2012). However, each infant displays a variability of physiological and behavioural responses specific to their level of neurological dysfunction, which makes assessment challenging (Jansson *et al.* 2010). Consolation therapies such as swaddling, non-nutritive sucking and cuddling are recommended supportive practices based on anecdotal evidence, or generalised from other groups, rather than the systematic evaluation of infants with NAS (Velez and Jansson 2008; Hudak and Tan 2012). Additionally, the available research is limited and demonstrates contradictory and inconclusive results (Oei and Lui 2007). D'Apolito (1999) attempted to mimic intrauterine conditions with a rocking bed and maternal sounds but found this overstimulated those infants with NAS. Conversely, Oro and Dixon

(1988) reported that the use of waterbeds to represent intrauterine movement improved neurobehaviour in substance exposed infants. Ancona *et al.* (2015) aimed to decrease the length of hospital stay for infants with NAS using an innovative regime based on a controlled environment, clinical interventions, family involvement and staff and physician co-operation. A low stimulation approach to management was utilised and families were enrolled as partners in decision-making and care giving. This approach resulted in a decrease in the average length of stay by 50%, the need for medication management decreased by 24% and the number of infants discharged home on medication decreased by 29%. These improved outcomes resulted in a significant cost saving.

2.3.3.2 Pharmaceutical Management

If supportive practice alone is ineffectual to control the severity of withdrawal symptoms, pharmaceutical management is recommended (Lissauer and Fanaroff 2011; WHO 2014). This is indicated if the neonate experiences poor feeding with insufficient weight gain, fever, irritability, seizure activity or a combination of these. Pharmaceutical treatment uses medicinal protocols to alleviate the withdrawal symptoms, initially with a controlled reduction of substitution opiates to down regulating the μ-opioid receptors gradually. Second line therapies include sedatives and/or sympatholytic. These regimes are not without consequences, however, as all have the potential to cause respiratory depression and over-sedation. Additionally, they need to be gradually tapered before discontinuation due to the risk of relapse. Osborn *et al.* (2010a) reviewed pharmaceutical management and recommended the use of an opiate-based medication for opioid dependency in preference to either a sedative or supportive care alone. This guidance is adopted by the majority of institutes with 92% of UK and 63% of American hospitals prescribing morphine as the first line medication (O'Grady *et al.* 2009, Sarkar and Donn 2006). In their review of adjunct sedative treatment for NAS, Osborn *et al.* (2010b) suggested that phenobarbital was preferable to diazepam. However, the authors warned to treat their conclusions with

caution as the validity of the results were affected by the methodological quality of the included studies (Higgins 2008).

2.3.4 Breastfeeding and the Substance Exposed Mother and Baby

Department of Health guidelines acknowledge that confusion surrounds the issue of addictive substance use and breastfeeding but state that the benefits normally outweigh the disadvantages (DoH 2007). Their recommendations suggest that medical advice to refrain from breastfeeding should be taken on an individual basis, specifically if the woman is Human Immune Virus (HIV) positive or if there is impaired maternal functioning due to psychoactive drug/alcohol intake. However, the over-riding position adopted in UK health facilities is that healthcare professionals should not and cannot contravene a woman's wish to breastfeed.

Research on the impact of breastfeeding on NAS has consistently found an improvement in neonatal outcomes. There are limitations with this body of evidence, however, due to inherent issues of certain methodological approaches and heterogeneity of outcomes and definitions. Abdel-Latif *et al.* (2006) and McQueen *et al.* (2011a) conducted retrospective cohort reviews and reported a later onset and a reduced course and duration of NAS in breastfed infants. In contrast, Isemann *et al.* (2011) did not establish a significant association between breastfeeding and NAS onset but did note a shorter duration of treatment and length of hospital stay. Welle-Strand *et al.* (2013) observed a lower incidence of NAS and shorter course of pharmacological treatment in a cohort of 124 infants. Dryden *et al.* (2009) studied 450 exposed infants and found that breastfeeding for more than 3 days reduced the need for pharmaceutical treatment, whilst Pritham *et al.* (2012) noted a reduced length of stay associated with breastfeeding. Logan *et al.* (2013) explored the relationship between infant feeding and FS and noted that breastfed infants had lower scores in the first nine days than formula fed infants. The authors also reported that the onset of medicinal treatment occurred later for the breastfed infants. O'Connor *et al.* (2013) reviewed the outcomes of 85 buprenorphine exposed infants and found that those who were breastfed had a reduction in pharmacological treatment

(23% v 30%) and lower mean FS scores (8.83 v 9.65) than their formula fed counterparts. These results were not, however, statistically significant. Collectively, these retrospective reviews note an improvement in either the display or the management of NAS for breastfed infants, although there were noted inconsistencies across the measured outcomes. There are several possible explanations for these variations, however. They could be attributed to the different population sizes of the respective studies or the varying clinical protocols in place for the management of NAS. Some infants were discharged home to complete their course of pharmaceutical therapy as an outpatient, therefore affecting the length of stay. The study authors also differed in their definitions of breastfeeding when there was a concurrent use of formula milk. A number of presumed confounding variables may have influenced the findings. The synergistic effect of variables such as the type, volume and timing of concurrent drug use including nicotine; maternal and neonatal epigenetics and the quality of supportive strategies can affect measured outcomes. Additionally, several the variables are self-reported, which is dependent on accuracy of recall, veracity and social desirability bias. As the comparison groups were self-selected and retrospectively reviewed, the cohorts may not have been equally matched.

In addition to the more commonly adopted retrospective chart reviews, the body of evidence also included an observational study conducted by Ballard *et al.* (2002) and a matched case control study by Jansson *et al.* (2008). Ballard *et al.* (2002) compared an initial cohort of six infants prescribed opioid medication with a follow-up group maintained on breast milk containing methadone. The length of stay for the primary group ranged from 10-31 days whereas the breastfeeding cohort were hospitalised for 2-6 days. Jansson *et al.* (2008) undertook a study primarily to compare the bioavailability of methadone in breast milk and blood plasma between eight breastfeeding methadone exposed mother/infant dyads with eight formula fed dyads. Fewer breastfed infants required pharmacological treatment than their formula fed counterparts.

The underlying mechanism of action for improved NAS outcomes with breastfeeding is open to speculation. McCarthy and Posey (2000) quantified the bioavailability of methadone in breast milk and determined that the minute volume excreted was insufficient to have an adverse impact or a

therapeutic effect. This finding was substantiated by Jansson and colleagues who compared the concentration of methadone in breast milk and plasma over short and long-term lactation and found only minimal traces present (Jansson *et al.* 2004; Jansson *et al.* 2007; Jansson *et al.* 2008). This suggests that the substitution medication in the breast milk cannot be wholly responsible for alleviating the withdrawal symptoms. The physical act of breastfeeding, itself, can offer consolation and soothe the agitated infant, thereby acting as a supportive care measure. Breastfeeding has been shown to pacify infants during painful procedures and provide a degree of pain relief (Leite *et al.* 2009; Shah *et al.* 2012). Conversely, Abdel-Latif *et al.* (2006) reported a reduced course of NAS in infants who received methadone exposed breast milk via gastric tube and were not physically breastfed. O'Connor *et al.* (2013) speculated that increased maternal contact accompanying breastfeeding mimics supportive care measures. McQueen *et al.* (2011a) surmised that by choosing to breastfeed, women demonstrate a greater level of motivation and engagement with their child's needs resulting in a high standard of supportive care. This could support Abdel-Latif's findings, as maintaining lactation and expressing breast milk suggests that these mothers were fully engaged in their child's care and more likely to actively provide supportive care. Furthermore, the demographic characteristics of the bottle-feeding cohort in Abdel-Latif's research were predominately from areas of greater socio-economic deprivation, had poorer educational attainment and more were of indigenous (aboriginal) descent than the breastfeeding group. The authors concluded that these mothers may be less equipped to assess and provide appropriate supportive care in response to their infant's behavioural cues thus resulting in a more severe expression of NAS. Both Abdel-Latif *et al.* (2006) and McQueen *et al.* (2011a) observed that women who initiated breastfeeding had more comprehensive antenatal care compared to women who chose to formula feed. Additionally, the formula fed infants experienced a greater exposure to maternal poly-drug use and increased alcohol intake. Velez and Jansson (2015) suggested that opioid dependant mothers may lack physical and emotional availability because of long-term addiction on their own cognitive processes. Subsequently some may adopt maladaptive behaviours as a coping mechanism. A potential explanation could be that the breastfeeding

mothers had not reached this degree of maladaptation and were more aware of and responsive to their infant's support needs.

One consideration when ameliorating NAS with breast milk containing substitution medication is ensuring an appropriate weaning regime. Malpas and Darlow (1999) reported 2 infants experiencing rebound NAS after the abrupt discontinuation of breastfeeding. Isemann *et al.* (2011) noted the readmission of 5 infants (4% of 56 infants) in order to recommence NAS treatment within 2 weeks of discharge. Of these 3 infants were reported to have either discontinued or considerably reduced their intake of breast milk containing methadone. Whilst reduced breastfeeding may be implicated in this finding the authors speculated that limitations of their study methods may also be contributory. They proposed that due to their focus on promoting breastfeeding as a management strategy there may have been a degree of bias regarding premature and aggressive lowering of the dose of pharmacological treatment. This potentially resulted in the earlier, but inappropriate, discharge home of some infants. Considering their findings, however, these studies both caution against rapidly weaning infants.

Predominantly, the literature demonstrates that breastfeeding is effective in controlling the expression of NAS. However, the methodological limitations of retrospective studies must be considered when determining the reliability for evidence based practice. Retrospective studies are at risk of bias in the sampling method and are dependent on the accuracy of the record keeping and the measures recorded (Creswell and Clark 2011).

Additionally, the existing body of research evidence on substance use in pregnancy was reviewed by the World Health Organisation (2014) in response to the paucity of uniform or global guidelines available for both high and low income countries. This resulted in the publication of a document aimed at providing technical advice for professionals on the identification and management of substance use and substance use disorders in pregnancy.

To review the current evidence base in relation to maternal substance use and infant feeding method a systematic review was undertaken. This compared encouraging breastfeeding with not encouraging breastfeeding; discouraging breastfeeding or recommending short term milk substitutes whilst discarding potentially unsuitable breastmilk. The literature search was unsuccessful in identifying any RCT's to inform the guidance, therefore the

summary was based on a narrative review of the available methodological designs. Consequently, the resulting quality of the evidence was classified as low.

The following recommendations were made regarding the various context of substance use, resource provisions and personal choice. The guidelines proposed that women with a substance use disorder should be advised and supported to discontinue drug use whilst breastfeeding, however, if this was not possible continued substance use should not be considered as a breastfeeding contraindication. For women with on-going substance use, the guidance stated that breastfeeding should be encouraged. This was accompanied by a caveat to perform a risk assessment to consider the specific advantages and disadvantages for the individual mother/infant dyad. The suggested assessment criteria included exposure to drugs and alcohol in the breast milk and specific pattern of drug use; HIV status; impaired maternal functioning and the availability and safety of formula milk and clean water. The strength of this recommendation was classed as conditional due to the personal beliefs and preferences regarding breastfeeding initiation of the individual and the lack of strong evidence of possible harms from low levels of substance use. For mothers stably maintained on substitution medication the recommendation was to encourage breastfeeding. The strength of this recommendation was considered to be strong despite the low quality of evidence. This was rationalised by the conclusion that the benefits of alleviating withdrawal symptoms in the neonate were greater than the possible disadvantages.

In conclusion, the WHO advisory committee felt that, in most instances, the advantages of breastfeeding were superior to any perceived disadvantages. They recommended that women with a substance use disorder should be encouraged and supported to breastfeed by health care professionals, unless the risks clearly outweighed the benefits.

2.3.4.1 Barriers to Breastfeeding in Substance Dependence

Breastfeeding rates amongst substance exposed women and infants are substantially lower than national averages (Balain and Johnson 2014). McQueen *et al.* (2011a) reported a 26% initiation rate, whilst Wachman *et*

al. (2010) reported a 24% initiation rate with a 60% drop off in the first week. This is supported by research undertaken by Goel *et al.* (2010) who reported that only 14.3% of their study population breastfed on hospital discharge. There have been several explanations forwarded for this. These include the historical position; safety profile of methadone in breast milk; the wide spread adoption of formula feeding within socially disadvantaged groups; physical feeding difficulties; maternal psychological issues and discouraging institution practices (Jones and Fielder 2015).

Historically, breastfeeding was contraindicated amongst opioid dependent women prescribed greater than 20 mg of methadone (Committee on Drugs 2001). This was due to concerns regarding the concentration of medication in the breast milk and potential side effects for the neonate (Malpas and Darrow 2000; Phillips *et al.* 2003). This recommendation was overturned in 2001 as a substantial body of evidence was accumulated which unequivocally concluded that only minute volumes of methadone were excreted in breast milk (Geraghty *et al.* 1997; McCarthy and Posey 2000; Begg *et al*. 2001). Concurrently, it was demonstrated that a stable concentration of methadone in the maternal blood stream optimised fetal outcomes (Gomella 2012). This challenged the existing practice of the time of reducing methadone during pregnancy to achieve abstinence prior to the birth of the baby.

Those who reside in areas of socio-economic deprivation are less likely to breastfeed and statistics show that women involved with addictive substances predominantly come from deprived backgrounds (McAndrews *et al.* 2012). This was demonstrated by Dryden *et al.* (2012) where 78% of the hospital population were classed as residing in socially deprived circumstances and had an overall breastfeeding initiation rate of 34%, yet amongst the opioid dependent mothers the breastfeeding rate dropped to 22%. A survey carried out in Norway reported that 77% of methadone treated women initiated breastfeeding, which was low compared to the national average of 98% (Welle-Strand *et al.* 2013).

Encouragingly, in a retrospective chart review O'Connor (2013) described an integrated model of care aimed at reducing some of the barriers to breastfeeding associated with opioid dependence. The authors recorded a breastfeeding initiation rate of 76% with 66% still breastfeeding at 6-8 weeks. All women accessed their antenatal and postnatal care in a single

setting with an 'infant-friendly' support programme. The authors speculated that their high initiation rate may be reflective of a liberal attitude to breastfeeding inclusion not seen in many other USA medical facilities, but the establishment and continuation rates are highly promising. Therefore, it appears that opioid dependence does influence the decision to initiate breastfeeding, beyond socio-cultural norms, but O'Connor's study demonstrates that expected behaviour can be modified with tailored promotional and supportive programmes.

A barrier to breastfeeding establishment is the impact of NAS withdrawal symptoms on the infant's feeding ability (Jones *et al.* 2013). During the withdrawal process, the neonate may experience feeding difficulties and be physically unable to latch onto the breast or sustain an adequate sucking rhythm (Gewolb *et al.* 2004). Jansson and Velez (2015) described fluctuating motor and tone control affecting suck/swallow co-ordination accompanied with incorrect positioning of the tongue and jaw. This disrupts feeding technique and results in excessive wind intake, neonatal agitation and frustration. The authors assert that this results in an inadequate calorific intake, weight loss and ultimately failure to thrive. It is a widely-held assumption that infants with NAS will demonstrate excessive weight loss and offering supplements with a high calorific feed is standardised in NAS management (DoH 2007; Hudak & Tan 2012). Dryden *et al.* (2012) retrospectively reviewed the charts of 354 methadone exposed infants and found that collectively the initial weight loss, from day 4 to 7, was greater than average with a delayed regain to birth weight. However, no complications were associated with the greater weight loss, such as electrolyte imbalance or NAS severity, and of the infants who returned for follow-up none experienced problems regarding failure to thrive. The authors recommended that in view of the reduction of NAS severity seen in breastfed infants a greater tolerance of early weight loss is indicated.

It is relatively common for a complexity of social and psychological issues to accompany substance dependence (NICE 2010). Women may not feel confident in their ability to negotiate challenges, such as breastfeeding establishment, due to a history of actual or perceived failures (Jambert-Gray 2014). Further, in this population there is an increased incidence of verbal, physical and /or sexual abuse (Velez *et al.* 2006). This may result in negative

connotations of the 'value' of their bodies, particularly viewing their breasts as sexual objects with no functional capacity (Wood and Van Esterik 2010). Given these collective barriers influencing maternal self-efficacy, it is understandable that many women consider bottle feeding as an easier and more acceptable option than breastfeeding.

Philipp *et al.* (2003) noted that HCP question the exact composition and safety of breast milk and routinely raise concerns over the concurrent use of illicit substances. This may indicate a lack of awareness in some institutions of the substantial evidence on the limited bioavailability of methadone/buprenorphine in breast milk (Bogen *et al.* 2011). Balain and Johnson (2014) surveyed the attitudes of practitioners towards breastfeeding of infants at risk of NAS. Both medical and nursing disciplines consistently displayed negative attitudes. Some professionals felt that breastfeeding should not be encouraged, whilst others believed that breast milk from substance dependent mothers was harmful. These unsupportive attitudes amongst healthcare staff may be a contributory factor to the low rates of breastfeeding establishment (Radcliffe 2011; Asti *et al.* 2015). This demonstrates a clear and urgent need for improved dissemination and a greater understanding of the existing evidence base regarding breastfeeding in substance dependence.

Collectively, there are substantial physical and psychological barriers to successful breastfeeding arising from the impact of substance exposure and maternal socio-cultural circumstances. Health service practices and practitioner attitudes may facilitate or deter successful breastfeeding for this cohort.

2.3.4.2 Health, Social and Economic Implications

Significant health, social and economic implications are associated with NAS and these increase exponentially with the severity of the withdrawal process. The consequences for infants who require pharmacological treatment include prolonged hospitalisation, interrupted bonding and increased prevalence of secondary, superficial infections (Boxwell 2010). Lloyd and Myercough (2006) noted that separation of the substance exposed mother and baby can adversely affect bonding and disrupt family dynamics. This will compromise

an already difficult transition to parenthood amongst a group who often experience a history of poor parenting and lack of positive roles models (Phillip *et al.* 2003; Jambert-Gray *et al.* 2009).

Continued in-patient admission increases the infant's exposure to hospital acquired infections, paronychia and groin dermatitis. These conditions can extend the duration of hospitalisation for secondary treatment with a corresponding impact on well-being and increase in NHS costs. Resource expenditure directly relates to length of stay, and pharmacological treatment has an estimated duration of 30 days compared to seven for supportive care (Dryden *et al.* 2009; Saiki *et al*. 2010; Patrick *et al.* 2012). In the current climate of austerity and finite NHS resources there is potential to optimise these costs with a reduction of hospitalisation for NAS treatment with improved supportive care such as the continuation of breastfeeding through targeted interventions.

2.3.5 Research and the Substance Dependent Population

It has been indicated that the substance dependent population may be reluctant to engage with research projects and that traditional methodological approaches and recruitment techniques may be contributory factors limiting participation (Etorre 2004; Taylor and Kearney 2005). In previous studies Jambert-Gray (2014) had to extend the number of study sites from one to three to recruit sufficient participants and Murphy and Rosenbaum (1999) incurred professional prejudice and obstructive gatekeepers limiting access to communities. Other authors have noted a general distrust and suspicion from this cohort in response to previous negative encounters and concerns regarding the use of research data to incriminate or discredit them in some way (Goode 2000). Banwell and Bammer (2006) suggested that interview participation can be perceived as threatening for vulnerable groups. Statistics also demonstrate that there is an increased percentage of illiteracy, articulation difficulties and lower educational attainment within this population impacting on the ability to complete research documentation (DoH 2007). These circumstances have the potential to restrict research participation.

2.4 Section 3: Complex Healthcare Interventions

A complex healthcare intervention has been described as,

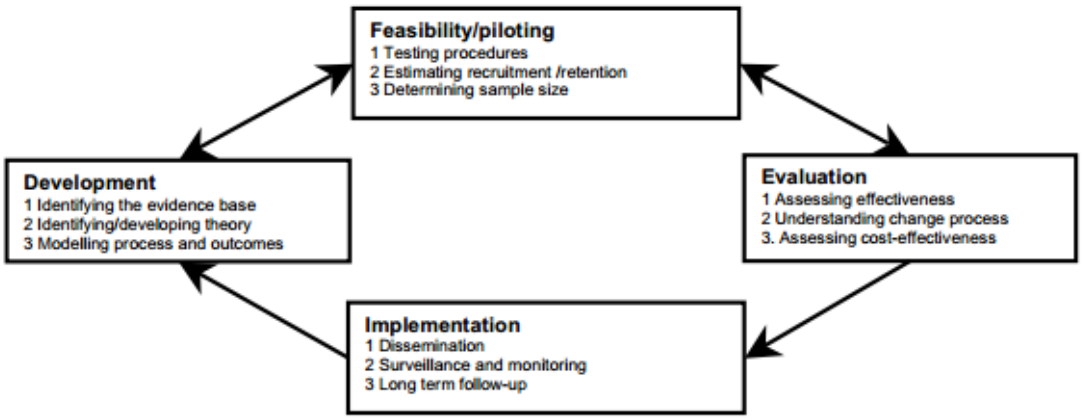
> *'An intervention comprising multiple components which interact to produce change. Complexity may also relate to the difficulty of behaviours targeted by interventions, the number of organisational levels targeted, or the range of outcomes'*
>
> (Medical Research Council 2010, p. 8).

This description emphasises the multiple elements at work in a complex intervention, and the difficulties associated with amalgamating several components into a single unified model are well documented (Campbell *et al.* 2000; Oakley 2006; Craig *et al.* 2008). This is of particular relevance in healthcare, where components may be influenced by potentially opposing clinical, social, economic and political factors (Blackwood *et al.* 2006). In response to this the Medical Research Council (MRC) produced a framework for the development and evaluation of randomised controlled trials for complex interventions. Their aim being to assist researchers to navigate the identified pitfalls in the hope of improving the generation of evidence suitable to inform practice (MRC 2000). This approach was found to be highly influential both nationally and internationally, with its recommendations adopted extensively across a diversity of research studies (Campbell *et al.* 2007). In 2006 the guidance was revisited to not only address noted limitations of the original recommendations but to also acknowledge the evolving nature of research methodologies and incorporate these into the framework (Craig *et al.* 2008). The revised guidance acknowledged the use of experimental and non-experimental research approaches in intervention development, rather than limiting the framework focus to RCT's exclusively. Additionally, the framework drew attention to the importance of intervention development and piloting phases; it proposed that an iterative approach may be a more judicious method than the previous linear model, and suggested that tailoring interventions to the local context may lead to more effective outcomes than those seen with standardised protocols.

The MRC guidance was reviewed for its relevance and suitability to the proposed research. On consideration of its substantial reputation within the

research community and its specificity to healthcare, particularly the requirement to be sensitive to the needs of diverse populations, this framework was adopted for use in the current study. Figure 4 depicts the MRC framework and its 4-step process for the development, testing, evaluation and implementation of complex healthcare interventions.

Figure 4: Development and Implementation Process (MRC)



2.4.1 Identifying the Evidence Base

The foundation of intervention development was to identify or establish a comprehensive and relevant evidence base and the MRC guidance suggested that a mixed methods approach is the most appropriate means of achieving this. The initial step is to assess existing evidence for a recent, relevant, comprehensive systematic literature review, and if this is not available to conduct one. As demonstrated previously, there is a paucity of research exploring breastfeeding support in the context of substance dependence, however there is an extensive body of literature on breastfeeding in other groups. In the absence of evidence which is wholly compatible with the intended phenomenon or group, Craig *et al.* (2008) advocate that an acceptable alternative is to explore the target behaviour amongst a transferrable population. This does, however, emphasise the imperative nature of conducting research specifically with the target population to ensure an insight is gained into their unique breastfeeding experiences and views on support components. Thus, enabling the development process to

be grounded in the factors influencing breastfeeding behaviour associated with opioid dependence. This approach also allows a comparison between the different sources of evidence in order to evaluate the applicability and transferability of the findings (Creswell and Clark 2011). In addition, existing guidelines note that breastfeeding interventions are more likely to be effective and accepted if key stakeholders such as local policy-makers, practitioners and patients are involved in the development process (NICE 2007). In line with this collective guidance on establishing a comprehensive and appropriate evidence base, it was considered judicious to undertake a systematic literature view of existing evidence and explore the views and recommendations of the target service users and providers associated with the proposed intervention.

2.4.2 Identifying or Developing Theory

Behaviour change theories aim to forward an understanding of the mechanism of change governing a behaviour and/or the contextual influences impacting on the decision-making process (Hardeman *et al.* 2005; Bowling 2009). There are significant benefits to be gained from identifying or developing the theoretical basis of an intervention. Some behaviour change theories state the causal association between behaviour determinants, mediators and the change process thus allowing an informed choice of behaviour change techniques to be made (Bandura 2004; Webb *et al.* 2010; Dombrowski *et al.* 2012). An understanding of the theoretically derived mechanism of change also enables an assessment of why, or why not, some interventions result in behaviour change. This can focus attention on weak associations or ineffectual links and provide an insight for design modifications (Michie and Prestwich 2010). Most significantly, interventions based on the theoretical principles of behaviour change are considered more likely to achieve successful outcomes compared to a-theoretical designs (Conner and Norman 2005; Craig *et al.* 2008; Davis *et al.* 2015).
Despite this, only a small number of interventions are noted to explicitly use theory in the development process or have a theoretically conceptualised basis (NICE 2007; Prestwich *et al*. 2014). A review of implementation studies undertaken by Davies *et al.* (2010) considered only 22% of 235 studies to

have a rigorously applied theoretical base and this finding was reiterated by Hoffman and colleagues (2014) during their collaboration to devise a template for improving intervention description. Further research suggests that intervention theory is often loosely applied, targets only a few constructs or an inappropriate theory, which lacks specificity to the target behaviour, is employed (Michie and Prestwich 2010) Michie and colleagues (Michie et al. 2005; Abraham and Michie 2008; Michie *et al.* 2009; Michie and Johnson 2012), in their extensive body of literature on behaviour change theories in healthcare, have repeatedly highlighted this deficiency and its detrimental impact on the validity and replication of healthcare interventions. However, identifying the most applicable theory for the intervention context presents a challenge for researchers due to the multitude of behaviour change theories, many of which have similar or overlapping constructs (Bowling 2014). NICE (2007) acknowledged that there is a lack of guidance on the appropriateness of the available theoretical models and the MRC suggests reviewing empirical evidence for demonstrated efficacy of set theories within similar settings or populations. The disadvantage of this approach is that an existing theory may not wholly represent the target behaviour or comprehensively address all the theoretical constructs, and previous efficacy is bound by the contextual circumstances of that research. On consideration of this situation the Theoretical Domains Framework (TDF) was developed specifically to assist the development, evaluation and implementation of healthcare interventions (Michie *et al.* 2005; Cane *et al.* 2012).

The TDF is a synthesis of key theoretical constructs from behaviour change theories grouped into associated common domains (Michie *et al.* 2014). Each domain is considered a main influencing factor in the behaviour change process. The authors initially reviewed behaviour change theories and theoretical constructs relevant to healthcare settings and identified 128 separate definitions. They amalgamated these into 12 theoretical domains; each representing a set of associated theoretical constructs. A theoretical construct being a component part of a theory (French *et al.* 2012). Cane *et al.* (2012) conducted further evaluation on the validity of the TDF to confirm the optimal number, content and definition of the domains. This resulted in the original framework being extended to 14 domains to offer a more

comprehensive coverage of the multifactorial influences informing healthcare development and delivery.

The TDF has been recommended for the development of healthcare interventions due to its ease of use and suitability for both expert and novice researchers. As there is sufficient available evidence relating to the individual TDF domains to facilitate those with basic awareness of psychology to map the results of behaviour analysis to appropriate interventions components (Grol *et al.* (2007). McEachan *et al.* (2008), however, criticised the TDF for being too prescriptive, with an inflexible structure limiting the identification of a full range of behaviour influences which may potentially constrain intervention development to the specified domains only. French *et al*. (2012) challenged this position by comparing TDF outcomes with a-theoretically developed interventions concluding that the TDF approach was capable of eliciting more beliefs regarding behaviour determinants than a-theoretical models. The TDF was also more likely to generate data on the impact of emotional factors on behaviour, which given the person-centric aspect of healthcare research, is highly beneficial and particularly suited to the emotive context of this study. In a recent review, Davies *et al.* (2015) considered the TDF as a valuable contribution to intervention development but noted that as the framework does not specify inter-relationships between domains or the influence one domain has over another this must be considered a shortcoming of its use. Webb *et al.* (2010) also highlighted a restriction of the TDF as the focus on individual level determinants to the exclusion of macro level influences arising from the environment and society. A suggestion to overcome this was to amalgamate the use of the TDF with additional theories, or expand the scope of the TDF, as this would offer greater potential to accurately target the mechanism of change with a more comprehensive range of change techniques (Davies *et al.* 2015).

Michie *et al.* (2011) responded to these limitations with the publication of the COM-B model of behaviour, a unifying theoretical model for use either in isolation or in combination with the TDF. The COM-B model hypothesises that behaviour is part of an interacting system involving capability, opportunity and motivation which reinforce a course of action (Michie *et al.* 2014). These three principles encompass physical, psychological, environmental, social and cognitive influences on behaviour, acknowledging the impact of individual

and global circumstances on decisions. The approach taken by the COM-B method also shares many similarities with the central tenants of other healthcare models of behaviour where strategies for developing, reinforcing and sustaining motivation are proposed as the main drivers of behaviour change (NICE 2007; Bowling 2014). Subsequently, the combination of the TDF/ COM-B approach is underpinned by the principles of established healthcare models of behaviour change whilst expanding on these to include the impact of the many levels of organisation and complexities inherent of a clinical setting (French *et al.* 2012).

Whilst the COM-B is a model of behaviour, it can also provide the basis for developing behaviour change interventions supporting its applicability for use in the current study (Jackson *et al.* 2014; Michie *et al.* 2014).

2.4.3 Modelling Process and Outcomes

Modelling a complex intervention allows the proposed components and mode of action of the intervention to be assessed as a conceptual exercise prior to actual implementation. This process clarifies the key components of the intervention and their interaction with one another which should, theoretically, result in the target behaviour. It provides the justification for the inclusion of behaviour change techniques either through a theoretically derived prediction of expected behaviour or from previous empirical evidence (Hardeman *et al.* 2005). Additionally, modelling integrates the synthesised evidence and theory to produce the intervention protocol. The protocol clearly details the practical application of the intervention and the context in which this occurs, by whom, where, when and how often.

2.4.4 Feasibility/Piloting Stage

The MRC (2008) framework recommends that a feasibility/piloting stage is conducted as part of the intervention development process. This stage enables the feasibility of the intervention and appropriateness of the research processes to be evaluated. It brings a scrutiny to the research design, focussing on whether the different research stages can be efficiently

implemented and that the methods are appropriate to measure the desired outcomes of a fully powered trial (Whitehead *et al.* 2014). It also draws attention to weaknesses of the intervention and allows for refinements to be made prior to the allocation of resources for a substantive study (Tickle-Degnen 2013). Feasibility/piloting offers the opportunity to address outstanding design concerns and Craig *et al.* (2008) suggest that this may include testing procedures for acceptability, intervention fidelity and compliance, assessing the recruitment strategy and evaluating potential sample size. Although the specific issues in need of review will vary between individual studies the MRC identify the pilot/feasibility phase as a means of enabling the researcher to answer two fundamental questions. Firstly, whether they are confidence that the intervention can be delivered as intended and secondly, that safe assumptions can be made about effect sizes, variability and recruitment and retention rates for the main evaluation study. These questions should allow an appreciation of whether sufficient preparatory work has been done prior to further research. Indeed, increasingly amongst development and implementation research feasibility studies are being undertaken to explore design uncertainties and to optimise intervention and implementation strategy (O'Cathain *et al*. 2015). Ambiguity exists, however, within the medical literature as to the definition of a feasibility study, pilot study or an amalgamation of both as a preparatory evaluation (Hoddinott 2015). Contradictory views have been forwarded regarding the choice of and what constitutes a feasibility study as opposed to a pilot study, and which aspects of the preparatory work for the definitive trial these may address (Lancaster 2004; Arain *et al*. 2010; Thabane *et al.* 2010). The MRC view feasibility and piloting as an interchangeable phase which may be undertaken in one concurrent trial or as a series of evaluation studies to progressively refine the design. Conversely, the National Institute for Health Research (NIHR) consider feasibility and pilot studies as two distinct stages of the research process. They define a feasibility study as a piece of research which is undertaken to answer the question 'can this study be done?' (NIHR). The NIHR consider feasibility studies as a means of enabling an assessment of the parameters for sample size estimation, standard deviation of outcome measures, recruitment and retention issues, appropriateness of data collection tools and outcome

measures and time/resource requirements. The feasibility study would then be followed by a formal pilot study using the proposed design for the definitive trial. Pilot studies are seen as a more appropriate vehicle to evaluate research processes such as the efficacy of recruitment, randomisation and assessment.

Additionally, the structure of a feasibility/pilot study is open to interpretation. The NIHR propose that when the feasibility study precedes a randomised controlled evaluation trial it does not need to be randomised itself, whilst the MRC suggest that the design does not need to be a scaled down, exact replica of the proposed evaluation trial. Additionally, Bowen and colleagues (2009) state that it may be mixed methods if required to both qualitatively review barriers to participation and quantitatively estimate response rates but this is dependent on individual circumstances (Bowen *et al.* 2009). Communally, the literature agrees that the key objective of this phase is establishing that the design is appropriate to address the unknown variables of a full-scale trial.

Regardless of the terminology used, whether piloting or testing the feasibility of an intervention, this stage assesses whether the methodological approach used for the definitive trial is robust, workable and appropriate to meet the research aim. Additionally, in the current climate of finite resources, it may provide the grounds for the justification of conducting a fully powered trial to stakeholders and funders (Lancaster 2015).

One area of agreement is that the purpose of this stage is to assess feasibility and whilst data regarding the primary outcome of the definitive trial can be collated this must be considered as speculative. Indeed, it has been argued that these evaluation studies should only be used to assess feasibility and additional outcome measures are unwarranted (Hoddinott 2015). Yet, McGarth (2008) noted that the collection of patient data during the feasibility stage can serve a purpose in future planning and Arain *et al.* (2010) found that several preparatory studies do incorporate statistical tests. These outcomes can provide data suggestive of a trend towards an association between variables which allows the direction of a future hypothesis to be assumed. Therefore, it is not uncommon for feasibility studies to collect secondary data as a means of informing decisions regarding study modifications. However, Arain *et al.* (2010) and the MRC emphasise

that any resulting findings from feasibility studies should be viewed with caution and that these outcomes do not negate the need for further research.

Considering the fluidity of the guidance it appears that the specific requirements of individual research projects should dictate the choice of either feasibility then pilot study or a hybrid version of the two. In respect of the distinct context of the current research project, such as the paucity of previous RCT's and the innovative nature of the intervention, it would be prudent to undertake a feasibility study in the first instance. The primary outcome of this would be an evaluation of intervention feasibility inclusive of the level of maternal acceptability of research participation. This also provides the opportunity to collect numerical data on which to base a future power calculation.

Given that the aim of the eventual full scale trial is to evaluate clinical efficacy, a research method suitable for this purpose should be trialled as part of the feasibility assessment. There is a general consensus within the medical literature that when clinical efficacy is the desired outcome a quantitative, experimental research design is the most judicious approach (Greenhalgh 2014). Due to their methodological rigour, with processes designed to minimise inherent flaws and potential sources of bias, RCT's are considered the most robust of experimental research designs. Therefore, this project will proceed with a feasibility study with an embedded small scale RCT as the precursor to further evaluation.

2.5 Chapter Summary

The literature review explored the contextual issues informing the research with particular emphasis on the key uncertainties and research question posed in Chapter 1. There was a clear indication demonstrated for the need to support breastfeeding amongst substance dependent women. However, there were identified gaps in the knowledge base regarding the efficacy and acceptability of breastfeeding support components and a lack of evidence specific to the target population. The findings also highlighted a perceived

reluctance to engage in research amongst the substance dependent community with resulting implications for the proposed research design and methods to be as inclusive and acceptable as possible. The robust nature, flexible approach and relevance to applied clinical interventions of the MRC development and its evaluation framework underlined its suitability for use in the current study.

On consideration of the literature review findings the research questions identified in Chapter 1 were revisited and this is summarised in Table 7. This summation guided the choice of research methodology and methods, which are described in Chapter 3.

Table 7: Literature Review Summary

Research Question	Literature Review Summary	Aims and Objectives
What are the key determinants of breastfeeding continuation in the context of substance use?	Reviews of breastfeeding determinants in general population (Section 2.2.1). No subject specific research evidence available. Recommendation to conduct comprehensive literature review to inform intervention development (MRC 2008)	Conduct a comprehensive systematic literature review using a transferrable population (Section 2.4.1).
What are the key components of a breastfeeding support intervention within the context of substance use?	Literature suggests practical, psychological and institutional barriers exist to breastfeeding initiation and continuation (Section 2.3.4.1). No subject specific research evidence available on support components. Recommendation to involve service users and providers in the development of breastfeeding interventions (MRC 2008; NICE 2008).	Ascertain the views of service users and providers regarding the possible key components of breastfeeding support (Section 2.4.1).
Would opioid dependent women be receptive to research participation?	Existing research suggests potential challenges with recruitment and retention amongst this group (Section 2.3.5).	Feasibility study to assess recruitment and retention rates (Section 2.4.4).

Would a breastfeeding support intervention be acceptable to opioid dependent women?	No subject specific research available.	Feasibility study to assess retention rates and maternal satisfaction with intervention (Section 2.4.4).
Would a breastfeeding support intervention be feasible to implement?	No subject specific research available.	Conduct feasibility study (Section 2.4.4).
What is the efficacy of an intervention to support breastfeeding within the context of substance use?	Gap in the evidence base as literature recommends the promotion of breastfeeding for substance dependent women but no subject specific research available (Section 2.3.4). Recommended methodology for assessment of clinical efficacy is RCT (Greenhalgh 2010)	Small scale RCT embedded in feasibility study to evaluate the feasibility of this methodological approach (Section 2.4.4). Definitive full scale RCT required to assess clinical efficacy.
Would breastfeeding continuation affect the severity of NAS experienced by the substance exposed neonate?	Literature suggests improvement in NAS outcomes with breastfeeding (Section 2.3.4). Quality of existing evidence considered of low level (WHO 2014). More robust methodologies suggested.	Small scale RCT embedded in feasibility study to evaluate the appropriateness of this methodology, data collection tools and outcome measures (Section 2.4.4). Definitive full scale RCT required to assess statistical significance.

CHAPTER 3
Methodology, Methods and Ethics

3.0 Introduction

This chapter introduces the methodological approach used in the study. Initially, the research aim and objectives are given. This is followed by a discussion of the theoretical and philosophical perspectives underpinning the choice of, and rationale for, the research design. The research methods adopted for Phase 1 of the study are subsequently detailed. The research methods used in Phase 2 were informed by Phase 1 findings and therefore these are dealt with in Chapter 6 of the thesis to maintain a chronologically sound account of the research process. The chapter concludes with a consideration of the ethical implications for research with participants who are viewed as socially vulnerable.

3.1 Research Aim and Objectives

As detailed in Chapter 2, the research questions were revisited in light of the literature review findings allowing the aim of the study to be clarified and the research objectives formalised. Following MRC (2008) recommendations, the research process was defined as two distinct phases. The purpose of the initial phase was to inform the development of the intervention by establishing a comprehensive evidence base. In the second phase the intervention was realised as an applied support model based on theoretical constructs of behaviour change. This was subsequently assessed in a feasibility study with an embedded small scale RCT.

3.1.1 Research Aim

The aim of the research was set as:

- To design and assess the feasibility of an evidence informed and theory based breastfeeding support intervention for substance dependent women.

3.1.2 Research Objectives

The research objectives were set as:

Phase 1:

- To conduct a comprehensive systematic literature review of the effectiveness and maternal satisfaction of breastfeeding support for women from disadvantaged groups.

- To establish an Expert Advisory Group of Health Care Professionals and lay representatives to inform the development and implementation of a breastfeeding support intervention for women with a substance use disorder.

- To conduct 'think aloud' verbal protocols with women who breastfed their infant whilst prescribed substitution medication, and gain their recommendations on the development and implementation of a breastfeeding support intervention for women with a substance use disorder.

Phase 2:

- Based on the findings from Phase 1, to develop an evidence informed and theory based intervention to support the continuation of breastfeeding for women with a substance use disorder.

- To conduct a feasibility study with an embedded small scale randomised controlled trial of evidence informed and theory based intervention developed to support the continuation of breastfeeding for opioid maintained women.

3.2 Research Methodology: Theoretical and Philosophical Approach

Historically, scientific and academic disciplines were closely associated with a particular philosophical or theoretical position, with the general acceptance that research within a specific discipline would adhere to the predetermined expectations of its respective approach (Teddlie and Tashakkori 2009). This enabled a shared understanding of the governing assumptions and constraints of the research. With the multi-disciplinary nature of contemporary research, however, the inherent philosophical basis of individual studies may be less evident (Polit and Beck 2013). It is important, therefore, to clarify a study's underpinning theoretical and philosophical perspective from the outset to allow an assessment of the appropriateness of the research methods to address its aim and objectives (Creswell *et al.* 2011). It also helps the current and a future audience to situate the research methods and respective conclusions within the set expectations of its prevailing theoretical, philosophical and cultural perspective (Bowling 2014). Research is uniquely defined by its contextual boundaries of time, setting and of personnel involved. Professional and personal experience shape research personnel and their beliefs and preconceptions, and these inform the direction and development of the study. This includes the choice of research design, methods and which outcomes are considered important and valid to measure (Parahoo 2014). These choices are governed by the philosophical and theoretical position of the research team.

The theoretical and philosophical assumptions held by individuals are inherent of a distinct ontological and epistemological perspective (Denzin and Lincoln 2013). Ontology refers to a belief system regarding the nature of reality and how it is constructed. Epistemology is concerned with what constitutes knowledge and knowledge generation. Within the confines of research, these philosophical assumptions are categorised as research paradigms.

Bowling (2014) defined a paradigm as:

> "*A set of assumptions– or a way of looking at the world*" (p. 129)

Paradigms are viewed as a general orientation about the nature of knowledge. The paradigm(s) followed by the researcher governs the way a study progresses, providing both a framework for research conduct and the interpretation of findings (Polit and Beck 2014).

Traditionally, there were two distinct research paradigms, social constructivism aligned with qualitative methods and positivism associated with quantitative methods (Creswell *et al.* 2011). Recently, a third paradigm has gained credence, with the emergence of pragmatism which adopts a mixed methods approach using both qualitative and quantitative methods (Rolfe 2006).

3.2.1 Social Constructionism and the Qualitative Paradigm

Social constructionists advocate that reality is not a fixed entity but is 'constructed' by individuals in response to circumstances (Denzin and Lincoln 2013). The assumption being that reality exists within the confines of an individual's mind and the meaning they create to make sense of their world is relative to their socio-cultural perspective. Subsequently, there are multiple interpretations of reality, as each person, in each context, will form a different understanding of events. There are no 'right' or 'wrong' interpretations in qualitative research rather there are social constructs, which are situated in the worlds of and between both the researcher and the participant (Polit and Beck 2013).

Social constructionists favour qualitative strategies as the research methods most likely to answer the type of questions they pose. Qualitative research focuses on exploring social phenomenon and gaining an insight into the ways in which individuals or groups attribute meaning to their lived experience or behaviour. The research process is conducted in a naturalist setting, with data analysed inductively to build general themes, with a resulting interpretation of the meaning(s) assigned by the researcher (Bowling 2014). There is a strong rationale for incorporating a qualitative research approach within this study. Breastfeeding research often adopts qualitative methods to gain an insight into the multiple factors forwarded as determinants of

infant feeding behaviour (Entwistle *et al.* 2010; Schmeid *et al.* 2011; MacVicar *et al.* 2015).

A current focus is the use of qualitative methods to explore both the appropriateness and relevance of feeding support in relation to the socio-cultural context of the woman and her family (McInnes *et al.* 2013; Hoddinott *et al.* 2013). This approach would be particularly relevant for the substance dependent population as the pharmacological, social and economic restrictions of drug dependency defines their daily lives and needs. In their study of the experience of families living with substance dependence, Chandler and colleagues (2014) discuss the imposition of daily prescriptions, frequent health and social care appointments and the pathophysiological effects of addiction. Jambert-Gray (2014) reinforces this finding, as her research participants report they want to lead normal lives but this is constrained by their dependency. Therefore, it is feasible to hypothesise that these limitations will also influence the breastfeeding aims and support needs of substance dependent women.

A qualitative approach gives a voice to the study population. It allows the participants to reflect on their breastfeeding challenges and offer views and recommendations of the suitability of the support intervention. Additionally, if the intervention is considered useful and culturally relevant by this cohort of women it increases the likelihood that it will be also be acceptable to their peer group (Yardley *et al.* 2015). Considering the minimal available evidence regarding breastfeeding support for substance dependent women, identifying the particular needs and beliefs from the perspective of those with personal experiences of this phenomenon is considered a judicious course of action.

3.2.2 Positivism and the Quantitative Paradigm

Post-positivism originated in the philosophical writing of the 19th century. This challenged the earlier positivist and empiricist notion of there being an absolute truth, and that through scientific enquiry there was the ability to uncover indisputable answers to universal questions (Polit and Beck 2013). Post-positivism acknowledged and accepted that to claim there was an absolute or definitive answer to scientific phenomenon was unrealistic and

modified their propositions to a determinist theory, that cause probably determines effect and outcomes. The basic tenet being that it is impossible to be completely positive about human behaviour and actions and therefore all knowledge is conjectural (Parahoo 2014). The positivist tradition aligns most closely with quantitative research. This advances hypotheses or theories that attempt to explain phenomenon or the relationship between events and uses scientific methods to support or refute these claims. It adopts a reductionist approach where the intent is to reduce propositions into their component parts or variables (Creswell 2013).

Quantitative research uses experimental designs, observations and measurements to collect data. Objectivity is an essential factor of quantitative research, with neutrality and impartiality an integral part of the methodological process (Creswell 2012). Evidence generation should be as value and bias free as possible, promoting rigorous standards of validity and reliability in the data and of the inferences made. The findings can, subsequently advance knowledge by refining and rethinking existing theories (Craig and Smyth 2012). Quantitative research designs have the potential to provide the most powerful and robust evidence due to the inherent structures of strict randomisation and controlled conditions which should minimise bias and limit threats to internal validity (Greenhalgh 2014). Conversely, the controlled conditions needed to promote rigour can affect the transferability of the findings to a real world setting and reduce generalisability (Smith and Noble 2015).

There is a strong argument for the use of quantitative methods as part of this study. Quantitative evidence can provide an indication of the efficacy of existing breastfeeding support strategies and a systematic review of current quantitative research will identify the availability of this and the conclusions drawn from the findings. To determine clinically efficacy, it is necessary to conduct a statistically powered RCT, however, there is currently inadequate data on which to base the parameters of a fully powered efficacy study. Therefore, an initial step of the research process is conducting a feasibility study to generate the numerical data required. The feasibility RCT findings also offer the potential to inform the future study in relation to the data collection tools and the relevance and scope of the proposed outcomes.

Further, a trend or association between variables may be demonstrated, which can assist in hypothesis generation for the future definitive trial.

3.2.3 Pragmatism and Mixed Methodology

A pragmatic approach underpins mixed methodology studies. This adopts pluralistic methods that are considered the means to best meet the needs and purposes of the research at the given time (Bishop 2015). Pragmatism employs diverse approaches giving priority to the research question and objectives and valuing both subjective and objective knowledge (Davies and Hughes 2014). Mixed methodology is not committed to strict adherence to either philosophical stance but considers any or all available approaches from across constructivist and positivist paradigms to understand and find solutions to research questions (Morgan 2007). The emphasis is not on predetermined philosophical assumptions or traditions but on gaining an understanding of the situation and the practical application of research.

There is debate regarding the validity of mixed methods given that this approach derives from conflicting philosophical origins (Lincoln *et al.* 2011). Some common arguments forwarded for the contradictory, and therefore presumed incompatible, nature of mixed methodology is the disparity between designs, such as inductive and deductive approaches and the use of a naturalistic setting versus controlled circumstances (Parahoo 2014). Polit and Beck (2014) note the historical mistrust between the paradigms but state that they both represent equally valid methods of inquiry and Creswell and Clark (2011) endorses this by proposing that the paradigms should not be viewed as opposites but accepted as differing, but complementary means of exploring multi-facet research questions. A mixed methods approach can access the best evidence from both perspectives, countering the inherent weakness of one method with the other and by enlisting a variety of data generation techniques promote a comprehensive and holistic exploration of a phenomenon (Bishop 2015). Rolfe (2006) simply urges researchers to ignore the detractors and utilise all available methods to meet their research objectives and best serve the needs of clinical practice.

There are noted advantages for synergising mixed methods, which is reflected in the increasing trend for employing this approach (O'Cathain *et al.* 2015). Whilst quantitative methods evaluate clinical effectiveness, they do

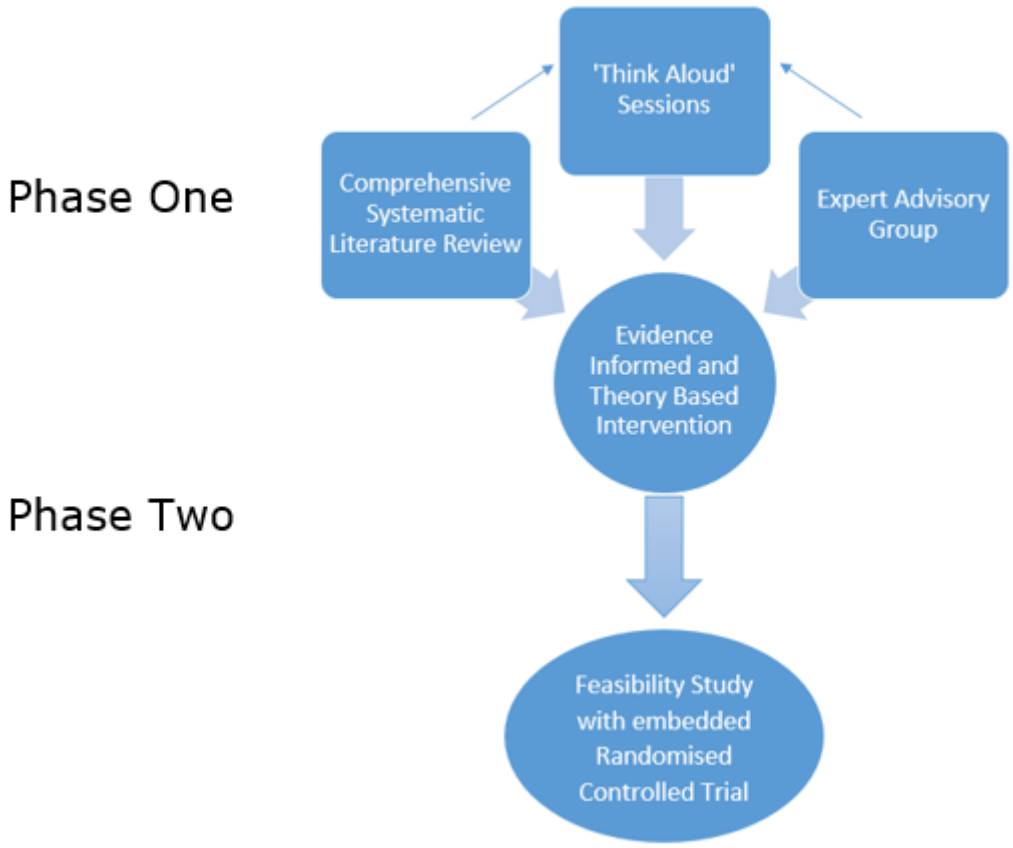
not explore why interventions work or, often more importantly, why they do not work. Concurrently, a qualitative approach provides an understanding of phenomena and personal experiences but do not assume cause and effect. Thus, the amalgamation of exploratory qualitative methods alongside an experimental quantitative design can be particularly insightful and a powerful evaluation tool (Lewin *et al.* 2009).

There are compelling reasons for the use of a mixed methods approach within the context of this study. Mixed methodology is increasingly adopted as a comprehensive and holistic approach to healthcare research, particularly for the development and evaluation of complex interventions (Oakey 2006; Yardley *et al.* 2015). A specific benefit of mixed methodology to this study is that it is particularly relevant for research with disenfranchised groups or those considered 'hard to reach' (O'Cathain *et al.* 2007). Adapting methods to the individual circumstances and needs of the client group maximises acceptability and engagement with the research and thus enables their unique experiences and perceptions to be heard (Kirst 2011).

3.3 Research Methods

Figure 5 depicts the mixed method components of Phase 1 and 2, the concurrent and synergistic nature of evidence generation and the structure of the study.

Figure 5: Research Study Structure



3.4 Phase 1: Comprehensive Systematic Literature Review

A comprehensive systematic literature review offers several generic and specific advantages as the basis for intervention development. Systematic reviews accumulate and evaluate large amounts of information within the context of predefined objectives and eligibility criteria (Greenhalgh 2014). By incorporating quantitative, qualitative and economic evidence this provides a wide-ranging assessment of a diversity of perspectives (Siu and Comerasamy 2013). In respect of the objectives of this study, this enables an understanding of the myriad of complementary and competing influencing factors. This is particularly relevant in a healthcare intervention where individuals are driven by differing motivational factors (DeJager *et al.* 2013). Additionally, the broad inclusivity policy of a systematic review promotes an evidence synthesis that is relevant, accessible and usable by a wide range of stakeholders and thus the perfect vehicle to inform clinical decisions (Munhall 2012).

Due to the absence of evidence focussing on substance dependence and breastfeeding a transferrable population with similar characteristics and infant feeding history was sought (Welle-Strand *et al.* 2012; Davie-Gray *et al.* 2013). Initially, the main characteristics of those using illicit substances were identified. National statistics describe the majority of known substance users as male (71%), aged between 25 to 34 years of age and predominantly living in the most deprived communities (ISD 2014). Due to the small number of women reported to use illicit substances, exact details such as age and location are not published to maintain anonymity. However, it has been documented that most women who access substance misuse services tend to be from a younger age group, and are therefore of reproductive age (ISD 2014).

A recent review of 561 illegal drug users accessing maternity services in the local study area documented a relationship between this group and socio-economic deprivation (Black *et al.* 2013). This study indicated that many women lived in areas classed as deprived and an overwhelming 96% of mothers reported that they smoked cigarettes in addition to using illicit substances. Extensive evidence has demonstrated the association between socio-economic deprivation and negative health behaviours such as

substance addiction, alcohol use and cigarette smoking (Pickett *et al.* 2009; Teixeira *et al.* 2009).

Women considered socially and economically disadvantaged were chosen as an appropriate transferrable population due to their similarities with substance dependent women. Those considered as 'disadvantaged' have been defined as living in areas of socio-economic deprivation, receiving welfare assistance, adolescents, of lower academic attainment and smokers (Renfrew *et al.* 2012a; Entwistle 2013). This group also have a history of poor initiation and high discontinuation rates of breastfeeding. As disadvantaged groups are considered at greatest risk of health inequalities, and would benefit considerably from the acknowledged protective properties associated with breastfeeding, a significant body of research has been undertaken on the efficacy of breastfeeding support in this populace (The Scottish Government 2011; Oakley *et al.* 2014; MacVicar *et al.* 2015).

The demographic characteristics of the substance dependent and disadvantaged groups compare reasonably well. Previous reviews of the breastfeeding experiences of disadvantaged women report similar practical and psychological issues as those identified in substance misuse literature (Jansson *et al.* 2008; MacGregor and Hughes 2010). It is accepted that the literature evidence will not be wholly comparable between disadvantaged and substance dependent women. However, it was considered a feasible and reasonable compromise given the identified similarities between these two groups.

3.4.1 Literature Review Framework

From the variety of systematic review frameworks available, the approach developed by the Joanna Briggs Institute (JBI) was used. The JBI method produces a highly evolved review process in a robust and transparent manner. It considers valid research, context of care, client preference and professional judgement as core evidence within the synthesis. These are all elements which have resonance for healthcare interventions and underpin the principles of evidence based practice. The comprehensive systematic review protocol, which includes full details of the methods, data appraisal

tools and supporting documents, is available in the appendices (MacVicar and Wilcock 2013, Appendix 1).

3.4.2 Inclusion and Exclusion criteria

Types of Participants

The review considered studies that included disadvantaged women who had elected to breastfeed. Eligible studies were those researching women considered disadvantaged due to socio-economic and demographic characteristics. This included women of low income, from areas of socio-economic deprivation, under 20 years of age, substance /opioid dependent or eligible for the special supplementary nutrition program for Women, Infant and Child in the USA. Studies researching the general population of breastfeeding women, inclusive of but not explicitly focused on disadvantaged groups, were excluded due to the potential moderating effect on the reported data. Subgroups with low breastfeeding initiation deriving from ethnic, cultural or religious practices, and therefore not representational of other disadvantaged women, were also excluded.

Types of intervention(s)/phenomena of interest and outcomes

Quantitative studies included those evaluating the effectiveness of professionally led in-hospital practices designed to support breastfeeding during the first postnatal week for women from disadvantaged groups. The phenomenon of interest for the qualitative studies was the perceptions and experiences of women of breastfeeding support and the expressed level of usefulness, acceptability and satisfaction with the support strategies. Breastfeeding support interventions reviewed included, but were not limited to, practical, educational and/or motivational strategies.

Types of studies

The quantitative component of the review considered both experimental and epidemiological study designs including randomised controlled trials, non-randomised controlled trials, quasi-experimental, prospective and retrospective cohort studies, case control studies, case series and analytical and descriptive cross sectional studies.

The qualitative component of the review considered studies including, but not limited to, designs such as phenomenology, grounded theory, ethnography, action research and feminist research.

3.4.3 Data Collection

Quantitative data were extracted from the papers using the standardised data extraction tool from JBI-MAStARI. Qualitative data were extracted from papers using the standardised data extraction tool from JBI-QARI. The data extracted included specific details about the phenomenon of interest; setting, geographic location and cultural context; interventions; populations and participants; study methodology and methods; author conclusion and outcomes of significance to the review question and objectives.

3.4.4 Data Analysis

Qualitative research findings were pooled using a framework adapted by JBI from the meta-ethnographic methods described by Noblit and Hare (1988). Noblit and Hare proposed a meta-synthesis method aimed at achieving a comparative understanding between several interpretive accounts rather than merely integrating the conclusions. This technique uses reciprocal translation of key metaphors and concepts based on topic similarity to identify overarching themes. The key tenet is that individual findings from several studies can be brought together to form a single, interpretive account, which is greater than the sum of its parts (Noblit and Hare 1988). This method involved the aggregation or synthesis of study findings (level 1 synthesis). The synthesised findings were assembled, rated according to their quality, and categorised into representational statements based on similarity (level 2 synthesis). Subsequently, each category represented a common theme or experience related to the phenomenon of interest. These categories were subjected to meta-synthesis, producing a single comprehensive set of findings that were suitable for use as the basis for evidence-based practice (level 3 synthesis).

The quantitative research findings were found to be unsuitable for statistical meta-analysis due to insufficient clinical homogeneity of outcomes measures. These were subsequently subject to narrative review.

3.5 Phase 1: Expert Advisory Group

It is recommended as good practice to canvass the opinion of local stakeholders when introducing new or complex interventions into existing services (Craig *et al.* 2008). This is particularly relevant if the research has the potential to conflict with deeply entrenched views or long-standing practices. Stakeholders familiar with the existing resources and personnel may be able to identify potential barriers and facilitators thus allowing measures to be taken to maximise acceptability and ease of integration (Oakey *et al.* 2006).

Hoddinott *et al.* (2010) experienced variability in the acceptability and efficacy of identical breastfeeding support programmes when delivered in different areas. This was mirrored by Rycroft-Malone *et al.* (2013) during implementation of a previously successful intervention with the authors attributing this to the distinct characteristics of each locale. Wells *et al.* (2012) described the contextual challenges to intervention implementation as complex, idiosyncratic and subtle. These may be intrinsically embedded in the culture or the setting and those with local knowledge can provide insight into social dynamics and relationships which otherwise may go unrecognised. Thus, convening an expert advisory group of local HCP and lay representatives with experience of opioid dependence and breastfeeding was a means of soliciting advice on the predominating contextual conventions; gaining recommendations on intervention development and optimising the success of integration within existing service.

3.5.1 Recruitment Strategy and Sampling

The research team (Researcher, Professor of Midwifery and Consultant Neonatologist) purposively identified a cross-sector group of HCP as potential members of the advisory group. These were recruited from obstetric, neonatal, midwifery, infant feeding and child-health specialities, all were

local practitioners and held a current role in service provision. It was felt that these professionals had unique knowledge and skill in their area of expertise and their opinions would complement the existing resources of the research team.

A letter of invitation, an opt-in form and a research information leaflet were posted to each identified HCP (Appendix 2). If the HCP returned the opt-in form, the researcher then made contact, either by e-mail or telephone depending on the method chosen by the HCP. A meeting was arranged between the potential recruit and the researcher, to offer further information and answer questions. When a participant expressed their willingness to be part of the advisory group, written consent was obtained. All the recruits were made aware of the voluntary nature of their consent and that they could withdraw from group participation at their discretion.

The specialist midwife was invited to identify potential participants who would be willing to act as lay representatives for the advisory group. The eligibility criterion was a community member with recent experience of the substance misuse service and breastfeeding provision in the local area. It was only possible to identify one woman who expressed her interest in the study and was willing to discuss participation. The gatekeeper offered a letter of invitation, an opt-in form and a research information leaflet at the next clinic visit to the prospective candidate (Appendix 2). Following return of the opt-in form, further contact was made by telephone and a meeting convened. During this meeting, details explaining advisory group participation were offered, the opportunity to ask questions and gain clarification provided and the voluntary nature of participation stressed. The respondent expressed her willingness to act as a lay representative and written informed consent was obtained.

3.5.2 Data Collection and Storage

Data was collected in the form of recruitment documentation, written informed consent and group meeting minutes. All documentation, and personalised data pertaining to specific individuals, were assigned a unique identification code. Participant identification details were stored separately from the identification code data. In accordance with the university policy

and practice, all documents were stored at either the NHS or the university premises, in a securely locked cabinet and only the researcher and one supervisor had access to this. Computerised data files were contained on a password protected secure server. All data collected is subject to Data Protection Act 1998 and adheres to the NHS Research Ethics Committee instructions. These procedures were to safeguard anonymity and ensure confidentiality.

3.5.3 Data Analysis

The minutes of the advisory group meeting were collated by an observer and transcribed verbatim. The provision of a formal data analysis technique was not a requirement given the format of the advisory group meeting. This is in keeping with existing recommendations on the role and function of this type of committee (MRC 2008; Creswell 2013). The researcher reviewed the meeting minutes to produce recommendations for the intervention design and its implementation.

3.6 Phase 1: 'Think Aloud' Verbal Protocols

It was anticipated that determining an effective and acceptable data collection method to gain the recommendations of opioid dependent women on intervention development may prove challenging. It is well-evidenced that this cohort is reluctant to engage in research and the unsuitability of formal data collection methods have been forwarded as one of the reasons for this (Murphy and Rossenbaum 1999; Etorre 2004; Radcliffe 2011). There was the likelihood of insufficient interest regarding formal interviews techniques with previous research noting either declined participation or guarded responses in fear of exposing illicit behaviour, being judged or incurring official reprisals (Kerwin *et al.* 2014). Additionally, it is not uncommon for questionnaires to have a poor response rate in the general public, which increased the probability that these would be incomplete, invalid or simply not returned by this group (Bowling 2014). Time issues may also present difficulties for women in the initial postnatal period due to

competing demands of child-care and the physical and emotional fatigue associated with recent childbirth. Amato *et al.* (2013) also reported the potential of substitution medication to cause pathophysiological issues such as impaired memory and short concentration span. Thus, there may be a limited time frame available to conduct the research sessions before interviewees become distracted or distressed due to their inability to recall details. A data collection method was sought that would not intimidate or make women feel uncomfortable and therefore discourage free expression of views, but was also logistically practical given the setting and population. Yardley *et al.* (2015) used a person-based approach to the development of a healthcare programme using local members to evaluate potential services. The authors carried out exploratory research to elicit user views of the prospective intervention and the behaviour changes required. Utilising a person-based approach in the current study was a means of guiding the choice of the best practical and emotional strategies to support breastfeeding in substance dependence from those with personal knowledge. The intervention could then be iteratively modified based on user's views to optimise design feasibility and acceptability.

A suitable method was needed, however, which supported a person-based approach and circumvented the challenges described with traditional methods. Subsequently, the innovative use of 'think aloud' verbal protocol was proposed, as this had been successfully used across diverse disciplines to elicit client preferences; demonstrate the usability of prototypes and study problem solving and decision-making processes (Ericsson and Simon 1983; Van den Haka 2007; Bradbury *et al.* 2015). The 'think aloud' process was viewed as particularly suitable for the current study as it encouraged participants to verbalise cognitive processes and express these thoughts in an 'unfiltered' sequence, thus overcoming issues of social verbalisation or construction coherence. The interviewees were asked to focus on completing a designated task and, therefore, should become less conscious about adjusting their response to meet social or researcher expectations (Koro-Ljungberg *et al.* 2012). Incorporating designated tasks or using pictures to represent the intervention also reduced potential issues with literacy and allowed a greater inclusivity of participants. Additionally, a 'think aloud' approach had been successfully adopted in developmental research

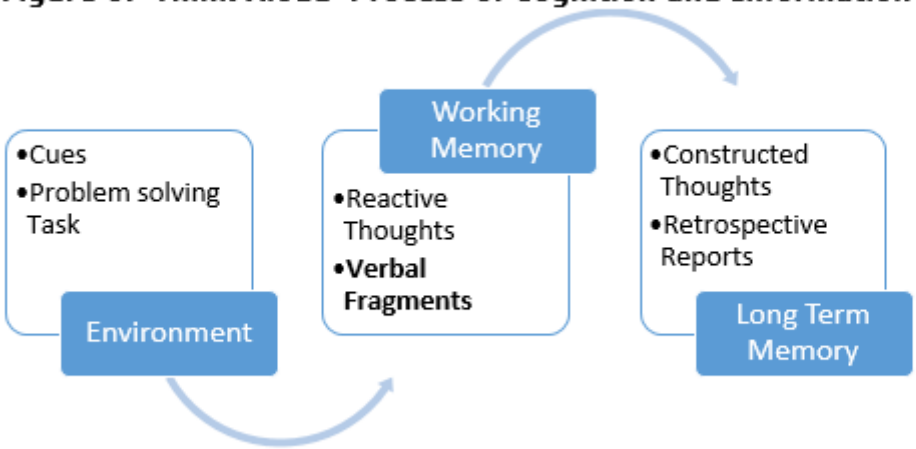
previously when there was existing information on the probable intervention elements, but this was not specific to, or was untested in, the population or setting (Yardley *et al.* 2015). On consideration, it was felt that the findings generated by this approach provided the opportunity to base the intervention on the perspective of those who would use it and enabled an understanding of how opioid dependent women viewed and engaged with the intervention. Additionally, there was the potential of confirming the relevancy of individual intervention elements whilst highlighting those which were surplus to requirements.

3.6.1 'Think Aloud' Method

'Think aloud' verbal protocol analysis was developed by Ericsson and Simon (1993) based on the theory that thoughts can be described as a series of states containing the end-products of cognitive processes. Cognition is the thought and reasoning processes that links data such as knowledge, experience and information with judgements and decisions (Thompson and Dowding 2009). The 'think aloud' technique offers a research method that turns hidden cognition into raw data in the form of verbal protocols. 'Think aloud' method consists of asking participants to verbalise their thoughts or '*think aloud'* whilst undertaking an activity. This may be solving a problem or considering a decision whilst completing a computer programme, puzzle or using pictures and artefacts (Bradbury *et al.* 2015). For example, a participant may be asked to complete a questionnaire whilst verbalising their immediate thoughts. As they engage with the 'think aloud' process they form initial, reactive thoughts associated with the format, content or understanding of the question. Then secondary reactive thoughts are formed and these will be related to the answers to the questions and are most likely to be based on instinct, heuristics or cultural conditioning. This is because reactive thoughts are not retrieved from long-term memory. Reactive thoughts are considered a product of the working memory and arise from information provided from the external environment, including cues suggested by the allocated task. This sequence is depicted in Figure 6. It is proposed that decisions arising from reactive thoughts are usually a more

accurate reflection of beliefs and potential behaviour than constructed responses (Maio and Haddock 2009).

Figure 6: 'Think Aloud' Process of Cognition and Information Construction



Although there were distinct advantages of adopting a 'think aloud' approach there were limitations in its use. The validity of 'think aloud' has been debated in relation to the impact of the additional cognitive demands of verbalisation, as this is a cognition task in its own right. It is suggested that since the speed of thought exceeds the speed of speech, the resultant verbal fragment may be an incomplete record, as it may only capture conscious reasoning (van Someren *et al.* 1994). This assumes that conscious reasoning is a cognitive process composed of several stages of decision-making. When a participant verbalises the initial stage of decision-making by thinking aloud, the next step which includes further influencing factors may be missed, as this stage occur whilst the participant is articulating their initial reactive thoughts. The following verbal fragments will then be the end product of the decision-making process. In summary, whilst decision-making may include a number of steps, not all will be verbalised because the act of having to 'think aloud' interrupts the process. Ericsson and Simon (1993) argued that 'think aloud' techniques capture inner speech, the spontaneous reactions which are normally suppressed, rather than socially constructed and reasoned speech. These are thoughts that are subject to rationalisation and

interpretation to ensure comprehensibility. Social speech requires a different cognitive process than conscious reasoning, and this is demonstrated in 'think aloud' methodology, where the verbal data is usually disconnected and fragmented. Therefore, it is argued, that the 'think aloud' approach is not impeded by the cognitive process of construction and reflection, which is part of social speech.

3.6.2 'Think Aloud' Participants

The recruitment process aimed to enrol women who were opioid dependent during their pregnancy and had chosen to breastfeed. Potential candidates were identified by their direct care team, who acted as gatekeepers. The aim was to enrol 4-6 women. This number was considered the optimum to gain a range of views and was also logistically feasible given the number of suitable participants in the locality. Qualitative studies generally recruit a smaller number of participants as the objective is to obtain an exploration of a phenomenon through an analysis of a narrative account. Therefore, the richness and depth of the data varies between individuals rather than the number of interviews conducted (Creswell 2013). This is also applicable to the 'think aloud' method, as although not designed to generate narrative accounts, the protocols return personal recommendations which differ between respondents in quality and quantity (Ericsson and Simon 1993).

3.6.3 Inclusion and Exclusion Criteria

The inclusion/exclusion criteria promoted the eligibility of a broad spectrum of substance dependent mothers with varying experiences and demographics. By including women who were both successful and unsuccessful in their attempts to breastfeed, it was hoped that a greater range of barriers, challenges and facilitators would be revealed.

Table 8: Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Women with substance use disorder during pregnancy Within 6 months of giving birth Initiates breastfeeding Read, write, speak and understand English 16 years of age or more	Women with known concurrent use of illicit psychoactive drugs Women with known concurrent alcohol issues

An age limit of 16 years was set to avoid informed consent regulations when conducting research with minors, although it was acknowledged that this may unfairly remove the opportunity for some to participate. This was discussed with the specialist midwife from the combined obstetric/substance misuse clinic who confirmed that her caseload did not include anyone within that age group. The exclusion criterion of English language only was in response to the basic principle of 'think aloud' that participants verbalise their thoughts spontaneously. The interviewer was restricted to English as a sole language and resources were not available to provide translators. A 6-month time frame was chosen as an optimum time lapse where participants would be able to recall their breastfeeding experience without it being coloured by subsequent events (Stull *et al.* 2009). Previous studies have indicated that long periods between the experience and the interview may cause recall bias but it has been demonstrated that information about life changing events, such as childbirth, are more readily retrieved compared to other phenomena (Bat-Erdene *et al.* 2013). Furthermore, this time frame was also due to maximising accessibility to potential participants for gatekeepers, as it was highly unlikely that women would still be in contact with maternity services beyond that point in time. A stipulation of no known concurrent use of psychoactive drugs or alcohol was imposed as this can result in physical/psychological or pharmaceutical impairment affecting ability to give informed consent.

3.6.4 Recruitment Strategy and Informed Consent

As a population considered as socially vulnerable, the potential participants were initially identified and approached by gatekeepers. The gatekeepers played an essential role in the research recruitment process and acted as advocates for their clients (Danchev and Ross 2015). Identifying the key gatekeepers was considered in tandem with convening the expert advisory group (Section 3.3.2). Senior practitioners in the substance misuse services, neonatal and postnatal teams were initially approached regarding advisory group membership. These individuals were either in the position to act as gatekeepers themselves or suggested alternative or additional personnel to contact. The intention of the recruitment strategy was to have a senior clinician who was a member of the advisory team in each of the clinical areas so that they could champion the research to the incumbent practitioners. However, this was not continuously maintained due to staff vacancies and movement within the departments.

The criteria for the gatekeeping role was deemed as a HCP engaged in the management of either the substance exposed mother or baby. Therefore, they were aware of any medical or social conditions affecting research eligibility. Thereafter, negotiations were held with these local practitioners and the research aim, objectives and details of the research design, including the eligibility criteria, were discussed. This enabled a collaborative and constructive dialogue regarding the practical application of the study specific to the distinct needs of each area. This discussion also provided the opportunity to offer instruction on the role of the gatekeeper and emphasise that the research team were available for guidance and support if needed. The contact details of the research supervisors were provided and the gatekeepers were also made aware of the sources of impartial advice such as the local ethics committee, should they have concerns regarding the ethicality of the research.

For this part of the study the gatekeepers included the midwife/nurse of the postnatal ward where the mother was an in-patient; the neonatal unit where the child was being treated for abstinence syndrome and members of the substance misuse services clinic.

The gatekeeper made first contact with the woman to assess her receptiveness to study participation. In addition to the specified eligibility criteria, the gatekeepers considered the physical and emotional status of the mother and child. This was to assess the appropriateness of approaching the candidates at that time regarding research participation. The postnatal period is a highly sensitive time and may be especially challenging for substance dependent women. Emotional vulnerability may be exacerbated by the additional physical or psychological issues associated with their condition. This is of concern if the baby is clinically unwell due to neonatal withdrawal and the long-term prognosis is undetermined. Furthermore, all infants born to substance dependent mothers are assessed post birth for the level of child protection deemed necessary. The outcome of this assessment, or the impending decision, can increase maternal anxiety and adversely impact on emotional resilience. The gatekeepers were aware of the circumstances of the mother and baby, and at their discretion determined whether proposing research participation would cause additional stress.

Following referral of those who expressed an interest, the researcher approached the potential participant and written information, including a letter of invitation, opt-in form and participation leaflet were offered (Appendix 2). When the opt-in form was returned, the researcher arranged to meet the prospective participant to discuss the study and answer any questions. The meeting took place in a private area in the maternity hospital to maintain confidentiality. If the participant agreed written informed consent was obtained. It was stressed that participation was completely voluntary, consent could be withdrawn at any time without reason and their decision would not affect the care offered to them or their child.

3.6.5 Data Collection and Storage

Data collection included details of the socio-demographic characteristics of the mother and neonate, obstetric outcomes and infant feeding status. These details were provided verbally by the mother during the 'think aloud' sessions or retrieved from nursing documentation. All further data were collected as verbal protocols during the 'think aloud' session.

The time allocated for and the duration of the 'think aloud' sessions placed constraints on data collection. The women were very sensitive of the need to attend to their baby and this led to time pressures. Therefore, the duration of the session was limited to 30 – 40 minutes. Additionally, some mothers were still physically and emotionally drained following labour and had limited reserves to co-operate beyond this time limit. It was considered expedient to schedule the session for early evening for the women who were in-patients in the postnatal ward. At this point women were physically comfortable as their substitution medication was at an optimum therapeutic level. One unanticipated challenge was supervision of the baby whilst the mother was being interviewed. To overcome this, the baby accompanied the mother to the interview room, and this proved to be a distraction for some but for others focussed their thoughts. For women visiting their child in the neonatal unit, the interview was arranged to co-ordinate with the infant feeding regime. Overall, the sessions had to be time limited and flexible.
Data management was a concern for some of the participants in relation to data retention, the permanency of the record and who might gain access to the information. These points had been discussed with members of the advisory group as some gatekeepers highlighted this may prove contentious. Recording the sessions was seen as a possible barrier to recruitment and may dissuaded some mothers from continued participation. The decision to take notes during the session and transcribe them post interview, was therefore made. A disadvantage of this was that the researcher had to document the verbal fragments whilst conducting the session. There was the possibility that this approach may result in an incomplete record of the interaction or that note taking could distract the participant or disrupt the connection between the participant and researcher. However, it has been proposed that following initial awareness of an observer/note-taker interviewees become unconcerned by the attention and attuned to the situation (Gerrish and Lathlean 2015). Fortunately, the format of the 'think aloud' approach was particularly suited to note taking as the participant responses were short fragments consisting of abbreviated sentences.
It was decided to craft the session into three sections to allow the participant to refocus with each change of topic. It also allowed a change in the dynamic of the session, particularly if the respondent was becoming uncomfortable or

losing concentration during the procedure. The 'think aloud' session was conducted as a three-stage process:

- Introduction: a general discussion on breastfeeding experience and collection of socio-demographic details to establish a rapport and ensure the participant was at ease with the session.
- Orientation: the 'think aloud' procedure was explained to the participant. An example exercise of presenting a picture of a house and asking the participant to count the windows in her own home, whilst verbalising her thought process out loud, was conducted (Ericsson and Simon 1993). Subsequently, the participants were shown pictorial representations of suggested intervention elements and asked to think aloud whilst considering their experience of and recommendations for breastfeeding support. The verbal fragments generated were assigned against the respective pictures.
- Conclusion: there was a brief review of the proposed questionnaire to conclude the session. This allowed participants to focus on aspects of breastfeeding support included in the questionnaire content.

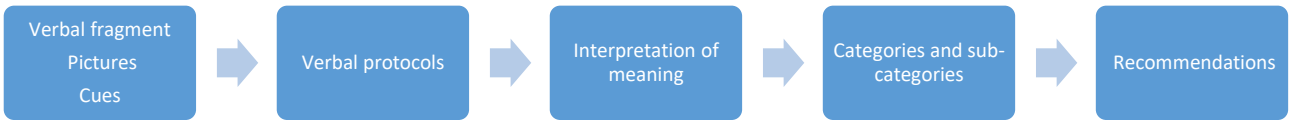
At interview termination, the women were invited to ask questions and were reassured of the confidentiality and anonymity of the report.

In accordance with university policy and practice all data are subject to procedures to ensure anonymity, confidentiality and stored securely. This is described in section 3.3.2.2. Reports, oral presentations and journal submissions have not contained information that could enable participants or their infants to be identified individually and all names within publications have been replaced with pseudonyms.

3.6.6 Data Analysis

The generated verbal fragments were documented in conjunction with contextual field notes. The data were transcribed into verbal protocols that were then qualitatively analysed using a structured approach recommended by Ericsson and Simon (1993). This technique involved the amalgamation of the verbal fragment, pictorial representation and any non-verbal cues into a verbal protocol. The researcher interpreted the verbal protocol to capture its meaning. The framework for the interpretation was guided by the research aim and objectives, which were the usefulness and acceptability of the proposed intervention components and the barriers and facilitators of breastfeeding support in the context of substance dependence. Each protocol interpretation was assigned into a sub-categories and categories. Finally, the categories were synthesised, according to similarity, into recommendations for intervention development. Figure 7 gives a depiction of the process used for data analysis.

Figure 7: Analysis of 'Think Aloud' Protocols



3.7 Research Rigour

It is important that consumers of research have a means of evaluating the quality of a study and it is absolutely essential that HCP and stakeholders can assess the credibility and safety of research findings, as clinical evidence, prior to inclusion in practice decisions (Noble and Smith 2015). Identifying and determining research rigour enables these judgements to be made. The founding principle of research rigour is that the highest degree of conduct and decision-making is adhered to during the research process, thereby promoting the integrity and quality of the findings and the conclusions drawn.

Within quantitative research methodologies the concepts of reliability, validity and generalisability are well established and accepted as evaluation criteria for determining the soundness of the research (Creswell 2014). Reliability focusses on the consistency of analysis across the data and the validity refers to the integrity and applicability of the data collection methods and precision in which the findings reflect the measured outcomes (Smith and Noble 2014). Threats to reliability and validity occur from sources of bias in the development or conduct of the research. Generalisability is the degree to which the findings can be applied elsewhere and external validity of research can be compromised if data is generalised beyond the sample population, setting or conditions to other contexts.

A clear consensus on the criteria implicated in the evaluation of rigour within qualitative research is lacking but the concepts of truth value; consistency; applicability and neutrality have been forwarded and set the foundation for assessment (Lincoln and Guba 1986; Denzin and Lincoln 2013). Within contemporary literature Creswell (2014) defined the validity of a qualitative study as its credibility, which is the truth or believability of the findings; dependability as the trustworthiness of the data and transferability as the ability to successfully replicate the findings. Procedures to enable internal validity encompass triangulation of data from various sources and methods, participant checking of the researcher's interpretation of their data and through explicit detailing of the researcher's role and philosophical perspective (Morse *et al.* 2002). Strategies suggested for promoting external validity include the transparency of procedures and provision of sufficient data to replicate the findings in a different context.

Given the existing ambiguity in relation to the concepts and terminology regarding qualitative rigour there is even less clarity surrounding the evaluation of rigour within mixed methods studies (Andrew and Halcomb 2009). Therefore, it is imperative that researchers undertaking mixed methodologies demonstrate transparency of reporting the development and conduct of the research; justify the relevance of the approach and methods and show congruence in the analysis of and inference drawn from the data (Brown *et al.* 2015).

Acknowledging this position, consideration was given to establishing research rigour in the current study in relation to both generic threats and specific contextual issues. Strategies employed within the theses include the presentation of an explicit rationale, justification and argument for decisions made and a transparent audit trail and detailed description of the research process. This enables scrutiny of the outcomes and facilitates judgements of the replicability of the research process to other settings and populations. Part of research rigour is identifying threats to validity and putting safeguard in place to minimise the potential for and impact of bias. The adoption of a randomised controlled design, which is considered the most robust method of achieving methodological rigour, due to its inherent procedures to limit possible areas of bias, allows the highest level of internal validity to be achieved (Greenhalgh 2014). The issues of cross-contamination bias, social desirability bias and recruitment bias in the study were considered. There is the possibility for cross-contamination bias between the intervention and control groups of the RCT. Cross-contamination bias occurs if participants from different arms of a trial compare their management and their view of the research is coloured by this discussion (Creswell and Clark 2011). Subsequently, the findings may not be a true reflection of the different support practices but influenced by the group allocation, therefore the resulting researcher interpretations are compromised. To minimise this, allocation to different hospital areas was proposed, thus limiting the opportunities for study participants to meet and compare their contrasting support strategies whist the trial was ongoing. Within this population group social desirability bias may occur during the 'think aloud' protocols and in the questionnaire. This happens when respondents give the answers they think are socially acceptable rather than their true opinions or actions. Due to the

nature of the 'think aloud' process the likelihood of this should be reduced and the anonymity of questionnaires has demonstrated that responses are more reflective of actual behaviour than data collected in face-to-face approaches (Bowling 2014). There was the potential for recruitment bias due to the use of gatekeepers as part of the referral process (Emmel *et al.* 2007). Whilst this was essential to ensure confidentiality and meet ethical standards it added an additional level of censorship instigated by the gatekeeper. Vigilance was required on behalf of the research team to acknowledge that this can occur and analyse the resulting data collected accordingly. The motivation for any supplementary criteria imposed on the recruitment process can stem from a variety to situations. The gatekeeper may be suspicious of the research process, have personal misgivings or harbour a fear of criticism from the findings of the research and deliberately curtail active recruitment. They may believe that imposing certain restrictions ensured non-maleficent to the potential recruits or operated a more liberal policy aimed at beneficence towards the researcher to increase the volume of data or, what they construed as, the best quality data? Alternatively, they may have been restricted by a lack of time to introduce the research study or simply disinterest in the proposed study.

Whilst the use of gatekeepers is unavoidable potential sources of bias may be minimised through good communication, rapport and collaboration between the research team and the gatekeepers to ensure clarity of the study aims. With a heightened awareness of the possible motivations underpinning decision-making assumptions arising from the generated data can be viewed accordingly.

The suitability and the capacity of the data collection tools to accurately measure the proposed outcomes can impair the quality of the data. This can be limited by adopting tools with proven validity and verifying findings through triangulation. Triangulation refers to data collection from a variety of methods and different sources producing multiple perspectives thus providing a comprehensive and comparable set of findings (Kuper *et al.* 2008). Adapting the questionnaire from an existing validated tool has implications both for and against maintaining the soundness of the data. The existing questionnaire has proven its reliability to assess breastfeeding satisfaction and maternal self-efficacy in other settings but not in this

population group. However, this lends confidence to the credibility of the findings as they were elicited using a similar format and with Likert scales which are standardised measures and accepted extensively in questionnaire surveys. Also, having a comparison between the RCT arms assists an assessment of internal validity of these findings. As a mixed method study the data from the questionnaire will be compared with other sources of information from other approaches within the study and with existing literature. This triangulation of data aids the trustworthiness of the conclusions drawn.

Establishing external validity is a difficult concept when measuring experience and perceptions as these are intrinsically bound by time, setting and circumstance. A deeply personal and complex phenomenon such as breastfeeding produces significant variability between individuals and in the same individual when exposed to different context. Providing an explicit account of the evidence generation process through transparency provides insight into how the findings were reached and conclusions drawn. This position aids the consumer to assess the transferability of the findings to their locale and population group.

Collectively, the identification and introduction of safeguarding procedures attempts to address the challenges to establishing research rigour and on-going vigilance during the conduct of the research supports this.

3.8 Ethical Approval and Implications

A key consideration for the study was to safeguard the rights of the participants and ensure fair and equitable practice. The research team liaised with specialists from the substance misuse service to discuss ethical considerations for the study population, with the issue of illiteracy and the implications of this for reading, understanding and completing study documents highlighted. Considering the challenges given the vulnerability of the target group, advice was sought from the local NHS Research Ethics Committee regarding operative procedures and the potential areas of conflict. Compliancy was checked between the research conduct and

ethicality using guidance provided by National Research Ethics Service for the NHS (2009) and local NHS good research conduct (Denscombe 2014).

3.8.1 Ethical Approval

Prior to active recruitment, ethical approval was requested from the appropriate regulatory bodies, i.e. the University and NHS. The research study was conducted on hospital premises and involved recruitment of current in-patients and out-patients. Therefore, research consent was sought, and obtained, from the North of Scotland Research Ethics Committee and NHS Grampian Research and Development department (NoSREC reference number 13/NS/0081; NHSG reference 2013OB005. As the study was part of a university research degree approval was gained from Robert Gordon University, Nursing and Midwifery Research Ethics Committee. In addition, the research adhered to the professional standards stipulated by the Nursing and Midwifery Council code of conduct (NMC 2015)

3.8.2 Ethical Considerations

An integral part of research design is an understanding of the ethical implications. Over the past decades, the definition of ethical practice has altered. There is a heightened public and professional consciousness of what is deemed acceptable. This is in response to socio-cultural changes in attitude and the exposure of incidences of ethical misconduct. Subsequently, there is extensive legislation and professional codes of conduct offering guidance (NMC 2015). These provide a framework for practitioners and indicate structural safeguards to minimise unethical, illegal or immoral actions. The founding principle of ethical practice being that research should be respectful of the rights, autonomy and anonymity of those involved; based on justice and fairness for all and conducted safely and competently. The ethos of beneficence, that research is beneficial to the participant and non-maleficence, the concept of 'do no harm' are particularly significant in healthcare research (Priest and Roberts 2010).

This study involved many ethical considerations due to the study population and the time period of the research. The study included research with a

cohort considered as a vulnerable group in society; it examined the personal and politically sensitive subjects of substance dependence and Neonatal Abstinence Syndrome, and was conducted during the highly emotive period of pregnancy and childbirth. Collectively, these accentuated the practical and ethical dilemmas of the project and emphasised the need for an approach both sensitive and empathetic to the participants.

3.8.3 Socially Vulnerable Groups and the Role of the Gatekeeper

The study aimed to sample from two groups deemed as socially vulnerable in terms of healthcare research (Kirst 2010). The first study population was that of women accessing substance misuse services during pregnancy and in the immediate postnatal period. This time is one of the most stressful for women and the transition to motherhood can be a life-changing event (McDonald *et al.* 2011). These circumstances pose challenges to ensure non-maleficence whilst respecting autonomy and avoiding paternalistic overtures. Many of those involved in illicit substance use are reported as having lower academic attainment with higher levels of illiteracy than national averages (DoH 2007). Thus, they may experience difficulties reading or fully understanding research documentation and may be reluctant to expose this. Additionally, statistics demonstrate that addictive substance use is closely associated with mental health problems (ISD 2014). It has also been forwarded that those actively involved in drug seeking behaviour frequently lead a disorganised lifestyle and can find it difficult to adhere to research commitments (Chandler *et al.* 2013). For potential participants this added an additional barrier of lessened physical and psychological availability to meet the requirements of research participation.

The second sample population were neonates. Extensive literature has discussed the difficulties that occur when inclusion criteria and study conditions applied to safeguard neonates place such constraints on research that the outcome lacks meaning in the clinical environment (Boxwell 2010; Lissauer and Fanaroff 2011). An overtly restrictive approach may deny the neonatal population effective healthcare due to the lack of robust research performed on their behalf (Janvier and Farlow 2015). Avoiding, or constraining, research with those considered socially vulnerable, however,

denies the opportunity for their unique perspectives to be investigated and marginalises them further (Kirst 2010). Therefore, it was essential to adopt a research approach which was empathetic to the needs of these populations. Decisions should not be made on their behalf nor their wishes presumed, whilst it was imperative that the research was conducted with an acute awareness of the sensitivities of the study population at all times. Given their essential role in the recruitment of vulnerable groups gatekeepers were utilised in the current study (Danchev and Ross 2015). The responsibilities of a gatekeeper are multi-faceted and the individuals concerned had to be assured of the ethical dimensions of the study and comfortable with assuming the associated tasks. It was anticipated that as a gatekeeper the practitioner would be in the position of making a judgement regarding which women were approached and the criteria by which suitability was determined. Implicated in this decision was the potential that the gatekeeper reflected on their own views of client advocacy and their biases regarding the safety of breastfeeding amongst opioid dependent mothers. Within the concept of ethical conduct opioid dependent women may be perceived as 'vulnerable', though this is not necessarily how they define themselves. Thus, the gatekeeper had to carefully balance their position of advocacy against placing constrains on client autonomy and enabling the women to exercise personal agency. Practitioner knowledge of the specific research context was complimented by the research documentation and during the gatekeeper/researcher discussions. This introduced the substantial evidence base on both the safety and efficacy of breastfeeding promotion in substance dependency.

It was deemed imperative that the HCP felt confident undertaking the role of gatekeeper and clearly understood the eligibility criteria, the ethicality of the research and felt assured of the credibility of the study and competency of the research team. Concurrently, as the researcher there was the need for strong interpersonal skills and to be adept at providing an environment conducive to constructive and open dialogue with the gatekeeper to explore their concerns. Thus, gaining and maintaining a mutual respect and understanding between the researcher and the gatekeeper was central to the success of the project.

3.8.4 Recruitment

Gatekeepers facilitated access to the participants, acted as advocates and provided a buffer to ensure client confidentiality of medical and social history from the research team during the recruitment process. Priest and Roberts (2010) proposed that vulnerable individuals may feel coerced to participate in research if approached by an unknown or perceived authoritarian figure. By ensuring that the initial contact with prospective participants was via a gatekeeper, who had already established a working relationship with the individual, it was speculated that they would not feel pressurised into enrolment. Conversely, it could be argued that some considered it expedient to be seen to be compliant to their lead care-provider and therefore felt obligated to agree to research participation. These assumptions form part of the complex interplay inherent of the power dynamics of the professional/client relationship. Being aware of this phenomenon, and being vigilant to the implications of this, was reflected on as a consideration of the ethicality of the recruitment process. This situation heightened the importance of stressing the voluntary nature of research participation during study recruitment and of ensuring this principle was re-iterated at all stages of the research process. Participants who opted into the study following referral from the gatekeeper were asked to reconfirm their consent following the birth of their baby and verbally prior to each intervention session.

3.8.5 Inclusivity

The study aimed to be as inclusive as possible and maximise research recruitment and accessibility. Concerns were raised concerning the exclusion criterion of those who could not read or understand English. The psychological/motivational aspect of the support model determined excluding languages other than English. A therapeutic and respectful relationship between the participant and supporter facilitates motivational strategies and a language barrier may impede this. Consideration was given to the use of the Language-line during the sessions, rather than excluding candidates. The Language-line facilitates a conversation between two people who do not share a common language, through a 3-way interaction with an interpreter using the telephone. It was felt that this, however, would interfere with the

rapport between the woman and support worker by imposing a physical barrier.

3.8.6 Informed Consent

Informed consent is a cornerstone of ethical practice and it was anticipated that challenges may arise due to the possibility of basic literacy and limited concentration in this population (DoH 2007). A safeguard adopted was to offer to read the research documents to the women and her partner, thus pre-empting literacy issues. There was additional time allocated during the recruitment process to discuss details at an appropriate level of understanding for the participant, or for repetition of information. A visual representation of the research time line and participant requirements was sketched for those who wished. The opportunity was given for the woman and her partner to ask questions and have their queries answered. A Language-line was available to discuss the trial if the circumstances arose, for example if a partner/supporter did not understand English. In actuality, the Language-line was not required as English was the first language of all involved. It was stressed to participants that taking part was voluntary, their decision would not affect the level of care they or their baby received and they could withdraw from the study at any time without providing a reason.

3.8.7 Anonymity and Confidentiality

An essential criterion for the study was to ensure the research did not identify women as opioid dependent. Substance use conveys a significant social stigma with pregnant women particularly vilified as subverting cultural expectations of motherhood (Fraser *et al.* 2007; Chandler *et al*. 2013). At each stage of the research process a high level of scrutiny was maintained to protect anonymity and confidentiality.

During recruitment, information packs were distributed in a sealed plain envelope with the acronym IBriS Study used rather than the title 'Intervention supporting Breastfeeding in Substance dependency' on documentation. The rationale being that if documentation was inadvertently

left in public view, it would not identify the woman as opioid dependent through her involvement with the study.

Participant recruitment took place in a private area of the maternity hospital to maintain confidentiality. For the RCT recruitment, initial contact was made at the substance misuse clinic where every attendant is on a substitution medication programme and hospital structures are already in place to ensure clinic anonymity. Women and babies in the intervention arm of the RCT were accommodated in a single room in the postnatal area to prevent study modification possibly identifying them as opioid dependent. Advisory group meetings met in private in the maternity hospital, removed from the main in-patient areas. The healthcare professional group members received a copy of the minutes and a final report summary with the option to veto any information they felt could identify them. As with all research, the personal data collected were anonymised, pseudonyms used as required and all data stored securely.

3.5.8 Beneficence and Non-maleficence

The benefits and risks of a study need to be carefully weighed to determine ethicality and to be able to explicitly and accurately explain the advantages and disadvantages of research participation to potential recruits. This includes any actual or perceived threats to individuals. It was speculated that an outcome of the 'think aloud' sessions may be a degree of emotional distress (Mitchell 2011). Given the explorative nature of qualitative research, participant may become upset reflecting on their own breastfeeding and early parenting experiences whilst considering the intervention components. If this occurred, the procedure was to stop the interview to allow the interviewee time to compose herself and for the researcher to offer comfort. The interview was recommenced only at the woman's request. If it was wished, information and/or contact details for counselling services was available. In actuality, no participant displayed emotional distress or anxiety during the sessions. Alternatively, it has been suggested that some women may gain benefit from the chance to discuss their pregnancy experiences with an independent source (McDonald *et al.*2011).

During recruitment for the RCT, women were informed that the probability of randomisation into each arm of the study was 50:50 and this was computer generated. It was re-enforced that following randomisation, all would receive standard hospital care and breastfeeding support in accordance with BFI recommendations. The intervention group were allocated additional breastfeeding support, which was theorised as a source of benefit for the mother and baby but the control group were not disadvantaged in respect of expected services. There was the concern, however, that the study would raise the expectation of additional support, which for half of the recruits would not be realised. As the researcher, one of the most difficult parts of the study was informing women of randomisation into the control arm of the RCT.

Good research practice recommendations suggest that participants are provided with, or are aware how to access relevant sources of information after their involvement with the study ends. In this instance, this was deemed as breastfeeding advice, information on controlled weaning and an awareness of altered neonatal behaviour which may be indicative of secondary withdrawal symptoms. Prior to discharge, women were provided with information leaflets, contact details for professional and lay groups and verbal instruction regarding these situations.

Whilst the participant remained in hospital, continued breastfeeding support was given as per BFI recommendations. Following discharge, the community midwife and health visitor were available to assist with breastfeeding and women were supplied with leaflets regarding community breastfeeding groups.

There is the theoretical possibility that if formula feeding is introduced, thus limiting substitution medication via breast milk, neonatal withdrawal may be exacerbated. Whilst extensive research on methadone bioavailability concludes that the volume of breast milk is insufficient to result in adverse outcomes (Jansson *et al.* 2007; McCarthy and Posey 2000), others (Isemann *et al.* 2011; Malpas and Darlow 1999) have reported infants experiencing withdrawal following the abrupt discontinuation of breastfeeding. The available research evidence supports the promotion of breastfeeding but it also highlights the need for supervised weaning in view of these reports.

All neonates at risk of abstinence syndrome are notified to child health specialists as secondary NAS can occur at 10 -14 days, regardless of whether breastfeeding is discontinued. Following discussion with a paediatric consultant for child health (ex-officio member of the advisory group), it was agreed that their contact details would be included on the infant's discharge documents. This acted as an additional safeguard if there were concerns over secondary withdrawal. This also provided a point of contact for subsequent health professionals involved with the family.

3.9 Research Conduct

The dissemination of findings to both research participants and to the wider academic and professional community should be taken into consideration during the planning and conduct of a study. One aim of research is to contribute new knowledge to the scientific body of evidence and improving health outcomes is the ultimate goal of health service research (Bowling 2014). Therefore, it is important to cascade research findings, both successful and unsuccessful outcomes, to inform the existing evidence base and best meet client needs and expectations of health services (Hoddinott 2015).

A concern for the conduct of this study was the implications for the researcher, as there was the potential for conflict due to the dual clinical and academic role.

3.9.1 Dissemination

Dissemination of results to professional groups is an integral component of a study to both further research and academic knowledge and contribute to evidence based practice. This took the form of journal publications and both poster and oral presentations at healthcare conferences.

Making the results and outputs of the research available to the study participants is ethically good practice. However, this must be done in a manner that is both confidential and sensitive to changing circumstances. This is particularly pertinent if there has been a considerable time lapse between participation and publication of the findings. Therefore, participants were informed that they could contact the chief investigator (whose details

form part of participant leaflet) and a summary of the study findings would be sent to them. It was felt that the initial contact should come from the participant rather than the research team sending unsolicited information. This concerned the likelihood of inadvertently disclosing information if others in the household were not aware of the participant's history of opioid dependence. Additionally, following hospital discharge there may be subsequent child protection issues. It is not uncommon for a child supervision order made immediately after birth to place the child with the family. During the intervening period the child may no longer reside with the family and receiving the study report unexpectedly may cause the mother emotional distress.

3.9.2 Conflict of Role: Researcher and Clinical Practitioner

There was the possibility for conflict of interest due to the dual role of researcher and advanced neonatal nurse practitioner. As a member of the neonatal team, duties included responsibility for the medical care of babies that may be enrolled in the research study. Following negotiations with the clinical nurse manager, duties as a neonatal practitioner were confined to roles that would exclude contact with mothers and babies actively participating in the feasibility study.

3.10 Chapter Summary

This chapter outlined the research aim, objectives and its philosophical and theoretical underpinning. The initial research methods were identified and described. Ethical research conduct was of paramount importance and the above discussion highlights the complexities involved in this study and the need to balance advocacy whilst respecting participant autonomy.

CHAPTER 4
Phase 1 Results

4.0 Introduction

The chapter details the conduct and findings from each of the three components of Phase 1. Initially the comprehensive systematic literature review of breastfeeding support for disadvantaged women is described. This is followed by the outcome of the expert advisory group meeting and concludes with the findings from the 'think aloud' verbal protocols. An overview of the implications for intervention development arising from the findings concludes the chapter.

4.1 Comprehensive Systematic Literature Review

A redacted version of the comprehensive systematic literature review is given below. The published systematic review, which includes full details of the methods, critical appraisal tools and supporting documents is available exclusively from the publisher's website (MacVicar, S. and Kirkpatrick, P., 2014. The effectiveness and maternal satisfaction of breast-feeding support for women from disadvantaged groups: a comprehensive systematic review. JBI Database of Systematic Reviews and Implementation Reports, [doi: 10.11124/jbisrir-2014-1561]).

4.1.1 Background

The decline in breastfeeding initiation and early discontinuation in the UK has been particularly evident amongst those living in areas of socio-economic deprivation with only 21.3% of infants from the most deprived communities breastfed at seven days of age (McAndrews *et al*. 2012). This has been attributed, in part, to the emergence of a 'bottle-feeding culture' within disadvantaged groups, whereby the trans-generational adoption of formula

feeding has led to a loss of communal knowledge and expertise, limited vicarious experience and poor maternal self-efficacy (Dungy *et al.* 2008). Consequently, there is a self-perpetuating cycle of marginalising breastfeeding with formula feeding accepted as the social norm (Scott and Mostyn 2003).

The noted variability of breastfeeding continuation demonstrated between social groups suggests that universal strategies may be unsuitable to meet the support needs of women from different economic backgrounds and circumstances (MacGregor and Hughes 2010). Sustaining breastfeeding in the initial postnatal period lays the foundation for future breastfeeding success or failure, therefore, understanding maternal support needs during this pivotal stage is essential. Furthermore, this time includes close contact with healthcare practitioners, thus providing a window of opportunity to ensure that women are equipped to make infant feeding decisions that are as informed, accurate and evidence based as possible. Therefore, an exploration of the facilitators and barriers of this step should prove insightful for practitioners and stakeholders alike and aid the development of targeted in-hospital strategies.

4.1.2 Aim and Objectives

The review aim is to:

Investigate interventions that support breastfeeding establishment for women considered disadvantaged due to socio-economic characteristics.

The review objectives are to:

(1) Describe the interventions available to support the establishment of breastfeeding for women from disadvantaged groups.

(2) Assess the effectiveness of support interventions for women from disadvantaged groups as determined by the continuation of breastfeeding in the early postnatal period.

(3) Explore the experiences and perceptions of women from disadvantaged groups of the usefulness, acceptability and satisfaction of interventions supporting breastfeeding.

4.1.3 Search Strategy

The search strategy sought published and unpublished studies, in the English language only published between 1992 and March 2013. The commencement date of 1992 coincided with the WHO/Unicef launch of the BFI. An initial limited search of Medline and CINAHL was undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms was undertaken across all included databases. Thirdly, the reference lists of all identified reports and articles were searched for additional studies. Table 9 details the databases and keywords used in the search strategy.

Table 9: Search Strategy: Databases and Keywords

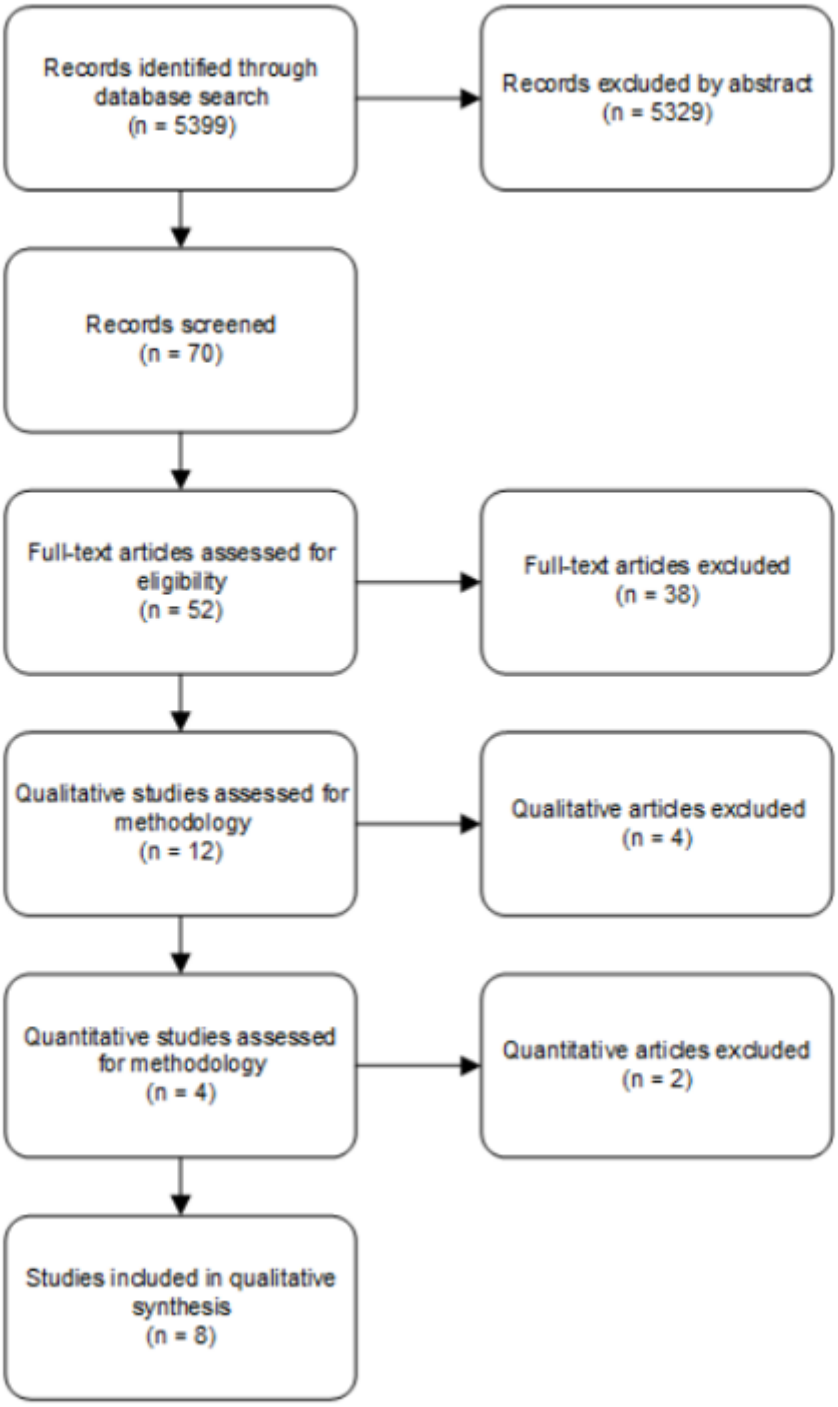
Databases	CINAHL Campbell Collaboration Cochrane Library E-thesis online Intermid Maternity and Infant Care Midirs Medline Sage Journals online Web of Science.
Keywords	Breastfeeding; Breast-feeding; Lactation Support; Intervention Disadvantaged; Deprivation; Deprived Low-income; Women Infant and Child (WIC) Teenager; Adolescent Substance dependent NAS; Neonatal Abstinence Syndrome; Neonatal withdrawal; Neonatal Narcotic Syndrome

4.1.4 Literature Search

A comprehensive literature search was undertaken for both quantitative and qualitative evidence between February and May 2013**.** The search strategy aimed to find both published and unpublished studies, including grey literature. The literature relating to breastfeeding support was comprehensive, with a substantial volume pertaining to women considered disadvantaged due to socio-economic factors. Comparatively few quantitative papers however, addressed the review objective of in-hospital strategies to support breastfeeding within the first postnatal week among women from disadvantaged groups. Several studies were unsuitable for review purposes as disadvantaged groups were not the primary focus but were assessed in conjunction with the general breastfeeding population.

A comprehensive search of all the identified databases initially returned 5399 studies of which 5329 were excluded after duplicates removed and inclusion/exclusion criteria applied. The remaining 70 studies were reviewed by abstract, and based on further analysis a further 18 studies were excluded as they failed to meet the inclusion criteria or study objectives; 52 complete studies were then retrieved and read in full. Following evaluation of the full text, another 38 studies were excluded due to lack of sufficient or relevant data to the review objectives. Fourteen studies were selected for methodological assessment.

Flowchart for study selection process



4.1.4.1 Description of Included and Excluded Studies

Of the 14 studies retrieved for methodological assessment, 10 were qualitative, two were quantitative and two mixed methods incorporating both qualitative and quantitative components. All studies were written in English and originated from the UK, USA, Canada, Republic of Ireland and Brazil. The type of disadvantage was split equally, with seven studies reviewing the breastfeeding experiences of adolescents and the other seven considering women with low income or residing in areas of socio-economic deprivation.

4.1.4.2 Assessment of Methodological Quality

Two independent reviewers assessed the studies selected for retrieval for methodological validity using critical appraisal instruments from the Joanna Briggs Institute (MacVicar and Kirkpatrick 2014). In relation to qualitative evidence, a variety of methodologies were adopted to explore maternal breastfeeding experiences. One-to-one semi structured interviews were conducted by five research groups (Bailey *et al.* 2004; Entwistle *et al.* 2010; Nesbitt *et al.* 2012; Nelson and Sethi 2005; Whelan and Lupton 1998). One review used a focus group approach (McFadden and Toole 2006). A further four studies incorporated both focus groups and individual semi structured interviews (Condon *et al.* 2013; Dykes *et al.* 2003; Shortt *et al.* 2013; Wambach and Cohen 2009). One group undertook telephone interviews and one used a postal questionnaire (Spear 2006; Hunter 2008). Following assessment of methodological quality, eight qualitative studies met the minimum requirements of the critical appraisal instrument for review inclusion.

The literature search uncovered very little high quality quantitative evidence to address the review questions. Of the four papers chosen for assessment, two were mixed methods. Hunter (2008) employed a postal questionnaire to audit teenage mothers on their experience of breastfeeding support in hospital using a survey design which included both closed and open-ended questions. Following assessment of methodological quality, this study was excluded from the review. Spear (2006) reported a descriptive case study using a convenience sample of teenage breastfeeding mothers. Following assessment of methodological quality, the quantitative component of the

study was excluded, whilst the qualitative component was included in the review. The remaining two papers, Lutter *et al.* (1997) and Ingram *et al.* (2002) were prospective cohort studies assessing in-hospital breastfeeding support. Both met or exceeded the minimum criteria from the critical appraisal instrument and were included in the review. The excluded studies, and rationale for their exclusion, are detailed in Table 10. The characteristics of the included studies are detailed in Tables 11 and 12.

Table 10: Comprehensive Systematic Literature Review: Excluded Studies

Excluded studies
QARI
Condon *et al*. (2013) **Reason for exclusion:** Philosophical perspective and researcher's cultural and theoretical stance unclear. The interpretation of results and whether conclusions have been drawn from participant data is open to speculation.
Hunter (2008) **Reason for exclusion:** Unclear congruity between philosophical perspective of research, the research objectives and the methodology chosen. Ethical approval was not sought, researcher's cultural influence on analysis of data not addressed.
Wambach and Cohen (2009) **Reason for exclusion:** Concerns over congruity of chosen methodology and representation, analysis and interpretation of results exclude study from review.
Whelan and Lupton (1998) **Reason for exclusion:** Unclear whether the conclusions arise from the data
MAStARI
Hunter (2008) **Reason for exclusion:** Lack of clarity regarding methodology- sampling, analysis and outcomes open to speculation.
Spear (2006) **Reason for exclusion:** Convenience sample, no comparison, unclear if outcomes assessed using objective criteria.

Table 11: Comprehensive Systematic Literature Review: Included Qualitative Studies, Methods and Findings

STUDY	METHODS	THEMES and KEY FINDINGS
Bailey *et al*. (2004) UK *'A 'give it a go' breast-feeding culture and early cessation among low -income mothers.'* <u>AIM/OBJECTIVE</u> To explore the experience of breastfeeding among low-income women.	Qualitative interviews. <u>ANALYSIS</u> grounded theory <u>PARTICIPANTS</u> 16 women - in first pregnancy who expressed a wish to initiate breastfeeding -women who had or attempted to breastfeed their infant.	The findings identified competing discourses of positive and negative aspects of breastfeeding. There was a pervading attitude that breastfeeding would be difficult to achieve with an expectation of failure. Women found a positive experience of formal support could make a crucial difference to their level of confidence in the early days of breastfeeding. Infant feeding decisions were based on multiple influences including practical, psychological and culture factors. Formal breastfeeding support in hospital varied with women identifying a supportive atmosphere, practical assistance and advice on potential problems, including how to overcome these as important. Support acknowledging the individual needs of the mother and baby and adaptive to the inherent changes of breastfeeding were deemed as most useful. A key issue identified was access to advice to facilitate breastfeeding establishment. Authors surmised that to facilitate maternal satisfaction and acceptability of support practices it is necessary to take into account the cultural context in which mothers make decisions.

Dykes *et al.* (2003) UK *'Adolescent Mothers and Breastfeeding: Experiences and Support Needs- An Exploratory Study.* ' <u>AIM/OBJECTIVE</u> To explore the breastfeeding support needs of adolescent mothers.	Focus groups and in-depth semi-structured interviews. <u>ANALYSIS</u> thematic analysis <u>PARTICIPANTS</u> Adolescents, 13–19 years; breastfed at least once. Focus group (n=7) 6 primips/1 multiparous -infants 2 weeks to 6 months -Breastfeeding duration 4 days to 5 months Interview (n=13) 12 primips/1 multiparous -infants 6 weeks to 19 weeks -Breastfeeding duration 2 weeks to 6 weeks (ongoing)	The study purpose was to allow both new understandings and support needs of breastfeeding adolescent mothers to emerge. The themes identified resonate with studies on breastfeeding mothers of all ages and demographics but appear accentuated in adolescent mothers. Teenage mothers demonstrated a need for psychological and motivational encouragement delivered within a supportive environment. Their confidence in their own ability to successfully breastfeed was susceptible and adversely affected by negative factors such as conflicting advice and inconsistent practices by health care professionals. The authors identified 5 themes to describe the support needs of adolescents - emotional; esteem; instrumental; informational and network support. The authors concluded that healthcare professionals should explore ways of developing and sustaining supportive relationships with adolescent mothers as a means of enabling them to prolong breastfeeding.

Entwistle *et al.* (2010) *'Breastfeeding support - the importance of self-efficacy for low-income women. '* AIM/OBJECTIVE To explore the views and experiences of low-income women in relation to the breastfeeding support received in the postnatal period.	In depth, open ended interviews. ANALYSIS mapped to concepts of self-efficacy theory. PARTICIPANTS 7 participants -10 to 18 weeks postnatal -living in socioeconomically deprived areas as defined by Jarman Index.	Qualitative data generated as part of a wider study that examined the impact of BFI training on midwives' knowledge and attitudes of breastfeeding support for low-income women. Key findings suggested that despite information provision on the benefits of breastfeeding, this was still insufficient to overcome the psychosocial barriers of low self-confidence and cultural expectation of failure inherent in some low-income women. With a greater understanding of the theory of self-efficacy and promotion of motivational support, healthcare professionals could further facilitate the breastfeeding aims of low income mothers. The emergent themes in relation to usefulness and acceptability of support were enhancing self-confidence with breastfeeding, knowledge of breastfeeding and the influence of maternity services on breastfeeding outcomes. These findings were consistent with the components that inform self-efficacy theory. Authors concluded that healthcare professionals should take the psychosocial aspect of breastfeeding support into account.

McFadden and Toole (2006) UK *'Exploring women's views of breastfeeding: a focus group study within an area with high levels of socio-economic deprivation.'* AIM/OBJECTIVE To explore the views of socioeconomically disadvantaged women in relation to breastfeeding, support and strategies which might improve feeding rates.	Focus groups ANALYSIS thematic analysis PARTICIPANTS 7 Focus groups Age range 17-40 years Prims and multiparous -4 mother/infant groups -2 adolescent groups -1 ethnic minority group 3 – 10 participants per group 63% breastfeeding /27% bottle feeding Breastfeeding duration 1 day to 1 year.	Key findings included the lack of knowledge of the physiological process of breastfeeding amongst disadvantaged groups. Women identified the negative impact of inconsistent and conflicting advice from practitioners with their confidence undermined by some institutional practices and attitudes. The key themes were varying levels of breastfeeding knowledge, maternal perceptions of support and positive and negative breastfeeding experiences. Support recommendations included an enhanced provision of information, strategies to address conflicting advice and poor professional practices, and implementing support mechanisms. Authors noted findings were consistent with previous studies, which identify women from higher income groups and those who have spent a greater time in education as more likely to breastfeed than low-income women.

Nelson and Sethi (2005) Canada '*The breastfeeding experience of Canadian teenage mothers.'* AIM/OBJECTIVE To discover the phenomenon of breastfeeding as experienced by adolescent mothers	Informal interviews, demographic questionnaire and recorded field notes. ANALYSIS grounded theory PARTICIPANTS 8 teenage mothers Age range 15 to 19 Purposive sample	Themes included adolescents feeling they had to continuously commit to breastfeeding. This was expressed as initially deciding to breastfeed, learning to breastfeed and sustaining breastfeeding. The views vacillating between the good things and hard things about breastfeeding, support and influences. Findings suggested that healthcare professionals require an understanding of the individualised needs of the teenage mother-infant dyad to facilitate continued commitment to breastfeeding.

Nesbitt *et al.* (2012) Canada *'Canadian adolescent mother's perceptions of influences on breastfeeding decisions: a qualitative descriptive study.'* <u>AIM/OBJECTIVE</u> To explore the facilitative influences and barriers to initiating and continuation of breastfeeding as perceived by adolescent mothers.	Semi-structured interviews <u>ANALYSIS</u> content analysis <u>PARTICIPANTS</u> 16 adolescent mothers Age range 15 to 19 years -infants less than 12 months of age	Study provided insight into active engagement and early assessment of potential barriers influencing breastfeeding decisions for adolescent mothers. Formal support can facilitate knowledge, skill and confidence in breastfeeding. Teenagers identified the need for hands on assistance in the early postnatal period. Positive encouragement motivated them to persevere with breastfeeding. Health workers were identified as a form of support for adolescent mothers through provision of information and advice on practical breastfeeding skills.

Shortt *et al*. (2013) Republic of Ireland *'A qualitative study of infant feeding decisions among low-income women in the Republic of Ireland.'* <u>AIM/OBJECTIVE</u> To explore infant feeding decisions among low-income women living in Republic of Ireland. To gain an understanding of the factors which influence breastfeeding initiation and continuation.	Focus groups and semi structured interviews. <u>ANALYSIS</u> thematic analysis <u>PARTICIPANTS</u> 33 low income mothers Aged 16 years or over Convenience sample Youngest child below 5 years of age.	Those who discontinued breastfeeding in the early weeks experienced feeding difficulties, and often lacked practical knowledge and experienced supporters. Women favoured a non-pressurised approach by health professionals and practical help regarding breastfeeding support. The review was specific to social and cultural context of the Republic of Ireland and this limit generalisability. It was proposed that the prudery of Irish society underlies the reluctance to breastfeed and contributes to the perceived embarrassment and stigma of feeding in both private and public sphere. A comprehensive review of factors influencing infant feeding decisions was given although data may be sensitive to recall bias as breastfeeding experiences of some participants were up to 5 years previously. Key implication for practice is a promotional effort to normalise breastfeeding and for training of health professionals in the provision of appropriate support.

Spear (2006) USA *'Breastfeeding behaviours and experiences of adolescent mothers.'* <u>AIM/OBJECTIVE</u> To explore the breastfeeding experiences of adolescent mothers.	Telephone survey of open and closed ended questions. ANALYSIS content analysis of verbatim transcript <u>PARTICIPANTS</u> 53 adolescent mothers Age range 13 to 19 years -Infants 5 months to 2 years	A retrospective study with a convenience sample of adolescent mothers recorded as breastfeeding on discharge from hospital. This design contributes to limitations of the data collected. Health care practitioners need to promote breastfeeding among adolescents in a better way, with guidance related to the physical aspects of breastfeeding warranted.

Table 12: Comprehensive Systematic Literature Review: Included Quantitative Studies, Methods and Findings

STUDY	METHODS	INTERVENTION/ COMPARATOR	KEY FINDINGS and RECOMMENDATIONS
Ingram *et al.* (2002) UK *Breastfeeding in Bristol: teaching good positioning, and support from fathers and families.* <u>AIM/OBJECTIVE</u> To determine whether a 'hands-off' breastfeeding technique could improve the chance of successfully breastfeeding and reduce incidence of feeding.	A non-randomised prospective cohort phased intervention study. <u>PARTICIPANTS</u> 1400 women Residing in lower socioeconomic UK city Breastfeeding on hospital discharge.	Phase 1 - Baseline breastfeeding data prior to a 'hands-off' breastfeeding technique taught to midwives Phase 2 – observation of how well women were mastering the 'hands-off' breastfeeding technique. Phase 3 – leaflet provided to back up technique. Phase 4 – assessment of whether midwives could incorporate the technique and apply its principles as part of their routine workload.	Findings demonstrated a significant increase in exclusive breastfeeding or of any breastfeeding on discharge from hospital. Factors associated with continued breastfeeding at 2 weeks were mother's perception of a plentiful milk supply; reporting having received enough support from hospital staff and experiencing fewer breastfeeding problems.

Lutter *et al.* (1997) Brazil *The effectiveness of a hospital-based program to promote exclusive breast-feeding among low-income women in Brazil.* <u>AIM/OBJECTIVE</u> To examine the effectiveness of a hospital program to promote exclusive breastfeeding	Prospective comparable cohort study. <u>PARTICIPANTS</u> Low-income women who delivered in either the intervention hospital or the control hospital during study period.	Comprehensive breastfeeding programme of rooming-in, early initiation of breastfeeding, breastfeeding assistance and talks. Information provided on the importance of exclusive breastfeeding for 6 months, how to solve common problems and where to find postnatal help. Philosophical underpinning of providing emotional support. Comparator: hospital with no breastfeeding programme but did practice rooming-in and prohibited free gifts of infant formula	Delivery in intervention hospital was associated with increased maternal awareness of breastfeeding continuation and support practices. Increased number of women breastfeeding on discharge from intervention hospital compared with control hospital. Study reported an overall improvement of exclusive breastfeeding for intervention participants for a median duration of 75 days compared to women in the control hospital who fed for a median duration of 22 days.

4.1.5 Narrative Summary of Quantitative Studies

A statistical meta-analysis of the two included quantitative studies was not possible as there was insufficient clinical homogeneity of outcome measures, and therefore the findings are presented as a narrative summary.

Ingram *et al.* (2002) discussed a non-randomised prospective cohort phased intervention study of 1400 women residing in a socio-economically deprived area. The study aim was to determine whether a "hands-off" breastfeeding technique could improve the rate of successful breastfeeding and reduce the incidence of feeding problems. The authors speculated that the most important factor in preventing poor feeding, inadequate milk supply and nipple damage was positioning and attachment of the baby at the breast. It was surmised that correct attachment, based on the physiology of sucking, should lead to a more effective infant sucking action, increased milk supply, and reduced nipple trauma and breast discomfort. The research comprised four phases with the initial phase involving the collection of baseline observational data. This phase also included the researcher instructing midwives on a "hands-off" breastfeeding technique, which they subsequently taught to mothers in their care. During Phase two, the research midwife assessed how effectively mothers mastered the technique and in Phase three the study participants were given an additional information leaflet. The research midwife withdrew from the postnatal area in Phase four to assess whether midwives could incorporate the technique and apply its principles as part of their routine duties. A statistically significant increase was reported in the proportion of mothers exclusively breastfeeding ($p<0.001$) and giving any breast milk ($p=0.005$) at two weeks compared to baseline figures. Additional factors associated with continued breastfeeding included no dummy/pacifier use and no supplementation with other fluids whilst in hospital. Additionally, successful establishment was associated with maternal reports of having received sufficient breastfeeding support from practitioners.

A limitation of the research was the two-year duration, which coincided with changes in hospital organisation due to severe staff shortages. This resulted in ward closures and a corresponding increase in the number of mothers accessing early discharge to community care. As these mothers were not admitted to a postnatal ward, they were not taught the breastfeeding

technique. Furthermore, those remaining in hospital were more likely to have experienced obstetric or neonatal complications, which may have impeded successful breastfeeding. The report of restricting pacifier use and no fluid supplementation must be considered when reviewing the outcomes. These are standard recommendations for supporting sustained breastfeeding and their detrimental impact has been widely publicised (Renfrew *et al*. 2012a; Entwistle 2013). Therefore, these are variables which may have impacted on breastfeeding success, independent of the intervention.

Lutter *et al.* (1997) conducted a prospective comparable cohort study to review a comprehensive breastfeeding programme which included rooming-in; early initiation of the first breastfeed; information sessions on exclusive breastfeeding and how to tackle common problems; practical assistance and where to access postnatal help. The study examined the effectiveness of the hospital programme to promote exclusive breastfeeding among low-income women compared to a control group at a hospital with no formal breastfeeding provisions. The promotion of breastfeeding practices at each hospital was assessed through maternal recall on discharge from hospital. Maternal exposure to breastfeeding activities was universally high at the intervention hospital compared to the control hospital where it was universally low. In all categories of breastfeeding support (first feed observed/ no separation over 15 minutes/ practical assistance/ breastfeeding information given) the percentage of women exposed to these in the intervention hospital compared to the control hospital showed a statistically significant difference ($p<0.001$). Amongst the intervention participants, there was also an increased median duration of exclusive breastfeeding of 53 days compared to those in the control group using multivariate survival analysis. The authors accepted that breastfeeding duration could be affected by variables such as infant birth weight; type of delivery and antenatal infant feeding advice. When these confounding variables were controlled this did not change the result. A limitation of the study was the accuracy of the assumption that the comparison cohorts were similar in all respects apart from exposure to the intervention. Suggested confounding factors included maternal motivation to breastfeed and self-selection of the intervention hospital due to its reputation for promoting breastfeeding. Furthermore, the

intervention hospital encouraged a respectful, positive and supportive environment, which may have contributed to increased maternal receptiveness to breastfeeding strategies. The authors acknowledged that the value of peer support and the accessibility of knowledge within the mother's social environment may have been a factor in the prolonged duration of breastfeeding.

In summary, the studies suggest that enhanced technical expertise, practical assistance and information appears to enhance the level of knowledge of and the rate and duration of breastfeeding in cohorts of low income women, although both studies have limitations. The findings indicate that when using support strategies in combination there appears to be a greater impact and the effectiveness of the support is increased. This mirrors the outcomes reported by Renfrew *et al.* (2012a) who surmised that support practices have a synergistic effect and the use of a combination of strategies is more effective than single practices when used in isolation.

4.1.6 Meta-Synthesis of Qualitative Studies

Ten studies were included in the review. These were read and reread to gain an overall perspective, before identifying and extracting relevant findings. The findings consisted of quotes and metaphors which mothers used to describe their experience of breastfeeding and support practices. The findings were synthesised into 10 categories reflecting determinants influencing breastfeeding continuation. The categories were integrated into three overall themes representing practical skill and knowledge of the breastfeeding process; psychological factors influencing maternal perceptions of breastfeeding capability and the provision of a person-centred approach to breastfeeding establishment and support. Table 13 details the meta-synthesis of qualitative findings into overarching themes.

Table 13: Summary of Meta-Synthesis of Qualitative Findings, Categories and Themes.

Overarching Themes: 3rd level synthesis	Categories: Second level synthesis	Findings: First level synthesis
Theme 1: Practical skill and knowledge	Practical ability	Level of breastfeeding skill
		Negative impact of conflicting advice
		Efficacy of health service practices
		Availability and accessibility of practitioners
	Unprepared for the realities of breastfeeding	Misconceptions of breastfeeding
		Unprepared for time demands of breastfeeding
		Discomfort of breastfeeding
	Breastfeeding Knowledge	Degree of breastfeeding knowledge
		Ability to identify and pre-empt challenges
		Available and accessible information provision
Theme 2: Psychological influences	Self-efficacy	Degree of vicarious experience
		Impact of physiological symptoms on psychological state
		Degree of self-confidence
		Expectation of failure
	Facilitative relationship	Establishment of a collaborative relationship
		Adequacy of service provision
		Continuity of care-giver
	Emotional response to breastfeeding and motherhood	Stress of unsuccessful breastfeeding
		Pressure of responsibility for infant nutrition/well-being
		Positive attachment and bonding
Theme 3: Person-centred approach	Socio-cultural context	Impact and expectation of societal norms
		Impact and expectation of cultural norms
		Value attributed to breastfeeding
	Relational support	Availability of positive role models
		Availability of family support
	Personal preference	Breastfeeding embarrassment- public and private
		Compatibility of breastfeeding with other family commitments
	Individualised care	Negative impact of stereotyping and /or presumptive attitudes by healthcare professionals
		Acknowledging individual objectives
		Judgemental, authoritarian attitudes by healthcare professionals

Theme 1: Practical Skill and Knowledge

"I wasn't sure how to breastfeed to be honest"
(Shortt et al. 2013)

The theme of practical skill and knowledge incorporates three categories. The categories include maternal practical ability, existing breastfeeding knowledge and unprepared for the realities of breastfeeding.
Practical skill and knowledge relate to the level of maternal technical expertise and awareness of the normal physiological process of breastfeeding. This encompasses the practical aspects of breastfeeding and the ability to recognise, pre-empt and react appropriately to common challenges. Knowledge includes a realistic understanding of the breastfeeding process and the benefits of breastfeeding. This is also implicated in the third category of unprepared for the realities of breastfeeding. The findings suggest that adequate provision of professional assistance and advice to equip women with the ability to master the practicalities of breastfeeding was instrumental for sustained breastfeeding.

The findings note that many women lacked the **'practical ability'**, to successfully establish breastfeeding and candidly expressed awareness of their limited skill set:

> "Sorry I don't know what to do."
> (Nelson and Sethi 2005)

There was an identified need for professional support to both assist with the technical aspects of breastfeeding but also to facilitate mothers to acquire these skills for themselves:

> "She was putting him on for me but not showing me how to do it myself."
> (Dykes *et al.* 2003)

Women valued assistance from practitioners and it resonated across the studies that professional support strategies, which equipped mothers to meet the practicalities of breastfeeding, were perceived as constructive and supportive:

> "Nurses in the hospital showed how to get the baby to latch on."

(Spear 2006)

However, several reports noted the demoralising impact of inadequate service provision with unavailability or lack of continuity of staff:

> "The midwives used to come in... then you never used to see them again until the next midwife came on shift."
>
> (McFadden and Toole 2006)

Institutional and professional actions both encouraged and discouraged mothers in their breastfeeding aims. Mothers identified the need for practical and informational assistance but they also felt that the environment and constraints on service provisions affected their ability to assimilate the proffered advice. There was overwhelming evidence that the lack of practitioner contact and minimal time spent with the mother and baby affected perceptions of support:

> "Nobody will sit with you and explain what to do. It's just okay, she's breast feeding, go to the next bed."
>
> (Shortt *et al.* 2013)

This included the approach adopted by healthcare professionals:

> "Definitely be patient…because I remember sometimes the nurses in the hospital were so frustrated."
>
> (Nelson and Sethi 2005)

Many low income and teenage mothers felt their limited **'breastfeeding knowledge'** negatively influenced the continuation of breastfeeding**.** They lacked a complete or accurate understanding of the breastfeeding process, and inadequate information provision exposed their difficulties further:

> "All kinds of medical terms and stuff then it's really hard to listen."
>
> (Nelson and Sethi 2005)

This included information omitted, conveyed via an unsuitable medium or given at an inappropriate level for the target audience:

"I mean anyone can read a leaflet and not understand it."
(Shortt *et al.* 2013)

Conflicting advice further compromised maternal understanding and confidence in professional support:

''They would say different things... all of them... which was confusing."
(Dykes *et al.* 2003)

Variations between the strategies promoted by professionals both confused mothers and cast doubts on which practice was most effective, if any, and which course of action the mother should adopt:

"One nurse told me to use a rough wash cloth but another nurse told me not to. It was confusing."
(Spear 2006)

Contradictory strategies also undermined the professionalism of other practitioners and ultimately reduced maternal confidence in the information and advice given:

"Not all the midwives would do this and they don't agree with it, but I'm going to give you a shield."
(McFadden and Toole 2006)

Many women felt ill informed about the benefits of breastfeeding and their knowledge was often incomplete or at times inaccurate:

"I mean you do hear that breast is best and it is promoted but it doesn't actually tell you why."
(McFadden and Toole 2006)

Additionally, women expected healthcare professionals to promote the benefits of breastfeeding and to be a ready source of information:

"Doctors and nurses need to give more information about how good it is to breastfeed and reinforce the benefits more."
(Spear 2006)

The findings suggest that teenage mothers were particularly '**unprepared for the realities'** of breastfeeding:

> "I thought it (breastfeeding) would be like a quiet resting time where he'd eat and then he'd sleep for 3 to 4 hours. I didn't think he'd eat, I'd have to burp him, change him, put him down for 5 minutes and he'd wake again. Like, I was not prepared for that."
> (Nelson and Sethi 2005)

They were surprised by both the physical demands of feeding and the time required:

> "I think the worst bit is when you start feeding and they're really sore' 'I was just really tired."
> (Dykes *et al.* 2003)

Some mothers acknowledged their lack of awareness of what breastfeeding entailed but also felt it was the responsibility of health practitioners to pre-empt and address this:

> "They need to prepare you more about breastfeeding."
> (Spear 2006)

Theme 2: Psychological Influences

"If they had encouraged me a bit more...I would have carried on"
(Dykes et al. 2003)

Psychological factors had both positive and negative influences on maternal perceptions of breastfeeding capability. This theme arose from the categories of maternal self-efficacy, establishment of a facilitative relationship and emotional responses affecting breastfeeding decisions. Women who lacked confidence in their ability to master breastfeeding were more likely to become demotivated; whilst those who were confident displayed greater determination to meet and overcome barriers. The establishment of a facilitative relationship also impacted on self-efficacy levels and mothers who were offered reassurance and encouragement were more likely to sustain their commitment to breastfeeding. Additionally, for many women the cumulative impact of pregnancy on their physical and psychological well-being affected their emotional resilience. Fatigue, feeding discomfort and postnatal pain, and the perceived stress associated with these, all tested maternal coping mechanisms with a resulting influence on decisions regarding breastfeeding continuation.

The category of **'self–efficacy'** derived from the findings of an expectation of failure and low maternal self-confidence. An expectation of failure was present in the language and metaphors used by women:

> "Love to try. Don't know until I've tried. 'I just wanted to give it a go."
>
> (Bailey *et al.* 2004)

Mothers expressed a wish to initiate breastfeeding but this was often accompanied by the proviso that a successful outcome was not assured. Many women considered breastfeeding as a gamble with a resulting increase in anxiety levels regarding their ability to nourish their baby:

"I don't feel confident... what if I'm not doing it right."
(Dykes *et al.* 2003)

There was an expressed lack of confidence amongst disadvantaged mothers and encouragement bolstered maternal belief in their ability to master breastfeeding:

"I felt encouraged and it helped me with the actual how to do it properly."
(Nesbitt *et al.* 2012)

Recognition of the mother's capability and praise for her skill set was considered as supportive and instilled a feeling of self-confidence:

"They pretty much said I was a natural at it."
(Nelson and Sethi 2005)

The findings demonstrated that positive reassurance aided maternal motivation to sustain breastfeed:

"They (midwives) said 'you're doing really really well' and that's when I really wanted to persevere with it."
(Dykes *et al.* 2003)

These findings are consistent with the theory of self-efficacy, which associates verbal persuasion and practical mastery with increasing an individual's perceived capability to perform a task.

Breastfeeding support was more readily accepted and acceptable to women when delivered within the confines of a '**facilitative relationship'.** Women who viewed their relationship with practitioners in a positive light, were more likely to feel confident in their breastfeeding efforts:

"The midwives were brilliant, told me not to worry."
(Bailey *et al.* 2004)

Women reacted positively to encouragement from a trusted source:

"She connects very well."
(Dykes *et al.* 2003)

However, the lack of continuity of care-giver impeded the formation of a collaborative relationship:

> "Because I didn't know them -I felt uncomfortable asking."
> (Dykes *et al.* 2003).

Alternatively, some professional actions and attitudes inhibited the establishment of a mutually respectful relationship with many women perceiving this as unsupportive. This included practitioners who covertly gave 'permission' to discontinue breastfeeding by instilling doubts in the mother's decision-making ability and implying that breastfeeding difficulties would continue:

> (Midwife said) "You don't want to dread feeding time; you want to enjoy your baby."
> (Entwistle *et al.* 2010).

Facilitative support was particularly important for mothers from disadvantaged groups as professional actions undermined their already fragile self-confidence, emphasising perceptions of inadequacy:

> "After they'd fed her, she just slept...she was just screaming when I put her near."
> (Dykes *et al.* 2003)

The '**emotional response'** generated by the transition to motherhood influenced maternal breastfeeding perceptions of self-efficacy. Women expressed feeling a loss of control, isolation and vulnerability due to the experience of both childbirth and hospitalisation. For many mothers breastfeeding was an additional stressor in an already emotively charged and physically challenging situation:

> "It was like everything I'd expected had started to go wrong.... it was like everything crumbled."
> (Entwistle *et al.* 2010).

Yet, for mothers who successfully established breastfeeding the unexpected emotional rewards and psychological benefits were expressed in terms of an epiphany:

> "Breastfeeding empowered me as a young mother."
> (Spear 2006)

Theme 3: Person-Centred Approach

"Breastfeeding wasn't mentioned…because I was so young"
(Shortt et al. 2013)

Person-centred approach relates to the provision of tailored advice and support. This includes acknowledging and addressing the personal aims and preferences of women and the importance of delivering socially and culturally relevant breastfeeding support. The theme comprises the impact of socio-cultural context, the availability of relational support, maternal choice and an individualised approach to breastfeeding support.

'Socio-cultural context' encompasses the cultural norms inherent of certain disadvantaged groups where the adoption of formula feeding has marginalised and eroded breastfeeding knowledge and ability. For many breastfeeding was neither an acceptable nor a feasible infant feeding option. Several mothers voiced their socio-cultural experience of breastfeeding as:

> "Not the done thing."
> (Shortt *et al.* 2013)

Mothers acknowledged formula feeding as socially accepted and expected. There was an embarrassment and perceived stigma attached to breastfeeding in both the public and private sphere:

> "There is a taboo about it. Ah look at her with her diddy (breast) out feeding the baby."
> (Shortt *et al.* 2013)

Furthermore, some mothers experienced peer pressure not to breastfeed with attempts made to dissuade them:

> "'My friends discouraged me because they said it was going to hurt. I still said I would give it a go."
>
> (Nesbitt *et al.* 2012)

Women who did contemplate breastfeeding had the additional concern of how to access peer support in areas where formula feeding was predominant. For these women the availability of peer and '**relational support'** was essential. It was important to identify potential sources of support for practical assistance:

> "Mum's had three of us and breast fed the lot, quite a few of my friends too so I know that they'll all be a great help."
>
> (Bailey *et al.* 2004)

There was an acute awareness of the importance of relational and emotional support:

> "He (husband) is very comfortable with the idea of breastfeeding which helps I think."
>
> (Entwistle *et al.* 2010)

However, for the women who identified the combination of limited social support and minimal breastfeeding experience, either actual or vicarious, there was an increased emphasis on accessing assistance from professional sources. The findings demonstrated the consequences of inappropriate strategies in hospital to both identify and address maternal support needs:

> "I was embarrassed in the hospital, but when I got home I said ah well I'll just try, but I didn't know what to do."
>
> (Shortt *et al.* 2013).

Women based infant feeding decisions on '**personal preference'** such as family circumstances and individual choice. There was the assumption that breastfeeding would be incompatible with other work/family commitments:

> "You have the school run and everything else so it was just easier to put it in a bottle."
>
> (Entwistle *et al.* 2010)

Some identified sharing accountability for infant care as an issue, with the level of commitment and responsibility associated with breastfeeding as an additional stressor:

> "He was so pleased and proud that he could give her a bottle feed...I don't feel so tied down."
>
> (Dykes *et al.* 2003)

Unsupportive professional practices were associated with prescriptive strategies, which did not acknowledge or respect the '**individualised care'** needs of the mother and infant. Further, adolescent mothers identified staff attitudes as a contentious issue, stating that they felt judged by health practitioners:

> "You always feel that you're being watched to see whether you're able to look after your baby."
>
> (Dykes *et al.* 2003)

Teenager mothers reported instances of stereotyping because of their age, with practitioners failing to discuss or promote breastfeeding:

> "Breastfeeding wasn't mentioned…because I was so young."
>
> (Shortt *et al.* 2013)

Several studies noted that healthcare staff presumed that mothers from disadvantaged groups would unquestionably formula feed their infant without verifying the mother's wishes:

> "I wasn't asked how I was feeding. I was asked how many ounces he is having."
>
> (Dykes *et al.* 2003)

4.1.7 Key Findings

The meta-synthesis highlights the multifactorial influences associated with supporting breastfeeding for low income and teenage mothers. There were three key findings identified. Firstly, many of the respondents lacked sufficient practical skill and knowledge of the normal physiology of breastfeeding to navigate common infant feeding difficulties. Secondly, psychological issues could both positively and negatively affect maternal perceptions of breastfeeding capability. Thirdly, women from disadvantaged backgrounds were unreceptive to health service strategies which did not respect and practice a person-centred approach to breastfeeding support. Cumulatively, the review demonstrated the need for support practices which specifically target these varied but interdependent determinants of breastfeeding behaviour.

The availability of practical assistance and advice was the most frequently quoted support need. Women considered it an essential component of supportive practice to be enabled to acquire the technical skills and knowledge to pre-empt and address breastfeeding challenges. There was an identified need for a greater awareness of the practice, knowledge and benefits of breastfeeding among low income and teenage mothers. With limited understanding of the practicalities of breastfeeding and minimal vicarious experience, many women from disadvantaged groups were unprepared for the realities of breastfeeding and lacked confidence in their own ability. The respondents were candidly aware of the gaps in their breastfeeding knowledge. There was an expectation amongst the participants that healthcare practitioners should and would be able to provide the information they required. The findings noted, however, that information provision was frequently inaccurate, conflicting or given in an inaccessible medium to be of benefit. Women who did feel supported in their aim to master breastfeeding, however, reported the positive effect this had on their motivation to persevere even in the face of feeding difficulties and their own lack of expertise.

Whilst the systematic review noted the positive effect of practical and informational assistance there was a corresponding negative impact if women felt that professional support ineffectual or irrelevant. Women were unreceptive to practices that either did not engage their attention or were

considered unacceptable to their individual circumstances, with culturally relevant advice considered as more acceptable and effective in meeting their breastfeeding objectives than generic practices. Women felt it was imperative that practitioners acknowledged social, cultural and personal influences informing maternal infant decision-making when formulising support strategies. Disadvantaged groups appeared particularly sensitive to institutional and professional practices, behaviours and attitudes that stereotyped and judged them. HCP who acted on presumptive or paternalistic opinions without establishing maternal preferences contravened the mother's autonomy and undermined her confidence to make infant feeding decisions.

Maternal perceptions of staff being 'too busy' appeared to be the root of unsatisfactory and counterproductive encounters for many. Staff availability was implicated as a barrier to establishing a facilitative relationship between the woman and her supporter. Women were more open to support strategies when given the time and opportunity to establish a rapport with the practitioner, thus enabling a more individualised assessment of their support needs. Reports of 'conveyer belt care' contrasted with those who felt that practitioners had taken time to get to know them and their infant (Author et al. date and page). The effectiveness of encounters was enhanced if continuity of care-giver was achieved and participants reported feeling more comfortable if there was a degree of familiarity with the supporter. Additionally, the findings suggested that prolonged contact may be equally as important in bolstering maternal self-efficacy and confidence as the practical skills acquired.

An overarching theme of the meta-synthesis was the impact of psychological factors on breastfeeding decisions, particularly strategies which could influence maternal self-efficacy levels. Many of the respondents displayed low levels of self-efficacy, with a lack of belief in their own capability to master breastfeeding coupled with a prevailing 'expectation of failure' (Bailey et al. 2004 and page). Several studies reported maternal anxiety and poor perceptions of capability as reflective of a societal undercurrent that breastfeeding was not the accepted or cultural norm within disadvantaged communities. These circumstances resulted in an erosion of maternal confidence and for many their breastfeeding intention was expressed in

terms of a 'give it a go' attitude and accompanied by a pessimism that failure was a more realistic outcome than breastfeeding success (Bailey et al. 2004 and page). Subsequently, an emphasis was placed on the need for health professionals to bridge this gap in terms of both enabling practical expertise and minimising self-doubt. The respondents spoke of their renewed commitment to breastfeeding continuation when they were encouraged and offered positive reinforcement, thus enhancing self-efficacy levels. For women who encountered negative HCP attitudes and undermining practices this vindicated their own view that they lacked the capability to successfully breastfeed.

Self-efficacy levels were also affected by the physiological status of the mother with the pain and fatigue experienced in the postnatal period testing their resolve to overcome breastfeeding challenges. The vulnerability experienced during this stressful period emphasised the importance of a facilitative relationship and an encouraging environment. It was noted that the promotion of a conducive, supportive environment aided mothers to be more receptive to breastfeeding advice and practical assistance. Conversely, women spoke of their surprise and the sense of empowerment gained by overcoming the anticipated breastfeeding challenges.

4.1.8 Strengthens and Limitations

A strength of the review includes its relevance to current national and international policies regarding breastfeeding and its role in tackling health and social inequalities (Unicef 2009; The Scottish Government 2011). Global initiatives are committed to breaking the cycle of health inequalities passing from one generation to the next through prevention and early intervention of poor life style choices. Reviews of the efficacy of breastfeeding support practices and specifically the acceptance of such strategies to socially disadvantaged mothers can contribute to the development and implementation of future evidence based programmes of support.

Research exploring personal preference is particularly pertinent to current practice initiatives aimed at meeting person-centred quality ambitions (The Scottish Government 2010). A major healthcare impetus is to ensure that services are responsive to the needs of the individual by demonstrating

compassion, understanding and shared decision-making. Examining maternal perceptions of breastfeeding support helps identify the areas deemed by mothers as important in fulfilling their infant feeding objectives. By gathering, sharing and responding to the public's experience of healthcare, and its impact on their quality of life, mutually beneficial partnerships, which respect the individual's health related aspirations, can be achieved.

A strength of the review process is the rigorous system adopted in the identification, evaluation and analysis of the available evidence. The review process was meticulously conducted with two reviewers independently evaluating the suitability and reliability of evidence for inclusion. The JBI mechanism for reporting of the evidence allows transparency of method and reproduction of findings (Joanna Briggs Institute 2015).

Additionally, the review utilised a broad inclusive approach to evidence. The combination of both qualitative and quantitative evidence enables a comprehensive account of the personal experience of breastfeeding and the global outcomes. The quantitative component identifies the practices that are effective in establishing and continuing breastfeeding whilst the qualitative findings offers an insight into why these specific practices worked, or did not work, from a maternal perspective. This is of the utmost importance when considering a phenomenon such as breastfeeding, where outcomes are influenced by a multitude of complex, contradictory and complementary actions and attitudes. Reviewing the determining factors from macro to micro level and from an institutional to personal perspective allows policymakers to customise strategies to deliver more effective and acceptable evidence based practices.

However, there were noted limitations to the review process and its outcomes. Available research on support for breastfeeding establishment in socially disadvantaged groups was limited, and this was indicative of the small number of suitable studies found. All the included articles originate in high income countries; therefore, it cannot be assumed that the findings will apply to other geographic settings where health service provisions or cultural context may differ. The review considered studies published in the English language only and may not be fully representative of all literature on breastfeeding support. A further review undertaken for studies published in other languages is, therefore, recommended.

4.1.9 Implications for Intervention Development

The comprehensive systematic literature review provided insight into the breastfeeding support needs of women from disadvantaged groups. Perceptions of breastfeeding ability appear to be influenced by practical, psychological and personal circumstances and women from disadvantaged groups display less resilience than their more affluent peers to navigate challenges. This has implications for the substance dependent community as statistics show that they predominantly resided in areas of socio-economic deprivation.

The collective implications for intervention development gained from the systematic review were:

PRACTICAL

- Assess existing level of maternal practical skill and enable technical expertise through the availability of practical assistance
- Enhance maternal knowledge and awareness of the normal breastfeeding process through the availability and accessibility of accurate and realistic information and advice
- Information on the benefits of breastfeeding
- Eliminate conflicting advice and prescriptive practices

PSYCHOLOGICAL

- Impact on maternal perceptions of breastfeeding self-efficacy through verbal persuasion such as encouragement and reinforcement
- Address the impact of physiological symptoms on psychological status
- Foster a facilitative relationship through accessibility and continuity of care-giver
- Acknowledge emotional impact on breastfeeding continuation, reinforce positive and address stressors

PERSON-CENTRED

- Dispel common myths and misconceptions of breastfeeding
- Acknowledge, respect and incorporate maternal individualised aims, objectives and preferences in breastfeeding support strategies
- Offer socially and culturally relevant support practices
- Respectful, non-judgemental attitudes

These findings will be reviewed in conjunction with the outcomes from the remaining two components of Phase 1. Collectively these will be integrated and synthesised to give the determinants of breastfeeding behaviour associated with substance dependence.

4.2 Expert Advisory Group

The expert advisory group comprised of six HCP and a volunteer lay representative. Initially, nine HCP were contacted regarding their participation as part of the advisory group. Of those invited, six agreed to actively participate in the group, two professionals accepted an ex-officio position and one professional declined. Table 14 details those approached and the outcome of the recruitment phase.

During the study period, there were two changes to the initial advisory group personnel. The obstetric clinician moved to another position. The successor to this post was not appointed until the later stages of the study and therefore it was considered unnecessary to approach them regarding advisory group participation. The midwifery practitioner from the substance misuse service left this role and was replaced by an existing member of the team who was aware of the research aim and objectives. This professional was already active in identifying potential recruits for the 'think aloud'

sessions and had expressed an interest and enthusiasm for the research, and subsequently joined the advisory group.

Table 14: Expert Advisory Group Recruitment

Specialism	Invited Personnel	Accepted/Declined
Neonatal clinicians Clinical leads for infants at risk of Neonatal Abstinence Syndrome	Neonatal (1)	Accepted invitation Group chair
	Neonatal (2)	Declined invitation Accepted ex-officio position
Obstetric clinicians Combined Obstetric/Substance Misuse Service	Obstetric (1)	Accepted
	Obstetric (2)	Declined
Midwifery	Postnatal service (1) (2)	Accepted (1) Accepted (2)
	Substance Misuse Service	Accepted
	Infant Feeding service	Accepted
Paediatric clinician Substance Misuse Service	Paediatric (1)	Declined invitation Accepted ex-officio position
Lay representative Community member	Lay representative	Accepted

4.2.1 Introductory Meeting

The introductory advisory group meeting considered the logistics of intervention development and implementation within the confines of the existing hospital infrastructure and amenities. A proposed schedule was sent to the group members prior to the meeting. This detailed the agenda, which consisted of introductions and the background to the research study; verification of the terms of reference; the proposed intervention design and implementation strategy and any other matters. Members who were unable to attend were given the option to pass any queries or points they wished to raise to the chair, who presented these on their behalf.

4.2.1.1 Group Attendance

Table 15 details the attendance of the group members and additional personnel at the advisory group meeting.

Table 15: Initial Expert Advisory Group Meeting Attendees

Attendants	Representing	Attendance
Group Members	Neonatal (1)	In attendance (Chair)
	Obstetric (1)	Absent
	Midwifery-Substance Misuse Service	Absent
	Midwifery-Postnatal (1)	Absent
	Midwifery-Postnatal (2)	In attendance
	Midwifery-Infant feeding	In attendance
	Lay representative	In attendance
Personnel	Chief researcher (Doctoral student)	In attendance
	Academic supervisor (of doctoral student)	In attendance

4.2.2 Introductions

The group chair opened the meeting by clarifying the current situation, both locally and nationally, regarding opioid dependence in pregnancy and neonatal outcomes. The objective of the joint research studentship between the university and health board was outlined and the background to the project topic given by the doctoral student.

The lay representative asked for the opportunity to introduce herself to the group. She wished to explain her circumstances and reasons for volunteering to be part of the advisory group. She discussed her dependency on substitution medication prior to and during her pregnancy and that she was aware that this put her baby at risk of neonatal withdrawal. She spoke of her experience of opioid dependence and attempts to breastfeed her baby. In the first days in the postnatal ward she felt the midwives were very busy – too busy to give enough time to support her wish to establish breastfeeding. Her baby was admitted to the neonatal unit at a few days of

age and she was told this was due to excessive weight loss. Signs of neonatal withdrawal were present and the baby had problems latching onto the breast. Formula feeding via bottle was introduced at this point, as advised by medical staff. She felt that more practical breastfeeding assistance and support on the postnatal ward would have helped. Although she was unsuccessful in her attempt to establish breastfeeding she bottle fed her baby expressed breast milk for several months. She felt the neonatal unit provided a more positive environment to establish breastfeeding, as it was quieter and calmer. The lay representative also reported that she felt the staff in the neonatal unit had better attitudes towards her as an opioid dependent mother. Overall, she felt that her baby latched on and sucked for longer once in the neonatal unit, although ultimately breastfeeding was not established.

4.2.3 Terms of Reference

The terms of reference, which defined the role and remit of the advisory group, were outlined (Appendix 3). The primary role of an advisory group member was specified as informing the intervention development and implementation by considering the existing local service provisions, facilitators and barriers to breastfeeding continuation for substance dependent women. The group remit included liaising and consulting with the clients or professionals that the member represented and providing access to the community if needed. A function was also to act as an advocate by reporting on the advisory group activities and championing the research project within their sphere of influence. All attending members agreed the group's purpose and conduct.

4.2.4 Discussion

The meeting agenda forwarded the following points for discussion. Firstly, the ideal location to conduct the feasibility study and the type of room most suitable to accommodate the participants. Secondly, the potential facilitators and barriers to implementing the intervention into the current service.

The advisory group reviewed these points and members also proposed recommendations in relation to the research design and outcomes measures.

4.2.4.1 Designated Research Area

The intervention protocol proposed a dedicated intervention versus control area and a designated single room for research participants. The objective was to ensure the fidelity of environmental modifications, maintain confidentiality and limit opportunities for cross-contamination bias.

The feasibility of assigning one postnatal ward as the intervention area and the other ward as the control area was considered. Separating the control and intervention cohorts into different wards should limit the risk of cross-contamination bias between groups (Creswell 2014). Following discussions, the postnatal (2) midwife agreed that this ward could act as either the control or intervention area. A point of note was made to contact the postnatal (1) midwife, who was unable to attend the meeting, and forwarded this proposal for discussion.

The protocol identified a single room as the preferred option for research recruits but concerns were raised regarding possible adverse implications. There are advantages and disadvantages to single room use versus multi-occupancy rooms within health facilities. Institutions cite infection control measures, such as the ability to limit cross contamination, as a main factor in the move towards all single room accommodation in hospitals (Pennington and Isles 2013). Patients report that they sleep better in single rooms as they are less likely to be disturbed by others. Alternatively, some people find single it isolating and lonely (van de Glind *et al.* 2007). Individual rooms provide the environment to discuss confidential or sensitive matters without the fear of being overheard. This has resonance for the substance dependent population and would be advantageous during the feasibility study to enable women to talk openly. A single room also affords a degree of privacy, particularly during the vulnerable and emotionally challenging time of early motherhood. McInnes and Chambers (2008) explored maternal experiences of breastfeeding within the maternity service and found that some mothers considered shared postnatal areas as a source of social support whilst others found them distressing, noisy and unfamiliar.

The group discussion proposed that single room use might limit interaction with other mothers and reduce opportunities for peer support. Peer support is considered beneficial for breastfeeding continuation, with women who discuss experiences with contemporaries gaining confidence and learning to trust their own judgement (Lutter *et al.* 1997; Renfrew *et al.* 2012a). The lay representative acknowledged that multi-bedded areas may enable social support but she was wary of other patients discovering that she was opioid dependent and therefore deliberately avoided contact.

A single room can highlight women as having additional or different needs but the likelihood of whether this identifies this as related to opioid dependent is open to conjecture. Furthermore, existing hospital guidelines recommend that substance dependent mothers are accommodated in a single room, if available, due to potential risk of blood borne virus transmission and therefore they are already at risk of being 'singled-out'. Consideration was given to a dedicated multi-bedded area for opioid dependent mothers and babies. Again, the issue of identification was raised and additionally it was considered relatively unusual to have sufficient women, at one time, to justify a dedicated multi-bedded area. Due to the contradictory opinions expressed, the group consensus was to explore this from the perspective of opioid dependent mothers during the 'think aloud' sessions. A secondary point noted was the importance of highlighting the possibility of single room accommodation during the RCT consent process. As single room occupancy appeared to be a matter of personal preference it was necessary to ensure women were aware of this research condition, enabling their decision regarding participation to be as fully informed as possible.

4.2.4.2 Environmental Modifications

The proposed environmental modifications included reducing external stimuli such as noise, bright light and the level of activity within the immediate patient area. This involved installing blackout blinds for subdued lighting, providing a modified infant cot designed to limit light and noise and putting measures in place to reduce the level of through traffic of hospital personnel. There were concerns regarding the blackout blinds, and how dark the room

would be. It was clarified that the blinds would be in place for use as and when required dependent on day/time/weather conditions.
The logistics of restricting access to the participant's room, to reduce the volume of through traffic of hospital personnel, was discussed. Displaying a 'do not disturb' sign had implications for identification and the possibility of carrying out cluster tasks was another suggestion. It was forwarded that this would impinge on the daily tasks of all staff. The group agreed that this would have the greatest impact on the domestic team and, therefore, recommended that the researcher discuss the needs of the study with the domestic supervisor once the trial was ongoing. This was carried out once the trial was on-going and undertaken on a one-to-one basis to maintain the highest degree of confidentiality.

4.2.4.3 Health Service Personnel

The postnatal (2) midwife enquired whether the research study would affect the existing workload of staff members. Reassurance was given that the appointed dedicated breastfeeding support workers would be fully responsible for intervention delivery. There were concerns voiced as to what, if any, expectations there were of the postnatal staff. Clarification was given that ward staff should assist all those in the study as per routine hospital policies. Indeed, it was emphasised that the existing staff should not alter their normal routines or practices as this has implications for introducing performance bias. Performance bias can occur when participants or practitioners adjust their normal behaviour, whether in the control or intervention arm of a trial, as they are aware that the outcomes of their actions are being observed or recorded (Creswell 2014).

In consideration of these issues it was agreed that staff engagement sessions would be advantageous to provide information of the research aim and address any concerns or questions. Subsequently, informal meetings with postnatal staff were introduced during the recruitment stage of the 'think aloud' sessions and continued during the RCT. Ongoing sessions were considered the most effective due to the high turn-over of staff with students and rotational midwives frequently joining the hospital personnel. The researcher conducted the sessions giving an overview of the research and its

current progress. Within the neonatal unit the study was presented to nursing and medical personnel as part of educational meetings. These sessions actively promoted the study, identified the researcher as a point of contact for queries and aided staff engagement with the aims of the research.

4.2.4.4 Research Design and Implementation Strategy

Several questions were raised regarding the proposed research design and the measured outcomes. The first query concerned the definition of and ability to judge what constituted continued or establishing breastfeeding, as an outcome measure. It is very common to have some degree of mixed feeding during the acute neonatal withdrawal phase due to NAS gastro-intestinal symptoms and increased metabolic demands. Therefore, the use of exclusive breastfeeding as an outcome measure was not a feasible option. The intended measure proposed was to record the proportion of breastfeeding to mixed feeding in the audit form (control arm) and daily log (intervention arm). Additionally, the mother's view of whether she considered breastfeeding was on-going was requested as part of the questionnaire. Collectively, evidence of breast milk given and a maternal statement that she was actively pursuing breastfeeding was acceptable for study purposes.

The neonatal clinician raised the issue that existing protocols use Finnegan Score to determine the severity of NAS. This scoring system is subjective with recognised inconsistencies which may challenge the reliability of measured outcomes. To address this additional outcome measures including neonatal admission and need for pharmacological treatment were used as indicators of NAS severity.

The possibility of providing tailored breastfeeding promotional information in the antenatal period to increase initiation rates was raised. Presently, generic breastfeeding leaflets are available as per standard recommendation for all pregnant women. Discussions on the impact of breast milk on withdrawal symptoms are dependent on the individual consultation between the woman and her midwife. The lay representative highlighted that some women may feel too guilty to breastfeed due to the damage incurred during pregnancy to

the baby, especially if they also smoke or use other drugs. She felt that promoting breastfeeding might exacerbate their feelings of guilt. The benefits of breastfeeding promotion were acknowledged and noted as an area of practice worthy of investigation at a future point. It was not, however, within the remit of this research study.

4.2.5 Group Conclusion

The initial advisory group meeting concluded following discussion of the set agenda and no further questions were forthcoming. Outstanding questions remained over the acceptability of single room accommodation and the recommendation was to explore this further during the 'think aloud' sessions. The meeting was terminated with plans to reconvene a future meeting once the feasibility study was underway.

4.2.6 Second Advisory Group Meeting

The original intention was to convene 2-3 advisory group meetings during the study period, with the second group meeting to be held during the feasibility study. The purpose of this was to discuss the study progress and address any identified barriers. However, it was not possible to hold a second advisory group meeting due to HCP schedules and commitments as a suitable date could not be determined when sufficient group members could attend. Additionally, two original members of the advisory group were no longer directly involved with the substance misuse service. Although an individual meeting was held with the newly-appointed specialist midwife for the substance misuse service clinic, following her appointment to replace her retired colleague. This was to provide an update on the current progress of the study.

During the RCT two incidents occurred regarding the research progress which would ideally have been a matter for advisory group discussion. Problems arose with the process of referral from labour suite, and with the allocation of a single room in the postnatal area. The intended referral process for women admitted to labour suite who had already opted into the study requested that the attending midwife should contact the researcher following

the birth of the baby. This allowed verification of their continued research eligibility, the process of randomisation and arrangements to be made for admission to the appropriate postnatal ward. However, a few referrals did not occur and the admission of these participants to the hospital was only noted several hours later. This resulted in one woman being omitted from the study due to the time delay. A one-to-one meeting between the researcher and the labour ward clinical manager was held to highlight this issue. Thereafter, there was an increased promotion of the research study including dissemination of the referral process through a global e-mail and posters highlighting the researcher contact details. This produced a short-term improvement in the situation.

The second issue involved a ward level decision that the allocation of single rooms for opioid dependent women was not required. This was irrespective of the research study but it compounded the difficulty of securing a single room. This occurred during the absence of the senior midwife, who was a member of the advisory group. This situation was resolved following a meeting with the senior midwife on her return. However, difficulties were ongoing with the allocation of a single room and on consideration it would have been beneficial to discuss this issue with the advisory group to ascertain if there were ways of overcoming this. It could be speculated that a group meeting, attended by several clinical leads, may have resulted in a more in-depth review of this situation. Perhaps determining a permanent, or more practical, solution for the on-going difficulty of single room availability.

On reflection, it was felt that the omission of continued advisory group meetings disadvantaged the study. Group meetings would have provided the opportunity to discuss the challenges encountered. Conversely, although it was not feasible to convene a collective meeting, group members were contacted individually for advice regarding difficulties related to their sphere of influence. Subsequently, the problems which arose during the study were contemporaneously discussed with the relevant group member. It could be argued that this approach resulted in a timelier resolution of issues.

4.2.7 Implications for Intervention Development

The expert advisory group discussed the provision of a designated research area and suggestions were forwarded regarding personnel engagement. Recommendations were also proposed for future versions of the study and improved service provision. Collectively the recommendations covered three topics including the research area; staff engagement and research design.

RESEARCH AREA

- Designated postnatal area for intervention group and separate postnatal ward for control group
- Further consideration needed regarding single room allocation

STAFF ENGAGEMENT

- To hold one-to-one meetings with staff regarding the use of cluster care for intervention group
- To conduct staff engagement sessions regarding the research ethos and expectations of existing staff during research period

RESEARCH DESIGN (Current and Future)

- Explore the perspective of service users on provision of single rooms during 'think aloud' sessions
- Ensure potential allocation of single room is mentioned during consent process for RCT recruitment
- Substance dependence specific breastfeeding promotional activities in antenatal period
- Audit reliability of Finnegan Score as an assessment tool
- Regular advisory group meetings during future trials

4.3 'Think Aloud' Verbal Protocols

The 'think aloud' method used pictorial representations of the proposed support components as prompts. The participants were encouraged to verbalise their thoughts regarding their perceptions of the efficacy and acceptability of the proposed support elements. The components were breastfeeding support elements informed by the literature review findings, advisory group recommendations and good practice guidelines for the care of infants at risk of NAS (DoH 2007; Jansson 2009; Hudak and Tan 2012). The pictures symbolised practical; informational; psychological; person-centred and environmental components of support

PRACTICAL COMPONENT: this component was represented by a healthcare worker supporting a mother to breastfeed. It was explained to participants that a dedicated support worker would be assigned to the individual mother/infant dyad and continuity of care-giver would be maintained.

INFORMATIONAL COMPONENT: this component was represented by a sign with ‘any questions?’

PSYCHOLOGICAL COMPONENT: this concept was very difficult to depict in pictorial form. A picture of a sign pointing to ‘advice’, ‘assistance’, ‘guidance’ and ‘support’ and ‘tips’ was eventually used during the sessions.

PERSON-CENTRED COMPONENT: this was represented by ‘one2one’ symbol to demonstrate it was individualised care structured around the personal needs of the mother and baby.

ENVIRONMENTAL COMPONENT: this was represented by a picture of a modified cot including blackout cover and containment bumpers. The concept of consolation techniques was represented by a swaddled baby and ‘do-not-disturb’ sign.

In addition, participants were asked their opinion of the questionnaire. The purpose of this was two-fold. It provided a review of the content, length and format of the questionnaire design. This was particularly important in a population group where there is the potential of limited literacy and heightened sensitivity. Secondly, participants were given the opportunity to forward suggestions or ideas not previously discussed based on the questionnaire questions.

4.3.1 Recruitment Outcomes

Recruitment for the 'think aloud' sessions was carried out over a 5-month period from November 2013 to March 2014. The gatekeepers identified seven possible candidates during this time period. One mother declined to participate and subsequently six women were recruited onto the study. Table 16 details the recruitment process.

Table 16: 'Think Aloud' Recruitment

Location	Approached	Declined	Accepted
Postnatal	3	0	3
Substance Misuse Service clinic	1	0	1
Neonatal	3	1	2
Total	7	1	6

Table 17 details maternal and neonatal socio-demographic characteristics. Of the six participants, all were Caucasian and the majority (n=5) were in a stable relationship; one was a single mother; all were enrolled on a substitution medication programme prior to pregnancy with five maintained on methadone and one on buprenorphine. The aim of the research was to gain the recommendations of women with a diverse variety of infant feeding experiences. This was achieved as the cohort contained a mix of women with previous experience of breastfeeding an infant at risk of NAS; two first time mothers and those who had previously breastfed but had not been opioid dependent at the time. Additionally, three respondents were establishing breastfeeding in the initial postnatal period (within 1-week post birth) whilst two mothers were 3-weeks and 4-months post birth respectively. Breastfeeding status differed as two women were exclusively breastfeeding, two were mix feeding, one was expressing breast milk to give by bottle and one had discontinued breastfeeding.

Table 17: Maternal and Neonatal Socio-demographics and Outcomes

Maternal Characteristic and outcome	Number
Age range	
<20 years	1
20 – 30 years	2
>30 years	3
Parity	
- Primiparous	2
- Parous	4
Previous Breastfeeding experience	
- Yes	2
- No	4
Birth Outcome	
- Spontaneous vaginal birth	3
- Instrumental birth	2
- Caesarean Section	1
Neonatal Characteristic and Outcomes	
Gestational age range	
<37 weeks	1
>37 weeks	5
Gender	
- Male	2
- Female	4
Neonatal Unit Admission	
- Yes	2
- No	4

4.3.2 Socio-Demographic Variables and Infant Feeding Method

Socio-demographic factors are known determinants of breastfeeding initiation and continuation (Renfrew *et al.* 2012a). These include ethnicity; socio-economic status; educational attainment; maternal age and previous breastfeeding experiences.

The differences in these demographics between participants are detailed to give a fuller picture of the socio-cultural and competing influences at play

during the 'think aloud' sessions. There was little if any variation in relation to ethnicity, educational attainment and socio-economic status between recruits. One teenage mother was recruited to the study, and it has been demonstrated that it is less common for younger women to initiate and continue breastfeeding (McAndrews *et al.* 2012). The remaining modifying demographic factor is that of previous breastfeeding experience. Previous breastfeeding outcomes, whether positive or negative, are a significant influence on the infant feeding decisions of subsequent pregnancies (Entwistle 2013). Women tend to form patterns of behaviour gained from their experiences with their first child (Dykes and Flacking 2010). Those who have successfully breastfed their child for six weeks or longer are more likely to initiate breastfeeding in following pregnancies (McAndrews *et al.* 2012). Women who discontinue breastfeeding prior to six weeks have lower rates of initiation than those with previous positive feeding experiences. First time mothers have the highest rates of breastfeeding initiation, suggesting previous infant feeding experience influence parous women in their subsequent pregnancies. In summary, previous breastfeeding success encourages mothers to initiate feeding in subsequent children and negative outcomes make some women reluctant to attempt breastfeeding in the future.

Amongst the 'think aloud' participants two were first time mothers and two had previous children but had not initiated breastfeeding. Both women explained their reason for formula feed previously was due to age as they had been teenagers at the time and it was not 'the done thing' to breastfeed. The remaining two mothers who had breastfed previously had, in general, positive experiences. One mother had successfully breastfed but had not been opioid dependent at the time. The other mother had breastfed two children before using addictive substances, and with her third child had initiated breastfeeding but was unable to establish lactation due to neonatal withdrawal. Consequently, she discontinued breastfeeding in the first week. The variability of breastfeeding experience presented the context to elicit a comprehensive range of views during the sessions.

4.3.3 'Think Aloud' Analysis

The effectiveness of the 'think aloud' approach varied between participants with one mother engaging fully in the process whilst others had to be prompted to continue to think aloud. Two mothers felt inhibited or unable to master the technique and offered a narrative report of their experience of breastfeeding and supportive practices. It was found that some respondents discussed certain aspects of breastfeeding support in connection with one picture whilst another raised the same or a similar point but associated it with a different component. This could be reflective of the interconnected nature of breastfeeding influences or, conversely it may suggest that the pictorial representations were too ambiguous. The maternal responses to the pictorial representations varied with their personal history of breastfeeding and support needs, as would be expected, however, this enabled the generation of a diverse mix of opinions. The following recommendations were forwarded during the 'think aloud' sessions.

Practical Component

"Would be good for some but I didn't need help"

This component represented the provision of a dedicated support worker who was available for a set period (1 hour) daily (5 days) to offer practical breastfeeding guidance and facilitate maternal technical skills.

All the participants considered practical assistance and advice as an essential element of breastfeeding support. Opinions did vary as to the level of support required, and this was very much dependent on previous experience. The two primaparous women considered practical support as especially important for mothers who had not breastfed before:

> "Being a first time mum it would have been useful to have help"
>
> *(Trudy: discontinued breastfeeding on 4th day).*

Those with previous breastfeeding experience demonstrated a greater level of self-belief in their ability to pre-empt and negotiate feeding challenges.

One participant who had successfully breastfed her other children identified previous experience as the reason for her level of confidence and presumed ability. Subsequently, she felt that practical assistance was not a major requirement in terms of breastfeeding support:

> "Didn't need help, fed my others"
> *(Aileen: 18 days mixed feeding).*

One respondent spoke of her confidence to establish breastfeeding but she would have welcomed the option of someone being available should a need arise:

> "Would have been handy to have some-one, you know, just in case?"
> (*Diane: 5 days exclusive breastfeeding).*

The inclusion of a dedicated breastfeeding supporter was seen as a positive component of the breastfeeding intervention. This was associated with maternal perceptions of the availability of staff. Indeed, the participants mentioned that the level of breastfeeding support they received or asked for was conditional on how busy the healthcare professionals appeared:

> "you don't want to bother them"
> (*Diane:5 days exclusive breastfeeding)*.

For others the problem and solution was simply expressed, they wanted:

> " not to have them rush off"
> (*Pam: 5 days exclusive breastfeeding).*

A recurrent theme noted throughout the sessions was a reluctance amongst the women to ask for help or advice, as they did not want to appear "demanding" (Wilma). Several of the mothers gave the impression, in their demeanour and through non-verbal signs that they undervalued themselves. This accompanied a poor regard for their own support needs and it was intimated that other mothers took precedence:

> "Don't want to bother them (midwives), other people need help"

(Fiona: 3 days mixed feeding).

A dedicated supporter with knowledge of opioid dependence and Neonatal Abstinence Syndrome was a source of information. Amongst the respondents, there was a noted lack of understanding of the additional breastfeeding difficulties experienced by infants suffering from withdrawal symptoms. One mother commented on her surprise that initially she found that (she) "can't latch him on" (Aileen). Many the participants were unaware that an infant at risk of neonatal withdrawal can have an uncoordinated feeding pattern and that technical adaptations to breastfeeding technique are required. Several mothers commented that they would have liked to have been informed of the possible feeding difficulties and would, therefore, have been better prepared. One mother summed up the feeling expressed by the others:

"Need to be told about this before"
(Diane: 5 days exclusive breastfeeding).

Overall, all the mothers felt that practical assistance and the availability of a dedicated breastfeeding supporter would be beneficial, even if they had not personally required assistance. There was a consensus that a dedicated HCP proactively inquiring about both maternal and infant support needs would offer reassurance.

Informational Component

"No-one told me"

This component of the support intervention represented both the availability and accessibility of information. It was proposed that the support worker would be available to offer advice on the normal physiology of breastfeeding and the effects of opioid dependence and withdrawal on breastfeeding. However, several participants discussed the breastfeeding process in relation to the pictorial representation of the breastfeeding supporter. Additionally, some mothers forwarded issues of poor communication encountered with professionals in relation to information provision.

In response to the usefulness of this component, most participants touched on their lack of awareness of the impact of opioid dependence on the normal pattern of breastfeeding. One mother commented that:

> "Don't know if he has had a proper feed yet"
> (*Trudy: discontinued breastfeeding on 4th day).*

Many participants had a limited understanding of the adverse implications of withdrawal symptoms on the infant's feeding ability. One mother noted:

> "Didn't know if it was normal"
> (*Aileen: 18 days mixed feeding*).

This was compounded by inadequate information both in preparation for the challenges of motherhood and guidance after the birth of the baby. Most participants noted that they would have liked more information specifically related to opioid dependence and the implications for the baby:

> "No-one tells you about the effects of the meth."
> (*Pam: 5 days exclusive breastfeeding).*

One mother discussed her experience of being given inaccurate advice in a previous pregnancy- that she could not mix breastfeeding and bottle feeding. This was not clarified during the current pregnancy and therefore she discontinued breastfeeding. She reported:

> "I thought I had to stop breastfeeding as he would be confused if given breast and bottle"
> (A*ileen: 18 days mixed feeding*).

She also felt that she could not seek advice nor did practitioners offer it when she mentioned her intention to formula feed. Several days later she was informed that this information was incorrect. Following this episode, she expressed breast milk but was unable to establish breastfeeding. She felt

that if a dedicated supporter were available there would be the opportunity to address questions relevant to personal breastfeeding needs:

> "It would have been good to have someone to ask"
> (*Aileen: 18 days mixed feeding*).

While considering the inclusion of an informational component there were various reasons forwarded regarding existing barriers. This included information being given via an inappropriate or inaccessible method. Several respondents touched on the negative impact of conflicting advice. One mother discussed the impact of substitution medication and its effect on both concentration and ability to retain information:

> "Sometimes you feel sleepy and you need things repeated"
> (*Fiona: 3 days mixed feeding*).

She felt uncomfortable asking the same questions repeatedly and the chance to get to know the worker over the course of the trial period would have reduced her inhibition. Several participants mentioned a noted reluctance amongst some staff to discuss opioid dependence with their queries redirected to other professional groups. Subsequently the information they required was not forthcoming or the situation had progressed beyond the original issue.

Two infants experienced severe withdrawal symptoms requiring neonatal admission. Both mothers felt they were inadequately prepared and had they been advised on precautions this may have prevented the withdrawal symptoms escalating. All the participants mentioned that professionals, "talk about weight loss", but this was neither explained in the context of abstinence syndrome nor why this was connected to the infant's feeding pattern. The focus on weight loss negatively influenced maternal perceptions of successful breastfeeding.

Overwhelmingly, opioid dependent mothers expressed negative experiences regarding the information, or lack of it, they were given. During the sessions, all participants said "no-one told me", at some juncture in relation to

decisions they had made. One mother commented that the lack of help and information demoralised her to such an extent that she decided:

"It just seemed easier to give a bottle"
(*Trudy: discontinued breastfeeding on 4th day)*

Overall, the importance of accurate, timely and accessible information was highlighted as an essential component of supportive breastfeeding practice.

Psychological Component

"Need encouragement"

This component relates to psychological influences on breastfeeding continuation, such as self-efficacy levels and strategies used to promote this including encouragement, reassurance and positive reinforcement. Some of the comments made in response to psychological support needs were interlinked to aspects of person-centred support.

The verbal protocols highlighted a range of psychological factors which were identified as influential in the emotional support required to sustain breastfeeding. These related to perceived breastfeeding ability, the consequences of maternal opioid dependence on the infant's well-being and maternal feelings of responsibility. Women varied in the levels of self-efficacy displayed, but several mothers felt that regardless of perceived confidence in their ability it was encouraging to have a professional both acknowledge and

praise their commitment. There was an identified need for motivation and positive reassurance to persevere with the challenges of breastfeeding:

> (You) "Need encouragement"
> (*Pam: 5 days exclusive breastfeeding*).

The participants discussed fluctuations in their emotional state, which affected their view of their self-worth and subsequently impacted on their resilience to continue breastfeeding. One mother expressed her feelings as "you feel defeated" (Fiona) and went on to talk of her reluctance to ask for practical or emotional support as she felt ashamed and worried that she would be blamed for her baby's condition. Many the mothers expressed guilt that their baby experienced withdrawal symptoms due to their lifestyle choices, with comments such as:

> "It's my fault he is like this"
> (*Fiona: 3 days mixed feeding*).

Furthermore, participants expressed the need for others to understand their emotional turmoil, vulnerability and responsibility they felt that their actions had directly contributed to the baby's distress. The respondents spoke of the importance of feeling comfortable with the support worker to be able to fully accept their advice and trust their guidance. Although one mother admitted she was perhaps "over sensitive" (Wilma), with her expectation of being criticised leading to her misinterpreting comments and actions. Throughout the sessions mothers referred to a general lack of awareness as "no-one understands" which subsequently increased feelings of isolation and a reluctance to ask for assistance.

Person-Centred Component

"I would hate to be seen as a 'druggie'"

The person-centred component of the intervention related to meeting the individual needs of the mother and infant dyad. This included addressing challenges exclusive to opioid dependence and abstinence syndrome. An overwhelming concern for all the respondents was the possibility that their baby would be transferred to the neonatal unit for abstinence syndrome management. Several mothers commented on this, with the general sentiment:

> "I worry he will be taken to the baby unit"
> (*Pam: 5 days exclusive breastfeeding*).

Maternal and infant separation was considered a major impediment to breastfeeding both practically and psychologically. Subsequently, the participants associated the main role of breastfeeding support as a means of preventing separation.

There were some concerns voiced in relation to the way mothers were perceived due to their history of substance dependency. This encompassed the issue of respect and the right to be seen and treated as an individual, not defined by circumstances or stereotype. One mother spoke at length about her concerns of being judged or stigmatised, stating:

> "I would hate to be seen as a 'druggie'"
> *(Diane: 5 days exclusive breastfeeding).*

Environmental Component

"She settled once she was swaddled"

It was apparent that the participants were not universally informed of all the recommended measures of supportive management. Additionally, knowledge of the range and function of supportive practices differed between respondents. Neither did it appear that these measures were consistently applied across the hospital setting. One mother explained that she was

aware of supportive techniques as she made a point of accessing information during pregnancy:

> "Read about this myself"
> (*Wilma: 4 months breastfeeding /EBM)*.

However, she went on to say that she had not seen the techniques applied by healthcare professionals or been advised of their use. Furthermore, she was allocated to a multi-bedded area and therefore she was limited in the modifications she could make.

The impact of external stimuli was demonstrated by one observation that the infant:

> "Was jumpy when it was noisy"
> (*Trudy: discontinued breastfeeding 4th day*).

This mother, however, was unaware that this was a sign of withdrawal which could be alleviated by minimising the source of stimulation.

Collectively, the women who used consolation techniques considered these as constructive elements of breastfeeding support as they were judged as beneficial in reducing neonatal agitation:

> "She settled once she was swaddled"
> (*Aileen: 18 days mixed feeding*)

One concern raised about environmental modifications was the potential that these could identify the mothers and babies as opioid dependent and lead to stigmatisation. Many participants did not consider this as an issue, however, with one respondent noting:

> "Would not single you out- everyone is looking out for their own baby"
> (*Trudy: discontinued breastfeeding 4th day*).

It was felt that although strategies would indicate that the mother or child required additional medical attention it would not necessarily identify them as substance exposed. As one mother commented:

"Everyone in hospital has problems of some kind – or they go straight home"
(*Pam: 5 days exclusive breastfeeding*).

Although it is recommended that infants at risk of withdrawal should be accommodated in a quiet environment this was not always practiced. There were mixed opinions regarding the allocation of a single room as part of the intervention. Some women felt a single room may be isolating and one reported that it:

"Feels like you have been put out of the way"
(*Pam: 5 days exclusive breastfeeding*).

The potential to gain peer support from other mothers was not seen as an obstacle if allocated a single room, as reported by one mother:

"I haven't spoken to the other mothers."
(*Diane: 5 days exclusive breastfeeding).*

Others considered the perceived benefits of reduced stimuli to the baby outweighed the possible barriers that may accompany the environmental modifications.

4.3.4 Key Findings

The verbal protocol analysis generated a diverse and complex range of views on the usefulness and acceptability of the support elements. Contradictory recommendations were expressed regarding some components, underlining the individualistic nature of both breastfeeding behaviour and the expression of neonatal withdrawal. A general consensus was achieved, however, on the applicability of several components as support elements, most of these mirroring the findings of the comprehensive systematic literature review. The key findings suggested that enhancing practice and knowledge of the breastfeeding process, psychological support and adopting a person-centred approach would be beneficial to support breastfeeding continuation. The proviso to this being that the acceptability of the support strategies was dependent on their appropriate use, in respect of the individual needs of the

mother and their relevance to opioid dependence. Awareness of the benefits of a low stimuli environment varied, but those who had used these considered the environmental modifications and consolation techniques effective.

All respondents considered practical assistance and information as essential intervention components. It was acknowledged that individual needs would vary, but the availability of a dedicated supporter, should this be required, was considered as a useful safeguard and provided a source of reassurance. This was associated with perceptions of the limited availability of HCP. There was a general lack of awareness of the consequences of neonatal withdrawal on infant feeding ability and this was compounded by minimal knowledge of alleviating measures. Several mothers noted they were surprised to encounter feeding difficulties and felt they should have been forewarned of this possibility.

The appropriateness and accessibility of information was an issue. The participants spoke of the need for the relevant facts on NAS but had experienced staff reluctance to discuss this coupled with instances of poor communication. This was further compounded by the impact of substitution medication on maternal understanding and retention, which was seldom considered during conversations. The importance of accurate, timely and accessible information was highlighted as an essential intervention function. Overall, a dedicated supporter with knowledge of opioid dependence and neonatal abstinence syndrome was considered as a source of practical assistance and information.

The 'think aloud' protocols identified psychological factors as influential in breastfeeding support with perceived breastfeeding ability, maternal guilt and feelings of responsibility impacting on self-efficacy levels. There was an expressed need for encouragement to sustain breastfeeding intention. The negative impact of judgemental attitudes and stereotyping was forwarded and, correspondingly, that respectful interactions increased maternal receptiveness to advice. This was associated with a heightened need for emotional support in response to the vulnerabilities experienced by opioid dependent mothers.

A person-centred approach to support was suggested as a potential intervention function, to both identify and address individual needs and

provide management options specific to substance exposure. The lack of open, honest and realistic dialogue regarding opioid dependence was mentioned by the respondents and also the importance of culturally relevant practices to enhance maternal receptiveness to support practices.
The aim of the environmental component was to provide practical modifications, additional resources of consolation equipment and to equip the mother with the ability to appropriately manage external stimuli to alleviate neonatal withdrawal symptoms. Many of the respondents were unaware of the range of supportive practices or they did not have a comprehensive knowledge of them. The possibility of environmental modifications singling-out women and babies as having additional support needs, not necessarily identify them as opioid dependent, was touched upon but the respondents felt that the perceived benefits to the baby outweighed this. Overall, the inclusion of an environmental component in the intervention was endorsed by the respondents. A key concern, and an overwhelming possibility, was prolonged hospitalisation of, and separation from, the baby due to withdrawal treatment and support for breastfeeding was welcomed by the women as a means of tackling this.

4.3.5 Strengths and Limitations

A strength of the 'think aloud' process was the accessibility and acceptability of this method to the target group. The challenge of poor research engagement amongst the substance dependent population previously forwarded was not encountered in this instance; indeed, there was an 86% acceptance rate. It appeared that the informality of the approach was a suitable medium to overcome the issues that can discourage participation. The 'think aloud' method was particularly suitable for use in this context as the process overcomes some of the inherent barriers to research engagement experienced by this group. However, the use of pictures to represent different concepts of breastfeeding support was both a strength and a limitation of the verbal protocol procedure. For some, considering a picture allowed them free expression of thoughts and views as they did not feel constrained by a set agenda, which may occur with pre-defined questions. Conversely, others struggled with the idea that pictures could

represent different facets of breastfeeding support. A pictorial concept requires a level of shared understanding and when this was not achieved some replies lacked relevance.

Not all the participants engaged in the 'think aloud' process and alternatively they offered a narrative of their breastfeeding experience and support needs. Although this could be considered a limitation of the methodology it still resulted in the fulfilment of the research objectives.

The decision not to use recording equipment during the 'think aloud' sessions was challenging in terms of ensuring that verbal fragments were not accidently omitted. However, this situation resulted in a more intimate and relaxed environment which was conducive to put the participants at ease. It enabled the women to talk openly about their drug use and experience of childbirth which are deeply personal and sensitive issues.

4.3.6 Implications for Intervention Development

The 'think aloud' recommendations highlighted the need for practical and informational assistance, psychological support and a person-centred approach which focussed specifically on the implications of substance exposure on breastfeeding outcomes. Additionally, environmental measures were considered as an essential component of the support model due to their targeted action to alleviate neonatal withdrawal.

The recommendations from the 'think aloud' protocols for intervention development were as follows:

<u>PRACTICAL and INFORMATIONAL</u>

- Practical assistance should be dictated by the existing level of maternal technical expertise and responsive to tailored feeding objectives
- Assess awareness of normal process of breastfeeding, provide accessible information and clarify maternal understanding

PSYCHOLOGICAL

- Psychological support acknowledging and empathetic of maternal feelings of guilt and responsibility and responsive to heightened maternal vulnerability
- Foster a facilitative and therapeutic relationship, eliminate judgemental or recriminatory attitudes, adopt respectful approach

PERSON-CENTRED

- Equip mothers to recognise and respond appropriately to the internalised/externalised signs of neonatal withdrawal
- Support practices responsive to the pathophysiological implications of substance use and opioid dependence
- Open, honest informed dialogue on addictive substance use and opioid dependence

ENVIRONMENTAL

- Provision and fidelity of environmental modifications
- Provision of consolation equipment and instruction on appropriate use of techniques

4.4 Chapter Summary

Phase 1 adopted a mixed method approach resulting in a comprehensive and wide ranging exploration of the factors influencing breastfeeding continuation in the context of substance dependence. The cumulative evidence provided the basis to derive the determinants, and the facilitators and barriers moderating breastfeeding behaviour. These findings were originally analysed using methodological approaches specific to their design and to maintain integrity of these processes the findings were brought together and where similarities existed integrated. The synthesis resulted in 5 amalgamated behaviour determinants suggesting that breastfeeding behaviour, perceptions and support needs are influenced by a complex and interdependent relationship between practical, psychological, information, person-centred and environmental factors. These are detailed in Table 18.

Table 18: Phase 1 Evidence Synthesis: Behaviour Determinant and Intervention Functions.

Behaviour Determinant	Synthesised Findings	Enablers	Barriers
Practical Aspects	Facilitate maternal practical skill and technical ability to breastfeed infant with NAS.	Enable technical expertise and perceptions of practical mastery Available and accessible practical assistance/practitioner	Limited technical ability Lack of awareness of impact of NAS on breastfeeding ability Prescriptive practices /conflicting practices
Knowledge Informational Aspects	Knowledge of NAS and impact on breastfeeding Knowledge of supportive management Awareness of the normal physiological process of breastfeeding	Provision of information on NAS and consolation techniques Provision of information on breastfeeding Confirm maternal awareness and understanding	Lack of knowledge of NAS Lack of knowledge of breastfeeding Conflicting advice Myths and misconceptions of breastfeeding
Psychological Influences	Psychological factors influencing perceptions of capability Influence of psychological /emotional support to enhance constructs of self-efficacy Influence of encouragement to reinforce breastfeeding commitment	Establish facilitative, therapeutic relationship Respectful approach Provide encouragement and reinforcement (enhance self-efficacy)	Heightened emotional vulnerability Feelings of guilt and responsibility Impact of physiological status on perceptions of self-efficacy
Person-centred Approach	Individualised support tailored for socio-cultural and physical context of opioid dependence Person-centred approach and relevancy of support practices	Individualised aims/objectives Tailored support practices Respect previous experience and knowledge Socio-culturally relevant support Open, informed dialogue	Judgemental or recriminatory attitudes Prescriptive practices Pathophysiological impact of substance misuse disorder and substitution medication
Environment and Resources	Environment modifications and consolation equipment to enable NAS supportive management Provision of additional breastfeeding support	Fidelity of environmental modifications Provision of consolation equipment Provision of intervention support worker	Inability to maintain suitable /low stimuli environment
Implementation strategy	Staff engagement	Cluster care Engagement sessions	Inability to maintain low stimuli environment

CHAPTER 5
Intervention Development and Implementation Strategy

5.0 Introduction

This chapter describes the development process for the intervention. An integration framework was used to operationalise the approach of linking the evidence generated in Phase 1 to intervention functions and underpinning these with the associated theoretical constructs of behaviour change. The chapter concludes by outlining the practical application of the intervention and implementation strategy in preparation for feasibility testing.

5.1 Theory/Evidence Integration

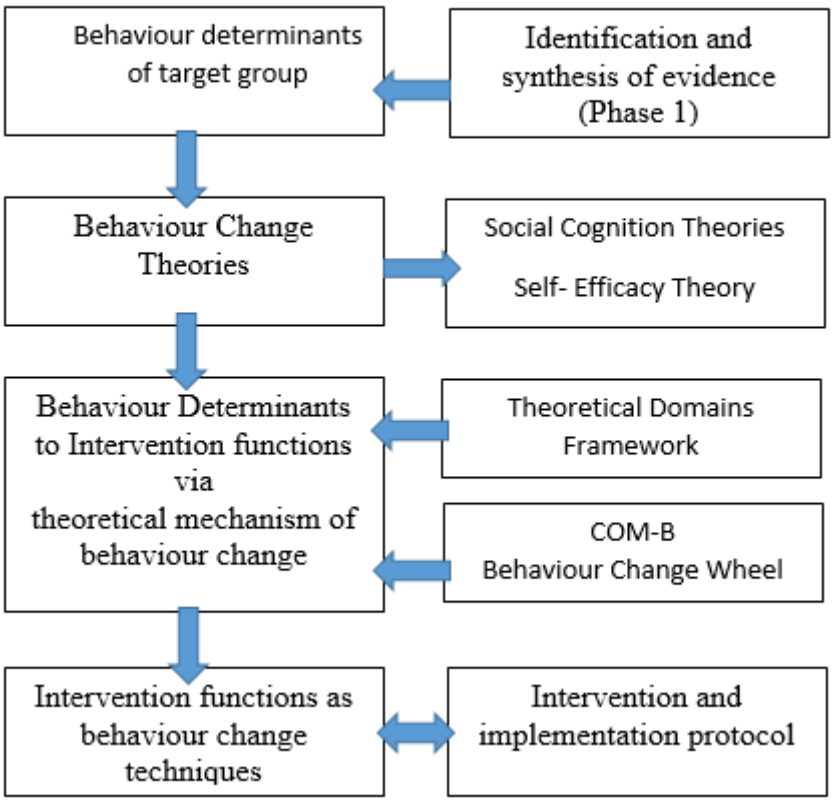
The study adopted the MRC framework for evidence and theory integration (MRC 2008). This model is designed to focus on the development needs of complex healthcare interventions, therefore it aligns with the research aim. The framework was devised through the consensus opinion of clinical experts in medical research, thus supporting its relevance for this study and lending credence to its robust nature (Campbell *et al.* 2007). It recommends a stepwise integration process which aims to optimise efficacy, assessment and future replicability of interventions (MRC 2010). The systematic, explicit and practical approach outlined by the framework also facilitates ease of use and understanding for the novice and experienced researcher alike.

The integration process steps:

1. Utilise a mixed methodology approach to generate evidence on the target behaviour, the key determinants, clinical setting and population groups involved
2. Review the applicability of existing theoretical models/theories to the characteristics and determinants of the target behaviour, population and setting
3. Align behaviour determinants to behaviour change techniques using either theoretically derived mechanism of change or proven efficacy demonstrated in empirical research
4. Develop intervention by characterising behaviour change techniques as practical components applicable to a clinical setting. Represent the integration of evidence and theory through a conceptual model.

Figure 8 depicts the integration process as applied to the context of this study.

Figure 8: Integration Framework



5.2 Key Determinants of Target Behaviour

Behaviour determinants are factors which influence decision-making and comprise of barriers, enablers and moderators. These exist both internally and externally to the individual (Thompson and Dowding 2009). Internal influences are categorised as psychological variables specific to the individual, whilst external influences are the prevailing environmental conditions (Kok 2014).

Internal influences are psychological entities such as beliefs, values, emotions, perceptions or concepts (Peters 2014). The nature of an internal influence is concise and distinct to a given situation. They are unique to the individual and are not overtly explicit but are explored by gathering evidence on behaviour traits through observation and narratives. Assumptions are made as to the nature of the beliefs held and their relationship with external influences (Michie *et al.* 2008a).

External influences are the moderators to a course of action or behaviour choice, and these arise from the prevailing environmental conditions (Peters 2014). External influences exist at multiple levels from individual resources, community or societal boundaries to global policies (Bartholomew *et al.* 2011). The strength of the influence upon behaviour is bound by either the actual or perceived degree of control that an individual feels they have to alter the external conditions (Michie *et al*. 2014). Concurrently, the strength of the association between an internal belief and the contextual conditions also affects the level of influence exerted on the decision-making process (De Bruin *et al.* 2009). Therefore, strongly held beliefs can be difficult to change whilst weak or irrelevant associations between influences can be susceptible to behaviour change techniques (Kok *et al*. 2015).

Phase 1 findings provided the basis from which to derive assumptions of the behaviour determinants influencing breastfeeding continuation for the substance exposed mother. The synthesis of Phase 1 evidence resulted in 5 overarching behaviour determinants which are described in Table 19.

Table 19: Behaviour Determinants

Behaviour Determinant	Synthesis of Evidence
Practical aspects	There was a need for breastfeeding assistance and advice on strategies to minimise the feeding difficulties inherent of NAS.
	Breastfeeding difficulties undermined maternal confidence and self-efficacy, in both first time and experienced mothers.
	Perceptions of capability to achieve practical breastfeeding mastery weigh decisions regarding continuation.
Knowledge /informational aspects	There was lack of knowledge of the implication of exposure to addictive substances on breastfeeding ability and the supportive strategies available to minimise these.
	Poor communication of information, inaccessible or conflicting advice undermined maternal confidence and ability to make informed decisions.
Psychological influences	Self-efficacy levels were influenced by breastfeeding difficulties.
	Poor perception of self-worth and expectation of failure associated with substance dependence resulted in an enhanced need for motivation and encouragement to reinforce breastfeeding intention.
	Feelings of guilt and responsibility heightened the need for a sensitive and supportive approach.
	Maternal physiological and emotional well-being was compromised due to substitution medication/long term effects of substance use disorder.
	Decisions were influenced by perception of whether breastfeeding success was achievable and this was reinforced by actions of others.
Person-centred approach	Opioid dependence presents unique barriers to breastfeeding requiring a person-centred approach and targeted support.
	Increased vulnerability to judgemental or recriminatory attitudes and behaviours and, subsequently, sensitive, open and honest approach more likely to engage receptiveness.
	Decisions informed by relevance of support to meet personalised needs.
Environment and Resources	Provision of environmental modifications and consolation equipment to minimise external stimuli and the resulting adverse impact of this on neonatal withdrawal symptoms and breastfeeding ability.
	Provision of additional and tailored breastfeeding support required to overcome challenges associated with substance exposure.
	Available resources and environment inform decisions on whether behaviour change achievable and on maternal perceived degree of control.

5.3 Behaviour Change Theory

The integration framework proposed a review of existing behaviour change theories to assess their applicability in respect of the target behaviour, population and setting. Behaviour change theories are models which hypothesise an association between the attitudes and determinants governing individual decision-making. Their aim being to advance an understanding of how and why a course of action is taken and under which circumstances (Maio and Haddock 2009; Davidoff *et al.* 2015). From an intervention development perspective, a behaviour change theory promotes an understanding of the underlying mechanism of change (Michie *et al.* 2008b). This affords the researcher the opportunity to identify behaviour change techniques that specifically impact on the change mechanism of the target behaviour (Dixon and Johnstone 2010).

With an awareness of the determinants of the target behaviour, an applicable behavioural theory, one that conceptualises a relationship between the determinants and either the behaviour techniques or the change process, can be identified. Maio and Haddock (2009) note that some theories include the behaviour change techniques associated with the change mechanisms. Although Gardner *et al.* (2010) frame this position from the opposing view that behaviour change theories rarely specify which techniques should be used to change behaviour. If both the theoretical constructs and the respective change techniques are defined within a theoretical model this simplifies the intervention development process. Alternatively, previous research may indicate behaviour change techniques with demonstrated efficacy in relation to the same or similar behaviour determinants as the target population and phenomenon. Adopting this approach is less than ideal, however, as the mechanism of change is not explicit and subsequently, there is a limited understanding of how and why the intervention performed as it did, thus restricting accurate replication in other contexts (Wells *et al*. 2012). Conversely, given the nature of internal beliefs as unexplained in any behaviour and only assumed, if the targeted behaviour change has been observed in previous research it is considered within the medical literature as sufficient justification for its inclusion in similar circumstances (MRC 2008). Social Cognition Theories have been applied previously to develop or assess breastfeeding support interventions with the use of the Theory of Planned

Behaviour and Self- Efficacy Theory, discussed in the literature review (Chapter 2) (Dennis 1999; Nichols *et al.* 2009; McMillan *et al.* 2009b; Lawton *et al.* 2012). These theories have shown efficacy in predicting or explaining breastfeeding behaviour but their use in opioid dependence is untested. Additionally, in isolation neither theory comprehensively address all the contextual behaviour determinants identified and this is in keeping with the current consensus that a single theory may be insufficient to underpin the complexities and unpredictability of human behaviour (Hagger and Luszcynska 2014; Kok 2014).

In respect of the applicability of the TPB to the current study its relevance was felt to be limited. TPB is primarily a predictive model and Hardeman *et al.* (2002) concluded that there is insufficient evidence to draw robust conclusions on its usefulness for intervention development. Indeed, the underlying principles of this theory are currently being challenged for their accuracy to predict behaviour (Sniehotta *et al.* 2014). The empirical evidence associated with TPB does, however, demonstrate a relationship between intention and reinforcement to sustain behaviour change (Swanson and Power 2005; McMillan *et al.* 2008) but this is countered by the absence of theoretically derived behavioural techniques to strengthen the association between intention and motivation (Sniehotta *et al.* 2014). The use of reinforcement is, however, theoretically implicated in Self-Efficacy Theory. On consideration, given the contradictory views of the suitability of TPB to inform intervention development and its overlapping constructs with Self-Efficacy Theory, it was determined that the use of the TPB was not applicable or necessary to inform the current study.

There is a distinct correlation between self- efficacy levels and sustained breastfeeding in empirical literature and theoretically a causative association with behaviour change techniques (Bandura 1997). However, the theory of self-efficacy did not sufficiently address the influence of the behaviour determinants unique to substance dependence. Thus, whilst the constructs of self-efficacy theory were considered applicable to breastfeeding behaviour in general, it was necessary to supplement these with additional behaviour change techniques. These techniques required to be specific to and theoretically derived from the evidence generated in Phase 1, to maximise

the intervention potential to comprehensively address all the key behaviour determinants.

5.4 Process of Evidence and Theory Integration

The study adopted the process of evidence and theory integration using a programme of research undertaken by Michie and colleagues. This forwarded a series of development and implementation strategies based on contemporary behaviour change theories and techniques (Michie *et al.* 2005; 2008a; 2011). This body of work included the Theoretical Domains Framework (TDF), the COM-B model and the Behaviour Change Wheel (BCW) (Michie *et al.* 2014). This was chosen to underpin the breastfeeding support intervention due to the comprehensiveness of the framework, its specificity to the healthcare setting and its successful application in existing health promotion research (Francis *et al.* 2009/2012; French *et al.* 2012; Phillips e*t al.* 2015).

5.4.1 Theoretical Domains Framework

The TDF is a method of categorising behaviour determinants into their relevant theoretical domains or constructs, thus offering a succinct but comprehensive coverage by eliminating overlapping constructs (Michie *et al.* 2005; Cane *et al.* 2012).

Considering the identified behaviour determinants not all the TDF domains were applicable for this study and some of the domains were beyond the scope of the intervention conditions. Discussions were held by the research team regarding the inclusion of the constructs of social role/identity and social influences. Previous research on the psychosocial aspects of breastfeeding initiation and continuation have implicated the role of social identity and influences as behaviour determinants (De Jager *et al*. 2013). Socio-cultural demographics associated with breastfeeding behaviour are considered as modifiable by long-term initiatives targeted at national and organisational level, which placed them beyond the scope of the research. Breastfeeding may, however, be implicated within the construct of social role and identity when it is equated with the perception of a 'good mother'

(Murphy and Rosenbaum 1999; Etorre 2007). This was of particularly relevant to this cohort as their credibility as a positive role-model and the adequacy of their parenting skills were already challenged, in their own view and by others, by their addiction (Chandler *et al.* 2014). Previous studies, and the findings of the 'think aloud' protocols, testified to the impact of substance dependence on maternal perceptions of self-worth including their ability to successfully parent (Jambert-Gray 2014). Concurrently, self-worth beliefs are considered psychosocial influences of breastfeeding and are embedded in Self-Efficacy Theory, thus implicating them as mediators in the behaviour change process (Entwistle *et al.* 2010). This emphasises the interconnected relationship between the determinants of breastfeeding behaviour.

On consideration, it was decided not to include the social domains as separate constructs on the understanding that these psychological influences were implicated in other domains, and in the behaviour change techniques associated with Self-Efficacy Theory. Whilst this query raised discussion amongst the development team it also highlighted the on-going contradiction within behavioural change science, with the complexity and the subtlety of the effect of intervention components not yet fully understood (Hoddinott 2015).

The identified behaviour determinants were mapped to the corresponding theoretical domains using the TDF, as detailed in Table 20.

Table 20: Breastfeeding Behaviour Determinants mapped to the Theoretical Domains

Theoretical Domain	Definition	Behaviour Determinant
Knowledge	An awareness of the existence of something	Knowledge/Informational aspects
Skills	An ability or proficiency acquired through practice	Practical aspects
Social role and identity	A coherent set of behaviours and personal qualities displayed in a social setting	Not applicable.
Beliefs about capabilities	Acceptance about an ability that a person can put to constructive use	Psychological influences
Optimism	The confidence that desired goals will be attained	Psychological influences
Beliefs about consequences	Acceptance about outcomes of a behaviour in a given situation	Psychological influences
Reinforcement	Increasing the probability of a response between an action and a given stimulus by arranging a dependent relationship	Psychological influences
Intentions	A conscious decision to perform a behaviour or act in a certain way	Psychological influences
Goals	Outcome an individual aim to achieve	Person-centred approach
Memory, attention and decision processes	The ability to retain information, focus selectively and choose between alternatives	Person-centred approach
Environmental context and resources	Environmental circumstances that discourages or encourages the development of skills or adaptive behaviour	Environment and resources
Social influences	Interpersonal processes that can cause individuals to change their thoughts and behaviour	Not applicable.
Emotion	Complex interplay between experiential, behavioural and physiological elements by which the individual deals with events	Psychological influences
Behavioural regulation	Anything aimed at managing or changing actions	Environment and resources

The TDF was originally designed to evaluate the mechanisms of behaviour change associated with HCP and the domains are distinct to the environment in which healthcare is delivered. Following the successful use of the TDF, further work extended its scope to the assessment of other population groups and operative systems within clinical settings (French *et al.* 2012). This culminated in the COM-B model of behaviour, which moved beyond healthcare practitioners to include any group of individuals, populations or organisations within a clinical environment (Michie *et al.* 2014).

As this intervention targeted healthcare recipients, the COM-B model was a useful addition to the current study to enhance the comprehensiveness of the analysis of breastfeeding behaviour influences.

5.4.2 COM-B Model

The COM-B model proposes that behaviour is part of a system involving one or all the identified components of capability, opportunity and motivation (Michie *et al.* 2011). These components either act independently or the causal links between the three components may interact to increase or decrease the effect of an intervention on decisions and behaviour (Michie *et al.* 2014).

The model theorises that behaviour is influenced by individual capability, and this encompasses either physical or psychological capability. The person or group concerned must have the physical ability or strength to undertake the behaviour and they require the cognitive processes and the knowledge of how to enact the behaviour. Opportunity includes external factors existing independently of the individual. This includes physical resources and social acceptance within the given environment. Physical resources are the facilities, time available and enablers/barriers to perform the behaviour. Social opportunity is the prevailing cultural norm and interpersonal influences. The third feature is motivation. Motivation implies that the individual has a sufficiently strong desire to want or need to perform the behaviour. This includes reflective motivation, such as conscious planning, goal setting and evaluation between the relative benefits and risks of different actions. Automatic motivation involves processes such as habits, emotions, impulses and associative learning.

Table 21 details the mapping of the TDF constructs to the COM-B elements.

Table 21: Theoretical Domains mapped to the COM-B Elements

COM-B	Theoretical Domains	
Capability	Physical	Skill
	Psychological	Knowledge
		Memory, attention and decision processes
		Behaviour regulation
		Reinforcement
Opportunity	Physical	Environmental context and resources
Motivation	Reflective	Belief about capability
		Belief about consequences
		Optimism
		Intentions
		Goals
	Automatic	Emotions

5.4.3 Behaviour Change Wheel

The Behaviour Change Wheel aids the process of linking the behaviour patterns identified as influential in breastfeeding by the COM-B analysis tool, to the relevant intervention functions associated with targeting behaviour change in that domain (Michie *et al*. 2014). The BCW was developed from the synthesis of 19 frameworks of behaviour change found in research literature (Michie *et al.* 2011b). The model consists of three layers with the COM-B elements at the centre. The internal ring of the BCW suggests nine interactive intervention functions which are aligned to the appropriate COM-B elements. Intervention functions are overarching components which target

the process of behaviour change through intervention strategies. The outer layer suggests seven generic organisational policies that may facilitate the delivery of the intervention.

The purpose of applying the BCW was to identify a comprehensive and broad base of relevant intervention functions. These were then aligned to behaviour change techniques. This involved exploring which techniques had demonstrated efficacy to change the target behaviour in clinical practice or were a theoretically derived construct of that behaviour. Table 22 details the mapping of the COM-B elements to their corresponding intervention functions as suggested by the BCW.

Table 22: COM-B elements mapped to Intervention Functions (Michie *et al.* 2011)

COM-B	Component	Description	Intervention Function
Capability	Physical	Technical skill	Education
	Psychological	Capacity to engage in the necessary cognitive processes	Training
Opportunity	Physical	Opportunity afforded by a conducive physical environment	Environmental restructuring Enablement
Motivation	Reflective	Reflective thought processes such as evaluation and planning	Persuasion Enablement
	Automatic	Automatic thought processes such as emotions, impulses, social conditioning and inherent beliefs	

As the primary aim of the study was to determine the feasibility of the support model, the tertiary level of the BCW suggesting organisational policies was beyond the scope of the project and was not applied.

5.5 Intervention Function

The BCW resulted in five intervention functions theoretically derived from the synthesis of evidence. The intervention functions were education; training; persuasion; enablement and environmental restructuring. The final stage of the design process aligned these functions with practical techniques. This included evaluating practical techniques in relation to their applicability to the target population, their feasibility given the clinical setting and justification for inclusion.

5.5.1 Education

An integral part of the intervention was the educational element. Information provision is one of the most commonly used and long standing behaviour change techniques. Traditionally, health promotion focused on providing information of the adverse consequences and/or positive benefits of a course of behaviour (Bowling 2014). This assumed that a lack of knowledge impeded informed decision-making and it was presumed that health advice on the advantages/disadvantages of the consequences of lifestyle choices would lead to the acceptance of the promoted behaviour (Chisholm *et al.* 2014). However, it is now evident that information provision as the single or primary component of a behaviour change programme has limited success, and in isolation is insufficient to maintain behaviour change (Bowling 2014). Recommendations for intervention development propose supplementing education as a behaviour change function with other techniques as part of a comprehensive package of support (NICE 2007)

A lack of knowledge regarding the breastfeeding process and specifically the consequences of NAS on breastfeeding outcomes was identified as a behavioural determinant during Phase 1. Concurrently, the inability to solve infant feeding problems, due to a lack of awareness, is one of the most commonly cited reasons for premature discontinuation of breastfeeding (Redshaw and Henderson 2012; Odom *et al*. 2013). This underpins the relevance, if not the efficacy, of information provision as an intervention function.

Despite the limited evidence on the effect of breastfeeding information on behaviour change within the context of substance use, the decision to include education was based on its reputation as an integral part of promotional programmes and the recommendations from the 'think aloud' sessions. Previous research indicates that education in conjunction with other behaviour change techniques can be effective in achieving and sustaining change (NICE 2007). Bartington *et al.* (2006) reported that breastfeeding support programmes that include appropriate and accessible advice have a positive influence on maternal levels of satisfaction with the support received. The availability of socially and culturally relevant information regarding infant feeding and substance withdrawal was cited during the 'think aloud' sessions as a required support element. The participants expressed the need for accurate information in a timely fashion on which to base infant feeding decisions.

In summary, it appeared that the inclusion of information provision was relevant, had shown efficacy to increase maternal satisfaction with support practices and was considered as an acceptable and necessary intervention element by the target population.

5.5.2 Training

The behaviour change technique 'training' was complementary to the educational component, as it added practical skill to knowledge of a subject. The objective of training was to enable the participant to acquire the technical ability to successfully establish breastfeeding with a baby experiencing withdrawal symptoms.

Practical breastfeeding difficulties are reported as a main determinant of early discontinuation or formula supplementation (Redshaw and Henderson 2012; Hoddinott *et al.* 2011). Substantial evidence supports the positive impact of facilitating women to acquire the motor skills required to successfully breastfeed, which enhances maternal perception of self-efficacy through improved mastery (McQueen *et al.* 2011b; Entwistle 2013). Women value direction on the technicalities of breastfeeding, rather than staff performing the task, and previous studies show that maternal satisfaction is enhanced when practical instruction is included in support programmes

(McInnes and Chambers 2008; Schmeid *et al.* 2011). During the 'think aloud' sessions participants reported feeling concerned that poor breastfeeding technique would result in inadequate feeding and contribute to withdrawal severity, which undermined maternal confidence and negatively impacted on self-efficacy levels.

Previous research based on the concept of self-efficacy has demonstrated success as a means of explaining the mechanism of behaviour change in relation to breastfeeding (Entwistle *et al.* 2010; McMillan *et al*. 2009a). Theoretically, enabling a mother to acquire practical mastery should facilitate her perception of capability and enhance self-efficacy (Dennis 1999). However, the application of training as a behaviour change technique to support breastfeeding in the context of substance dependence was untested. There was, however, sufficient evidence of the efficacy of training in relation to enhancing breastfeeding skill in both the general population and women from marginalised groups to consider its inclusion (McAndrews *et al.* 2012; MacVicar and Kirkpatrick 2014). Furthermore, there were explicit recommendations from 'think aloud' participants that training was needed to enable women to navigate the practical challenges of breastfeeding and acquire the necessary skills for themselves. Collectively, it was considered both appropriate and essential to include training as a behaviour change technique within the support package.

5.5.3 Persuasion

As a behaviour change technique, verbal persuasion is associated with Self-Efficacy Theory and therefore there is causal association of its influence on behaviour and decision-making (Bandura 2004). Verbal persuasion can be used to support the continuation of breastfeeding as a direct method of enhancing existing motivation. Miller and Rollnick (2014) proposed that verbal persuasion was a means of showing support for the reasoning behind the original decision, signalling approval of the decision and reinforcing the acceptability of the behaviour. However, the effectiveness of persuasion as a behaviour change technique is bound by certain conditions. Persuasion is more likely to succeed when delivered within the confines of a trusting relationship where the participant is receptive to the supporter's argument

(Hoddinott *et al.* 2013). The content of the persuasive discussion must also be perceived as relevant to the participant and applicable to their socio-cultural context.

Persuasion has shown efficacy in bolstering levels of maternal self-efficacy and a direct correlation between higher levels of self-efficacy and greater duration of breastfeeding have been consistently demonstrated (Entwistle *et al.* 2010; McQueen *et al.* 2011b; Otusko *et al.* 2014). The provision of reassurance and encouragement, as a means of persuasion, have been implicated as an important aspect of supportive practice in qualitative research on maternal perceptions of breastfeeding experience (Schmied *et al.* 2011; MacVicar *et al*. 2015).

The inclusion of persuasion as an intervention function was underpinned by its position as a theoretical construct in various models of health behaviour and explicitly its role in enhancing self-efficacy in breastfeeding research (Bowling 2014; Entwistle *et al.* 2010). The synthesised evidence highlighted the importance of emotional support, including encouragement and persuasion, for mothers if they were to sustain breastfeeding. Therefore, verbal persuasion was considered as an effective tool as part of the breastfeeding intervention, but supporters had to be aware of its limitations and maximise its potential by adopting an integrated individualised and person-centred approach simultaneously.

5.5.4 Enablement

Enablement as a behaviour change technique is defined as empowering the individual to cope with, understand and manage the situation to bring about the desired behaviour (Bowling 2014). A primary objective of enablement is to enhance individual coping strategies to deal with internal and external stressors, through a capacity building approach. The individual is provided with the resources, whether physical or psychological, to adopt and sustain behaviour change. Psychological and physiological stress influence perceptions of self-efficacy and high levels of anxiety, stress and guilt were reported by the 'think aloud' participants. Therefore, enhancing resilience through enablement was relevant for those with a substance use disorder.

Enablement has been associated with reinforcement and action planning as behaviour change techniques as a means of bolstering intention (Webb *et al.* 2010; Hagger and Luszczynska 2014). Reinforcement and planning are recognised and frequently applied components of change strategies and have demonstrated efficacy over a diverse range of health promotional strategies (Gollwitzer and Sheeran 2006; Adriaanse *et al.* 2011). As part of an integrated support package, enablement can act both as an independent reinforcement of the desired behaviour change and can complement other intervention functions to maintain maternal motivation. Subsequently, the association between enablement and bolstering self-efficacy perceptions suggested that this was an applicable intervention component.

5.5.5 Environmental Restructuring

Environmental restructuring incorporated physical changes to the immediate surroundings and the provision of resources to support behaviour change. For this study it included room modifications, equipment to minimise external stimuli, consolation aids and the appointment of a support worker. Environmental modifications are considered as 'good practice' as supportive care measures in the management of the substance exposed neonate (DoH 2007; Hudak and Tan 2012). There are, however, contradictory reports of the usefulness of this, with techniques demonstrating improved outcomes in one study (Oro and Dixon 1988) but not in another (D'Apolito 1999). This variability has been attributed to the uniquely personal nature of NAS (Bowie 2004; Jansson and Velez 2012). The 'think aloud' participants who had experience of supportive practices found them useful and felt they were a valuable strategy to relieve neonatal agitation. Enabling the mother to assess, interpret and address her child's cues, through providing the equipment and knowledge, can bolster her self-confidence and foster a therapeutic relationship for both. Overall, environmental modifications were regarded as an integral part of the management of the neonate at risk of NAS, justifying the relevance of this function and its inclusion as part of the support intervention.

5.6 Behaviour Change Techniques

Intervention functions are realised by behaviour change techniques, which promote, support and sustain the desired outcome (Abraham and Michie 2008). A behaviour change technique has been defined as the base element of the active components that comprise an intervention. Its function is to exert an influence on the theoretical constructs determining behaviour change (Michie and Johnstone 2012). The final stage of the development process was to link the five intervention functions to appropriate techniques. Assessing the choice of behaviour change technique not only included the predicted function but also whether it could be delivered with equipoise and fidelity given the setting, resources and target group (Peters *et al*. 2015). Michie and colleagues undertook a collaborative exercise to simplify, categorise and define frequently used behaviour change techniques resulting in a taxonomy of techniques specifically supporting the BCW functions (Abraham and Michie 2008; Michie *et al.* 2013; Michie 2015). Using this taxonomy, a selection of behaviour change techniques was made which were deemed as locally and clinically relevant, acceptable to the client group and feasible to implement as a cohesive intervention. Table 23 details mapping of the intervention functions to behaviour change techniques

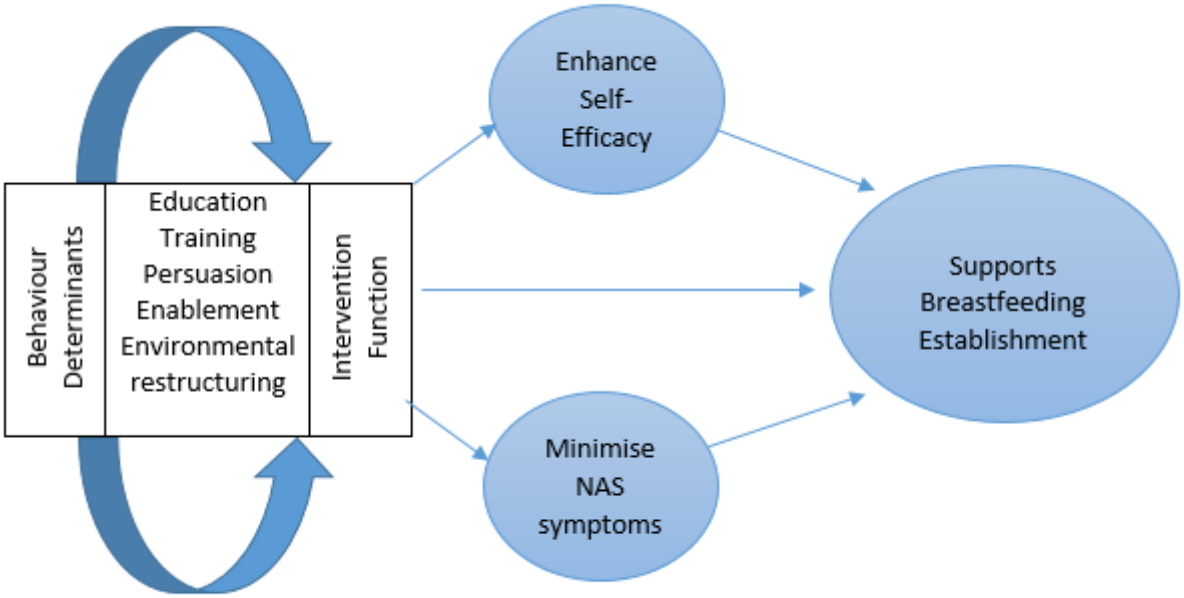
Table 23: Intervention Function mapped to Behaviour Change Techniques (Abraham and Michie 2008)

Intervention Function	Behaviour Change Technique
Education	Information provision Feedback on behaviour and outcomes
Training	Demonstration of the behaviour Instruction on how to perform the behaviour Feedback on behaviour
Persuasion	Information provision Feedback on behaviour, outcomes and consequences Verbal persuasion about capability
Enablement	Provide resources Modifications to the environment Goal setting, action planning and reviewing Problem solving
Environmental Restructuring	Provide resources Modifications to the environment Barrier reduction

5.7 Modelling Process

The modelling process enabled identification of the key components of the intervention and their interaction with one another, which theoretically should result in the target outcome. The is depicted as a conceptual model representing the integration of the behaviour determinants to the practical techniques, with the proposed empirical and theoretical mechanism of change leading to support for the continuation of breastfeeding. Figure 9 depicts a conceptualised model of the intervention and mode of action.

Figure 9: Conceptual Model of Intervention



5.8 Intervention and Implementation Summary

The identified behaviour change techniques were amalgamated to give a comprehensive and unified breastfeeding support intervention for use with opiate maintained women. The practical application of the support intervention is detailed in Table 24.

Table 24: Intervention Components

Practical and Informational Support
Scheduled daily visit up to 1 hour for first 5 postnatal days starting within 12 hours of birth
Dedicated experienced breastfeeding support worker
Continuity of care-giver
Practical assistance focusing on impact of withdrawal on feeding ability
Instruction on technical skills
Information provision on normal physiology of breastfeeding
Information provision on effects of opiates on neonatal behaviour
Psychological Support
Positive reinforcement
Enhance levels of maternal self-efficacy – mastery (assist mastery, praise mastery), verbal persuasion (encouragement), self-modelling, stress reduction (address physiological needs re pain/fatigue)
Open, honest dialogue
Respectful collaborative relationship
Enable maternal decision making and capacity building
Non-judgmental approach
Person-Centred Approach
Collaborative daily assessment
Acknowledge and adjust strategies to respect maternal experience and knowledge
Person-centric approach to identify individual objectives
Incorporate social/cultural constraints
Realistic goal setting with an individualised approach
Information on substitution medication and Neonatal Abstinence Syndrome
Environmental Modifications
Single room
Dimmed lighting
Cot cover to minimise external stimuli
Consolation and self-soothing techniques
Pacifier to promote non-nutritive sucking
Do Not Disturb policy
Cluster care – reduce through traffic

5.9 Chapter Summary

The chapter described the development of the evidence based and theory informed breastfeeding support intervention. This process resulted in the pro-active informative, practical, motivational and environmental infant feeding support model. Chapter 6 presents the next step of Phase 2 which was to assess the intervention in a feasibility study with an embedded small scale RCT.

CHAPTER 6
Feasibility Study
and
Randomised Controlled Trial

6.0 Introduction

This chapter presents the feasibility study. Initially, a discussion on the choice of research design and the assessment criteria for the feasibility study is given. This is followed by the research methods prior to detailing the qualitative and quantitative results. An assessment of the study feasibility concludes the chapter. A discussion of the key findings of the RCT is presented in Chapter 7 of the thesis in conjunction with a review of the research process as a whole.

6.1 Methods: Research Design

The feasibility stage was particularly invaluable for this study due to the uncertainties regarding the unknown level of demand for this type of intervention and degree of receptiveness to research participation by the opioid dependent community. Bowen *et al.* (2009) defined one of the primary functions of a feasibility study as the means of collating recruitment, retention and follow-up rates. These statistical parameters form the basis for the standard deviation of the outcome measures, which are needed to calculate an adequate sample size for the eventual full-scale study.
The feasibility study is not, however, designed to measure clinical effectiveness of the intervention but to assess the suitability of the chosen research design to address this. Thus, whilst statistical significance may be assessed in the feasibility study it is with the understanding that the relevance of this must be treated with caution as the sample size is not sufficiently powered to allow robust assumptions to be made (MRC 2008).

What it may demonstrate, however, is if an association exists between variables. It does, however, offer the potential to assess the suitability of the research procedures, data collection tools and outcome measures for the eventual evaluation trial. Therefore, the research design for the definitive trial, a RCT, was embedded into the feasibility study as a means of evaluating these processes and make refinements as necessary.

When an assessment of clinical efficacy is the desired outcome of a research study a quantitative, experimental design is the most appropriate choice (Greenhalgh 2014). The hierarchy of evidence pyramid classifies the relative weight of research designs as a means of assessing the merits of different methods based on their potential for bias. Due to their methodological rigour RCT's are considered the most robust design with systematic reviews (SR) and meta-analysis of RCT's at the pinnacle of the hierarchy triangle (Greenhalgh 2014). Below this are other controlled trials followed by observations designs such as cohort, case and control trials. Case series and reports are found on the lower level with editorials and expert opinion forming the base of the hierarchy of evidence pyramid. Therefore, if it is feasible and ethical to conduct one, an RCT should be the first-choice design to assess clinical efficacy.

However, the hierarchy is not without its detractors, with the absence of qualitative methods within the pyramid forwarded as a limitation, as this excludes many valid and important methodological approaches (Bowling 2014). In the complexity of applying evidence to clinical practice, it may be necessary, and advantageous, to draw on a range of methods enabling a comprehensive review of evidence (Craig *et al*. 2008). Additionally, many authors challenge the notion of basing the reliability and robustness of a study on its methodological approach. Higher-ranking studies, which are methodologically flawed, may result in less reliable evidence than a well conducted but lower ranked study (Noble and Smith 2014).

On consideration, the research design chosen for the feasibility study was a RCT, as this design is considered the 'gold standard' for assessing clinical efficacy (Greenhalgh 2014). The basic tenet of the design of the RCT is to test the impact of an intervention by comparing the statistically significant difference between pre-defined outcomes in the study groups. RCT's are comparative, prospective experimental design which generate data on the

effect of exposure to an intervention on two or more arms of a trial, one arm of which is a control group (Gerrish and Lathlean 2015). To maximise the probability that the cause of outcome difference is due to the intervention, and not by confounding variables, random selection and allocation of subjects attempts to create uniformity across study groups and promote equal distribution of variables (Davies *et al.* 2015). In theory, there should be no systematic differences between groups, either known or unknown, that may affect the outcome. This is, however, reliant on an adequate number of participants in the cohorts to balance the distribution of variables (Bowling 2014). To eliminate the risk of systematic bias RCT's should be conducted to the highest standard of methodological rigour to achieve interval validity (Moore *et al.* 2015). Internal validity relates to the degree to which the results occur due to the intervention and not to extraneous factors. All groups should be treated identically and ideally participants and assessors are unaware of their group allocation.

As with all methodologies RCT's have limitations. There can be difficulties maintaining the controlled conditions or excluding confounding variables. This can be particularly problematic in complex healthcare interventions (Bowling 2014). Additionally, the constraints applied during the conduct of a randomised trial may reduce the applicability of the results when used in real life settings (MRC 2000). This affects the external validity of the study and positive results produced in one setting or population may not be generalisable elsewhere. RCT's may produce the most powerful evidence but, in certain circumstances, their use may not be practical or ethical (Priest and Roberts 2010). In healthcare research, a consideration of patient preference must remain central to any treatment options and quantitative designs such as RCT's are limited in this regard (Gerrish and Lathlean 2015).

6.2 Intervention and Control Protocols for RCT

Following development of the intervention, as discussed in Chapter 5, the control and intervention group protocols were formulated to direct the conduct of the RCT. The evidence generated in Phase 1 was also utilised for the basis of the implementation strategy.

6.2.1 Control Group

The study protocol proposed that the control group participants were allocated to a separate postnatal area from that of the intervention group. Beyond this stipulation the aim was that control participants, as the study comparator, received routine postnatal care from existing midwifery staff. This included the management detailed in the existing hospital guidelines for women maintained on substitution medication and the care of the infant at risk of NAS.

The hospital guidelines for the mother enrolled on opiate maintenance treatment included the provision of a single room. This was part of the hospital infection control measures in relation to maternal substance use, as this poses a high risk of blood borne virus transmission. However, the availability of a single use room was at a premium and it was not possible to always meet this recommendation. As controlling environmental stimuli is a recognised aspect of standard NAS management, the allocation of a single room was mentioned by the research team, although allocating this was at the discretion of the attending midwife.

Infant feeding advice was provided by the ward staff and as a BFI accreditation facility, breastfeeding support was underpinned by Unicef Ten Steps to Successful feeding (Table 4). Additional infant feeding support was available to all women as part of the role of the infant feeding specialist midwife. This was arranged at the discretion of the attending midwife.

Local guideline for care of the infant at risk of NAS state that the infant remains as a hospital in-patient for at least 5 days. Supportive management is recommended. Neonatal withdrawal is assessed using the Finnegan scoring system. If the degree of withdrawal becomes severe, as denoted by an increasing FS score, the hospital policy is for the infant to be admitted to the neonatal unit for pharmacological management.

Under the research protocol, infants admitted to the neonatal unit were recorded as no longer receiving the standard comparator care management. The control group mothers were asked to complete the RCT questionnaire to give them the opportunity to register their view on the period that their infant was in the postnatal ward. Data collection of the stated outcome measures, in respect of length of hospital stay and infant feeding status,

were collected to enable a comprehensive evaluation of the feasibility study and to inform future trials. Table 25 details the control group protocol.

Table 25: Control Group Protocol

CONTROL GROUP: Postnatal Ward B	
Preparations	Request single room Inform ward staff that mother/infant dyad are RCT participants. Place staff information leaflet in participant's obstetric notes Provide researcher contact details Obtain maternal and neonatal socio-demographic/obstetric data
Day 1, 2, 3 and 4	Mother and baby receive routine care from existing postnatal staff in accordance with BFI accreditation and local guidelines for infant at risk of NAS. Collect daily infant feeding data Collect daily neonatal data (FS)
Day 5	Distribute questionnaire Collect infant feeding data Collect neonatal data

6.2.2 Intervention Group

The intervention participants received the same postnatal management as described for the control group. Additionally, they were allocated the breastfeeding support intervention which included the provision of a dedicated support worker and environmental modifications.

The practical application of the intervention consisted of a 1-hour daily scheduled session with a dedicated breastfeeding support worker. The first session was commenced within 12 hours of the birth of the baby, with subsequent sessions continuing daily until the 5th postnatal day. Although the timing of the initial sessions was dependent on the time of day or night of the baby's birth. The researcher negotiated a time the mother was happy to receive her first visit from the support worker. Each session was proactively led by the same worker to promote continuity of care-giver. Continuity encouraged the establishment of a facilitative relationship, enabling an ongoing assessment of skills acquisition and confirmation of the level of maternal understanding of previous advice given.

Training on breastfeeding technique, consolation therapies and assessment of the infant's feeding needs was the foundation of the daily visit. Individual instruction was built on existing maternal ability and dependent on her previous experience and support needs. Infant feeding instruction was given indirectly with pictures, videos, visual models and as advice on recognising and performing breastfeeding practice such as correct attachment, positioning and winding. A training objective was to enable mothers to recognise the internalised and externalised signs of neonatal withdrawal and use appropriate feeding and consolation techniques to overcome these. Feeding strategies were discussed on a one-to-one basis allowing the mother to dictate the pace, technical level, specific informational needs and individual support objectives. This enabled the support worker to assess the accuracy and completeness of the mother's knowledge and supplement this with evidence based recommendations. The predominant aim was to adopt a capacity building approach during the sessions to facilitate maternal mastery of breastfeeding skills and infant care.

A daily collaborative breastfeeding assessment provided the opportunity for the mother and health worker to review the status of breastfeeding establishment, identify barriers, problem solve and set goals. Additionally, it

gave a platform on which the supporter could positively reinforce the intention to breastfeed and cement this with information on the benefits and consequences. Feedback on performance was offered and unsuccessful outcomes situated in terms of progression and learning points, whilst accepting that realistically there would be challenges. Participants were encouraged to consider alternative ways in which they could approach similar situations in the future. Goal-setting occurred as a joint endeavour, with practices which were socio-culturally acceptable to the mother but concurrently acknowledged neonatal nutritional and neuro-behaviour needs. Environmental modifications were in place from the birth of the baby until the end of the trial period, at the earliest. Minimising external stimuli included assigning the mother and baby to a single room where noise levels and temperature could be regulated. A modified neonatal cot with a cover and shield limited exposure to excessive light. The provision of and instruction on the use of consolation aids was given to facilitate neonatal self-soothing. Attempts to reduce the volume of pedestrian 'traffic', such as ancillary staff, included organising cluster care when routine tasks were performed simultaneously. In actuality, the exact composition of elements varied between participants as the sessions were tailored to the individualised needs and contextual influences of the mother/infant dyad. However, the foundation of each encounter was the promotion of the five intervention functions.

As with the control group participants when the neonatal withdrawal process became too severe to be managed conservatively on the postnatal ward the infant was admitted to the neonatal unit for pharmacological treatment. As the infant was no longer rooming-in with their mother the intervention components were discontinued. Subsequently, routine neonatal support, including infant feeding guidance was available from the neonatal staff. The outcome measures of these infants, including length of stay and feeding method, were collected to enable a comprehensive assessment of the intervention. Additionally, the mother was asked to complete the RCT questionnaire. Table 26 details the intervention group protocol.

Table 26: Intervention Group Protocol

INTERVENTION GROUP: Postnatal Ward A	
Preparations (Researcher duties)	Request single room Install environmental modifications • black out blinds • modified cot • consolation therapy equipment Appoint Support Worker (for 5 days) Inform ward staff that mother/infant dyad are RCT participants. Discuss 'do not disturb' policy with staff groups Place staff information leaflet in participant's obstetric notes Provide researcher contact details Maternal and neonatal socio-demographic/obstetric data
Day 1/First Visit (Support Worker duties)	Mother and baby receive routine care from existing postnatal staff in accordance with BFI accreditation and local guidelines for infant at risk of NAS. ***In addition***, the intervention as detailed below, is provided. **First visit within 12 hours** Introduction Discuss/demonstrate use of consolation techniques Swaddling explanation and use **Individualised support – suggested strategies** Person-centred • identify immediate maternal needs/wishes/preference • discuss long-term breastfeeding aspirations Practical • infant feeding technique and withdrawal symptoms Motivational • self-efficacy strategies Informational • opioid dependent specific information • breastfeeding process • internalised and externalised signs of NAS Environmental • explanation of environmental modifications and reducing external stimuli • consolation techniques Daily assessment plan Arrange time for next visit Complete daily Log

Day 2 – 4 (Support Worker)	Mother and baby receive routine care from existing postnatal staff in accordance with BFI accreditation and local guidelines for infant at risk of NAS. ***In addition***, the intervention, as detailed below, is provided. **Individualised support (as above)** Information leaflets Daily assessment plan • review previous 24 hours • reinforce positive outcomes, reflect on other approaches if necessary • assess maternal feeding objectives • plan next 24 hours Arrange time for next visit Complete daily Log
Day 5 (Support worker)	**Individualised support (as above)** Continuation of measures to reduced stimuli post discharge Controlled weaning information Re-iterate swaddling instructions Daily assessment plan Complete daily Log
Day 5 (Researcher)	Distribute questionnaire Collect infant feeding data Collect neonatal data Informal debrief session with support worker

6.2.3 Implementation Strategy

The aim of the implementation strategy was to maximise fidelity of the intervention through staff engagement. Prior to the commencement of active recruitment, staff awareness sessions were carried out. The purpose of this was two-fold. Firstly, it gave the opportunity to explain what the study involved, the aim and objectives of the research and clarified the expectations of existing staff. It was emphasised that no additional burden of care would be placed on staff and that the research team would undertake all additional assistance or modifications. Practitioners were asked to maintain their normal routine and level of management to both the control and intervention groups. Secondly, the current hospital guidelines in relation to the management of the neonate at risk of abstinence syndrome were reinforced. This was to try to achieve parity of care between the two arms of the feasibility study. The researcher's contact details were made available within the clinical areas and staff groups were encouraged to get in touch with any queries.

The research study recruited five support workers. A funding request was submitted to the tertiary hospital perinatal endowment fund for an endowment grant to conduct the feasibility study. This funding enabled the five support workers to be employed. The support workers were current and respected employees of the maternity hospital who expressed both an interest and enthusiasm to participate in the research. They were experienced in the delivery of breastfeeding support and in the management of women and infants exposed to addictive substances. The use of local employees as research facilitators provides a local point of contact for other hospital workers and as an informal source of peer influence. A key step in the development process was familiarising the support workers with the ethos of the study, individual intervention components and documentation. This comprised of a 2-hour one-to-one session between the support worker and researcher to discuss the intervention functions and the behaviour change techniques which enact these. Debriefing sessions were also held following the completion of the block of 5 intervention sessions. A guide of the components recommended for inclusion in the intervention was given to each support worker (as Table 26). This was to maintain integrity and fidelity

of delivery within the context of maternal preference and individualised needs assessment.

6.3 Sample Population and Size

The sample population comprised opiate maintained women accessing obstetric services at the consultant tertiary maternity unit, with the sample size based on recruitment time rather than a power calculation. Johanson and Brooks (2010) report that it is appropriate to determine the sample size for a feasibility study on pragmatic reasons such as knowledge of the local conditions, time and cost constraints. Previous healthcare research has found that small sample sizes are sufficient for investigating the feasibility of procedures and methods as this is as informative in respect of recruitment, acceptability and implementation as larger cohorts (Hertzog 2008; Billingham *et al.* 2013). Therefore, a time limit of 1 year was set for recruitment and completion of the study.

An estimated number of trial participants was required to calculate resource provisions, finances and number of support workers needed to deliver the intervention. A guide figure of 20 was considered appropriate for the time scale available and given the average caseload of the clinic. The number of live births to substance dependent women in the recruitment hospital averaged 100 per annum in the previous 10 years (Black *et al.* 2013). Given that a percentage would opt to formula feed, some would be ineligible and others would not wish to participate it was felt that 20 recruits represented an achievable estimate.

6.3.1 Inclusion and Exclusion Criteria

Inclusion and exclusion criteria can influence the generalisability of the trial results and narrowly defined eligibility may limit recruitment (Creswell 2014). Therefore, it was important to be as inclusive as possible but maintain safety conditions and minimise confounding factors. Table 27 details the inclusion and exclusion criteria set for study participation.

Table 27: Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Women enrolled on an opioid maintenance programme 36 weeks' gestation or greater Intend to breastfeed Read, write, speak and understand English 16 years of age or more	HIV positive Pre-birth Child Protection Order in place Women with known concurrent use of illicit psychoactive drugs Women with known concurrent alcohol issues

National guidelines for breastfeeding in substance dependence, good research conduct recommendations and the practical conditions required for successful implementation of the project underpinned the eligibility criteria (DoH 2007).

An inclusion criterion for the study was maternal ability to understand written and spoken English. An integral part of the breastfeeding intervention included behaviour change techniques aimed at enhancing maternal self-efficacy levels. A psychosocial approach to optimising self-efficacy is considered most effective when a rapport is established between the mother and her supporter (Entwistle 2013; de Jager *et al.* 2013). It was felt that the lack of a common language might impede the ability to form a therapeutic relationship and therefore adversely impact on the efficacy of this intervention function. This inclusion criterion also related to the use of written study documentation as information leaflets and the recruitment and consent documents were in English. Translating these into other languages had cost and resource implication. Advice from the gatekeepers was sought regarding the possible number of mothers who may be excluded due to this inclusion criterion. At the time of the study there were no women accessing

substance misuse services at the tertiary clinic who did not have English as their first language.

An age limit of 16 years of age or greater was set as an inclusion criterion. This was due to consent restrictions regarding the participation of minors in research studies. During the recruitment period the clinic caseload did not include any women of this age. An exclusion criterion was maternal positive Human Immune Virus (HIV) status. This follows national guidelines, which contraindicate breastfeeding in the presence of HIV due to the transmission of the virus from mother to baby through breast milk (DoH 2007). However, this is the only blood borne virus contraindicated in breastfeeding in the UK. Women known to be Hepatitis positive are encouraged to breastfeed, in association with harm reduction strategies and timely immunisation of the neonate.

Intervention delivery required the mother and baby to room-in together for 5 days' post birth. Therefore, an existing or pending Child Protection Order (CPO), potentially ordering the separation of mother and baby at birth, was set as an exclusion criterion. All women enrolled on a substitution medication programme during pregnancy are assigned a named social worker with pre-birth and post-birth conferences convened to determine the level of support required by each family. A final decision on the degree of parental access to the child may only be made after the baby is born. It may include the recommendation that the child is removed from the unsupervised care of the mother, and be imposed immediately at birth or prior to discharge to the community.

UK guidelines on the management of drug dependency state that breastfeeding, in general, should be encouraged, even if the mother continues to use illicit substances (DoH 2007). This is accompanied with the proviso that extra vigilance is required during breastfeeding by women who are known to have concurrent use of illicit psychoactive drugs or alcohol. The exception to this is the use of cocaine/ crack cocaine or very high doses of benzodiazepines where the recommendation is to council the mother on the side-effects of these. The guideline acknowledges, however, that professionals should not contravene the wishes of the mother to breastfeed. Conversely, USA recommendations state that the continued ingestion of illicit drugs or alcohol is not compatible with breastfeeding, although this can vary

between states (Jansson 2009; Reece-Stremtan and Marinelli 2015). This stipulation is influenced by the presumption that these substances may impair maternal functioning and impose a safety risk to the baby. It is accepted that there is minimal, or an absence of, evidence on which to base these recommendations. The available evidence originates predominantly from animal studies or small case observations thereby limiting its generalisability (Sachs 2013). Therefore, given these contradictory statements and lack of robust evidence, the decision regarding citing concurrent use of addictive substances as an exclusion criterion was based on the hypothesised consequences of these conditions on the research outcomes. The use of addictive substances, including alcohol and psychoactive drugs, during pregnancy or whilst breastfeeding can result in medical and pathophysiological conditions. Infants exposed to alcohol in utero can display Fetal Alcohol Spectrum Disorder (FASD) post birth (Boxwell 2012). This syndrome varies extensively in its presentation, timing and the degree of disability experienced by the child. The majority of cases are not diagnosed in the neonatal period and may not become apparent until academic and developmental milestones are missed. Those who do present as neonates tend to display feeding difficulties due to neurological disruption. There may be concurrent abnormal facial features with structural anomalies of the jaw and face. This can impede sucking technique but these obvious signs are not always present (Lissauer and Fanaroff 2011). Given the limited ability to predict whether a fetus who has been exposed to alcohol is affected by FASD, it was considered advisable to stipulate alcohol use throughout pregnancy as an exclusion criterion.

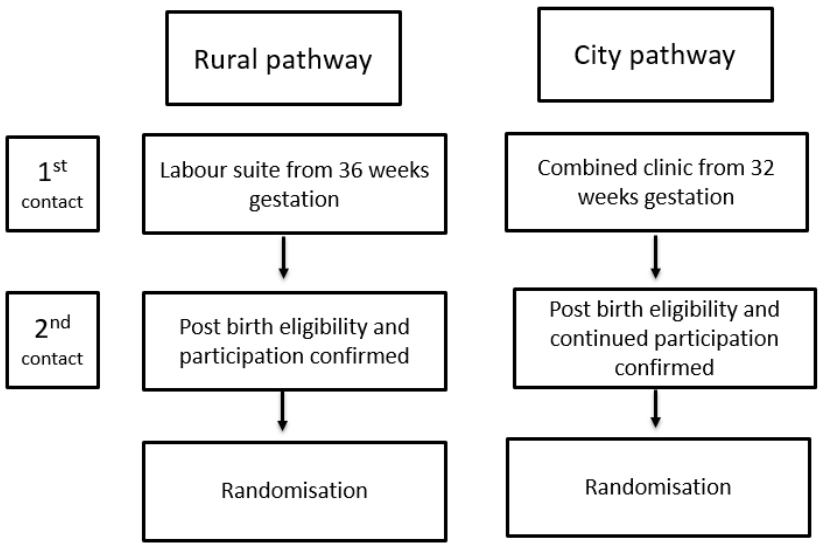
Concurrent use of illicit substances poses a medical and ethical dilemma. There is the theoretical possibility that the use of cocaine could result in vasodilation episodes if it is transferred from the breast milk to the baby (Sachs 2013). Due to the lack of evidence on the bioavailability of cocaine in human breast milk it is recommended that breast milk is expressed and discarded for 12-24 hours after the drug is administered (D'Apolito 2013; D'Avilo *et al.* 2015). Breastfeeding can then be recommenced. However, this is dependent on maternal disclosure of drug use and commitment to these precautions. Since the use of alcohol and illicit substances can affect the

feeding status of the baby, these variables may unduly influence the research outcomes and were therefore listed as exclusion criteria.

6.3.2 Recruitment Strategy

Recruitment proceeded over a 12-month period from April 2014 until April 2015. Obstetric and substance misuse services are provided in a consultant unit at the main tertiary hospital and in regional peripheral units. It is highly recommended that women enrolled on opiate maintenance treatment birth at the tertiary hospital due to the availability of neonatal services. Therefore, there were two distinct groups of prospective research participants, those following the rural pathway and those following the city pathway. Figure 10 depicts the rural and city pathways.

Figure 10: Rural and City Recruitment Pathway



<u>Rural Pathway</u>

Women who accessed services in the rural, peripheral clinics were approached regarding study participation when they attended the consultant unit. On consideration of the logistics of travelling from the researcher's base at the consultant unit and the time taken to identify and establish relationships with the gatekeepers, it was decided not to recruit women

directly from peripheral clinics during the antenatal period. The proposed recruitment procedure was to identify women as research candidates following admission to the consultant unit for delivery and postnatal services. The researcher discussed the aim of the study, and the referral process, with the labour suite clinical manager in the consultant unit, to gain her opinion and approval. Following her agreement, posters were displayed in staff areas to bring attention to the research study and methods. The details of the referral process and eligibility criteria were circulated to attending midwives. The referral procedure requested that if a woman meeting the eligibility criteria presented at the consultant unit the attending midwife could introduce the subject of research participation, at her discretion as a gatekeeper. Referral to the researcher was made if the woman confirmed her interest.

The recruitment procedure was dependent on the stage of pregnancy when the referral occurred. If a woman was admitted to the consultant unit prior to the induction of labour, the researcher arranged a convenient time to discuss the research and if the terms were acceptable to the mother, she was opted-in to the study. Women were not approached during labour. In the postnatal period, the research conditions were discussed, and if the woman found participation acceptable, written consent was obtained.

<u>City Pathway</u>

The main cohort of study participants came from women accessing the substance misuse service clinic in the tertiary hospital. The senior specialist midwife attached to the combined clinic was an active member of the advisory group and championed the project amongst her colleagues. The HCP within the joint clinic agreed to act as impartial gatekeepers and research details including participant eligibility criteria were provided. The research team relied on the discretion and expertise of the gatekeepers to determine the suitability of the women for referral. As a member of the direct care team, the gatekeepers had access to confidential maternal history regarding obstetric, illicit substance use and child protection issues. These factors may have been contrary to the study eligibility criteria. The gatekeepers used their knowledge of the medical and social circumstances of

their clients to assess whether it was appropriate to broach the subject of the research participation.

The gatekeeper initially approached prospective participants during their routine clinic visits from 28-week gestation. The gatekeeper established whether the woman was considering breastfeeding and her receptiveness to discussing research participation. If the women expressed an interest in the study, the gatekeeper, with the woman's verbal permission, forwarded her details to the researcher.

The researcher approached the candidate during a clinic visit, from 32-week gestation. This meeting constituted introductions and the offer of a research information pack. The pack included a written information sheet describing the nature of the study, an opt-in reply slip and a stamped addressed envelope. The reply slip asked the respondent to state her preference regarding contact, by telephone or in person at a clinic visit, in order to arrange a further meeting to discuss participation. Following the return of the reply slip, the researcher arranged a suitable appointment and allocated additional time at the woman's next clinic visit to discuss the study aim and conditions. If the woman decided to participate in the trial, an identification sticker and leaflet were placed in her obstetric notes to notify attending HCP. The leaflet explained the aim and nature of the study to the attending practitioner and requested that they contact the researcher when the woman presented in labour. It was emphasised to the woman that continued eligibility for participation depended on birth outcomes.

6.3.3 Randomisation Process

Following the birth of the baby, reconfirmation of continued participation in the study was determined. Eligibility criteria centred on the transfer of the mother and baby to the postnatal area to room-in together. This assumed that both mother and baby were fit and healthy, no congenital abnormalities were present and there were no child protection issues preventing unsupervised contact. The researcher reconfirmed that the mother still wished to participate in the study and that she intended to initiate breastfeeding. If continued participation was restated, then written consent

was obtained. If a woman was no longer eligible for continued participation in the study an explanation was given and assurances provided that she would be fully supported in her aim to establish breastfeeding by postnatal staff. Once maternal and neonatal eligibility was established, randomisation into a study group took place. A computer-generated randomisation process was used to assign the women to either the intervention or the control arm (Graphpad software). The randomisation allocation sequences were placed in consecutively numbered sealed envelopes and opened in the presence of the participant.

6.4 Data Collection and Analysis

Data collection consisted of both quantitative and qualitative data. The data collected was retrieved from a variety of medical, nursing and research documents. The type of data collected was determined by 3 objectives. The first objective was to obtain baseline socio-demographics on the research context. Secondly, to assess the feasibility of the intervention. The third objective was to inform the research design, methods and outcome measures of the future fully powered study. Table 28 details the data collection sets.

Table 28: RCT: Data Collection Sets and Rationale

Rationale	Data Collection Outcome measures	Data Collection Tools/Sources
Research context	Socio-demographic characteristics	Maternal obstetric record
	Maternal obstetric outcomes	Postnatal record
	Neonatal outcomes	Neonatal record
Intervention feasibility and implementation	Recruitment rate Retention rate Loss to follow-up	Research documentation- data flow chart of participant recruitment
		Combined clinic caseload
	Maternal satisfaction	Questionnaire
Inform future evaluation trial	Infant feeding method and rates	Daily assessment log
		Neonatal record
		Infant Feeding (6 weeks)
	Finnegan Score Neonatal unit admission rate Length of hospital stay	Neonatal Record

6.4.1 Recruitment and Retention Rates

The demand for and issues of recruitment and retention are evaluation criteria for intervention feasibility (Bowen *et al.* 2009). The number of women accessing the substance misuse service during the study period was obtained from the hospital database via the specialist midwife. The research team collated the flow of participants throughout the RCT to provide both numerical details of retention figures and reasons, if available, for discontinuation or disengagement from the trial.

6.4.2 Obstetric and Neonatal Record

Socio-demographic data may demonstrate the presence of extraneous or confounding differences between the arms of the trial. It also enabled inferences to be made on whether outcomes from the current study were comparable with previous research findings of similar demographic groups. A review of neonatal documentation provided data on the severity of NAS as denoted by the trend in FS, admission rate to the neonatal unit and the duration of stay. This documentation also yielded information on infant feeding method during the trial period and for follow-up feeding data at 6 weeks for neonates who were still in-patients in the neonatal unit at that time.

6.4.3 Daily Assessment Log

The support worker maintained a daily assessment log for the intervention group and recorded the infant feeding status for the previous 24 hours, as stated verbally by the mother (Appendix 2). A daily assessment log was completed following each intervention session. The data collected included the time of the session to allow evaluation of the intervention protocol in relation to timing and frequency of visits, this included whether the first visit was made within 12 hours. The duration of the session and any interruptions/barriers to implementation were recorded to inform subsequent intervention modifications. Infant feeding method for the previous 24 hours and any supplementation, and rationale for this, was documented. The support worker recorded the advice given in relation to the foundational intervention elements of practical and informational aspects; psychological aspects; environmental conditions and individualised support. The daily infant feeding plan for the previous 24 hours was reviewed and goal setting undertaken for the next 24 hours. The support worker was invited to make any additional comments/ discussion points as necessary.

6.4.4 Infant Feeding Follow-up

Follow-up data on infant feeding method at 6th postnatal week was requested from the relevant HCP (Appendix 2). The HCP received a cover letter and a feeding request. This asked whether the baby was exclusively breastfeeding,

formula feeding only or mixed feeding. Additionally, the opportunity to state that the patient was no longer at the practice or if they did not attend the clinic was given. This was included as there was the possibility that the baby was registered at a GP practice elsewhere as they were no longer under the care of the mother.

This request was sent to the health visitor at the registered GP practice for the women who accessed their substance misuse services out with the tertiary hospital. Alternatively, the community psychiatric nurse at the combined clinic, who maintained weekly contact with the mother until at least the 8th postnatal week, received this request. For the infants who were still in-patients in the neonatal unit information was obtained from their neonatal records.

6.4.5 RCT Questionnaire

Feasibility study participants were offered a questionnaire on or following the 5th postnatal day, following the completion of the last intervention session. Information was requested regarding their experience of breastfeeding establishment; the individual elements of supportive care management used to alleviate neonatal withdrawal symptoms and their attitude towards the infant feeding support provided. As previously discussed, difficulties may exist with the use of traditional data collection tools. It was felt, however, that as the women had already consented to take part in the research this demonstrated a higher level of motivation than average and therefore there should be an increased receptiveness to completing the questionnaire. Healthcare literature notes that there are both advantages and disadvantages of using questionnaires as data collection tools (Bowling 2012; Creswell 2014). One advantage is that most people are familiar with a questionnaire format due to its frequency of use. Arguably, it should be relatively simple to understand and complete, but it is accepted that some designs are more complex than others. Additionally, questionnaires rely on the assumption that respondents have a shared or similar understanding of any concepts, such as support. Questionnaires can generate standardised answers to closed questions and numerical, ordinal level data to Likert scale questions. Both types of data are relatively straightforward to analyse but they also limit the responses to those predetermined by the researcher.

Furthermore, these types of questions may result in responses which lack comprehensiveness and respondents may feel that they must choose an answer from the list even if it is not an accurate reflection of their views (Bowling 2014). Offering a mix of styles and free text comments can address this issue (Jones and Rattray 2015). Like other data collection methods, questionnaires are at risk of social desirability bias. This occurs when a participant provides an answer they feel is the socially acceptable reply, rather than a true reflection of their views (Creswell 2014). However, the anonymity of the questionnaire design may encourage some to be more forthright in their responses without feeling the need to be socially accountable.

Alternative data collection methods were reviewed for their suitability to elicit maternal perspectives. Interviews provide the opportunity to probe participants for more explicit, and relevant, responses. However, socially desirable responses are more likely to occur in an interview setting as the direct contact between the participant and interviewer increases the need to convey a positive image. This is an issue of significant relevance to this population group. Logistically, with an anticipated 20 interviews this would have proven resource and time intensive whilst questionnaires are relatively inexpensive to produce and quick to analyse (Bowling 2014). On consideration, it was felt that a questionnaire was the most appropriate data collection method.

An evaluation of the applicability of existing questionnaires to meet the study objectives was undertaken. Using a pre-existing questionnaire is a time effective measure, as questionnaire development is a complex and protracted process (Bowling 2014). It also provides a tool which has already established validity and reliability. However, there are disadvantages to this as its reliability can be called into question if the questionnaire was not designed with the target audience in mind. Additionally, the content may lack the accuracy required to address the research objectives of the proposed study (Creswell 2014). Following an evaluation of the pre-existing questionnaires it was considered that the most judicious approach would be to construct a questionnaire specific to the research outcomes as a data collection tool.

6.4.5.1 Questionnaire Construction

The primary aim guiding questionnaire construction is to be succinct with a combination of question styles to suit different literacy levels. Jones and Rattray (2015) suggest that the initial step is to review pre-existing questionnaires designs and refine the content and format to reflect the key concepts of the current study objectives. Ho and McGarth (2010) systematically reviewed 77 studies on self-reported scales measuring breastfeeding attitudes, experience, confidence and satisfaction. This highlighted the reliability of the Breastfeeding Self-Efficacy Scale (BSES) originally designed by Dennis (2003) and subsequently adopted extensively in contemporary literature (Dennis *et al.* 2011). This measure was reviewed and in conjunction with a recent questionnaire successfully applied in the local area, these were integrated and adapted for use for this study (Hoddinott *et al.* 2012b).

The next step of the development process recommends that members of the intended respondent population should be consulted on the structure, question content and to check if the tool is performing as required. Sjetne *et al.* (2015) note that this can prevent unnecessary items and exclude sensitive or controversial items that may result in non-completion. During the 'think aloud' sessions the participants were asked for their opinion of the questionnaire. One recommendation was to change the terminology of one question as two mothers queried the meaning of the word 'pacifier' and this was altered to the more colloquial term 'dummy'.

6.4.5.2 Questionnaire Format

The questionnaire format was composed of three short sections with Yes/No questions, Likert rating scale, open-ended questions and free text sections. Section 1 collected socio-demographic characteristics and previous breastfeeding experience. Section 2 consisted of a variety of questions types and topics with the initial questions related to the expected breastfeeding support inherent of a BFI facility. These questions provided an

indication of the fidelity of delivery of BFI practices to the control group, as the intervention group comparator.

The following questions assessed the presence of other variables, known to either influence breastfeeding establishment or affect neonatal withdrawal symptoms. Question 5 asked whether the mother had offered her baby a dummy. As part of the BFI ten steps to successful breastfeeding, pacifiers are contraindicated. However, they can be a useful consolation technique in the control of withdrawal symptoms by enhancing non-nutritive sucking. As such, it is an important piece of data to inform, and justify, the intervention design for future research.

Question 6 was concerned with breast milk expression. Supplementing breastfeeding with additional milk is a routine practice in NAS management with expressed breast milk (EBM) preferable to formula milk. The following items focused on NAS supportive care; common problems of breastfeeding and NAS symptoms related to breastfeeding. These conditions can directly affect both the physical ability to breastfeed and maternal motivation to continue breastfeeding.

In section 3 respondents were invited to rate their experience of breastfeeding support, and perceived satisfaction with this. This consisted of five questions, rated on a Likert scale from 0-10; with zero being strongly disagree with the statement and 10 being strongly agree. The final item asked the mothers to discuss which aspects of breastfeeding they found supportive, what improvements could be made and, if wished, to contribute any further comments. (Questionnaire included in Appendix 2).

6.4.6 Data Storage and Analysis

In accordance with university policy and practice all data were subject to procedures to ensure anonymity, confidentiality and stored securely. This is described in section 3.3.2.2.

The findings were analysed and interpreted in a variety of forms given the mix of qualitative and quantitative data collected.

6.4.7 Quantitative Data

In respect of the quantitative data, numbers and responses were calculated and entered into Statistical Package for the Social Sciences (SPSS) statistical software for quantitative analysis. A summary of the data as descriptive statistics, percentages, mean and Standard Deviation (SD) were obtained. Mann Whitney U tests were applied to calculate the statistical differences between groups. Chi Square tests were used to calculate associated relationships between the groups. The statistical significant difference was set at $p=\leq 0.05$.

6.4.8 Qualitative Data

Thematic Analysis was chosen to interpret the questionnaire qualitative findings. This technique is used to analyse textual data by identifying patterns and illuminating themes. The key characteristic of this method being the systematic process of coding, examining the meaning and providing a description of the social reality by creating themes (Clark and Braun 2013). Vaismoradi *et al.* (2016) proposed that thematic analysis is particularly suited to a pragmatic discipline such as nursing where the aim is often to develop clinically relevant findings to enhance the impact of nursing practice. The end product of thematic analysis is a theme which can be adapted to reflect an explicit description of a phenomenon, rather than an abstract interpretation, underscoring its applicability to devise practical solution and clinical applications (Tuckett 2005). An advantage of TA is that the method accommodates smaller data sets, as it does not rely on the reoccurrence of themes. A single comment is considered as relevant as repeated themes or topics subject to affirmation between participants. The data can also be used to produce data-driven or theory driven analysis dependent on the requirements of the research objectives.

Braun and Clarke (2006) devised a version of thematic analysis which proposes a flexible approach to analysis and does not adhere to a predetermined theoretical perspective. This allows an exploration of the data from differing complementary or competing discourses. Subsequently, the approach adopted is that which best fits the needs of the research question and the type of data collected (Creswell *et al*. 2011). Additionally, the lack of

complexity of the approach makes it achievable and accessible to researchers and readers of all levels of experience (Vaismorandi *et al.* 2013). However, it is this flexibility and simplicity of TA to analyse a diverse range of data that is frequently cited as a criticism of the method. That it does not prescribe to one particular theory is incorrectly equated with an absence of theoretical underpinning, thereby leading to the claim that the method is lacking in sophistication (Braun *et al.* 2014). The range and diversity of healthcare research, which has adopted TA, however, validates and strengthens the position that it is both an acceptable and an effective approach to data analysis.

Clark and Braun (2014) proposed a six-phase approach to thematic analysis, which was adopted for the study. Initially the questionnaire comments were reviewed to gain familiarisation with the findings. The primary coder (doctoral student) read and reread the quotes to assess the scope of the data. The responses were sorted into relevant words and/or concepts to develop a coding framework guided by the aim and objectives of the research. Next, codes were assigned to create categories and sub-categories. The following step involved review and coding of the data by a second coder (research supervisor). Subsequently, discussion of the data sets and framework between the reviewers achieved a final coding by consensus. This gave consolidated codes representative of themes related to the research objective. Finally, the themes were reviewed, defined and named.

6.5 Results

Due to the substantial quantitative and qualitative data produced these are presented in six sections.

These are:

(1) Recruitment, Completion and Loss to Follow-up Rates

(2) Maternal and Neonatal Socio-Demographics and Outcomes

(3) Infant Feeding and Neonatal Abstinence Outcomes

(4) Breastfeeding Practice and Outcomes

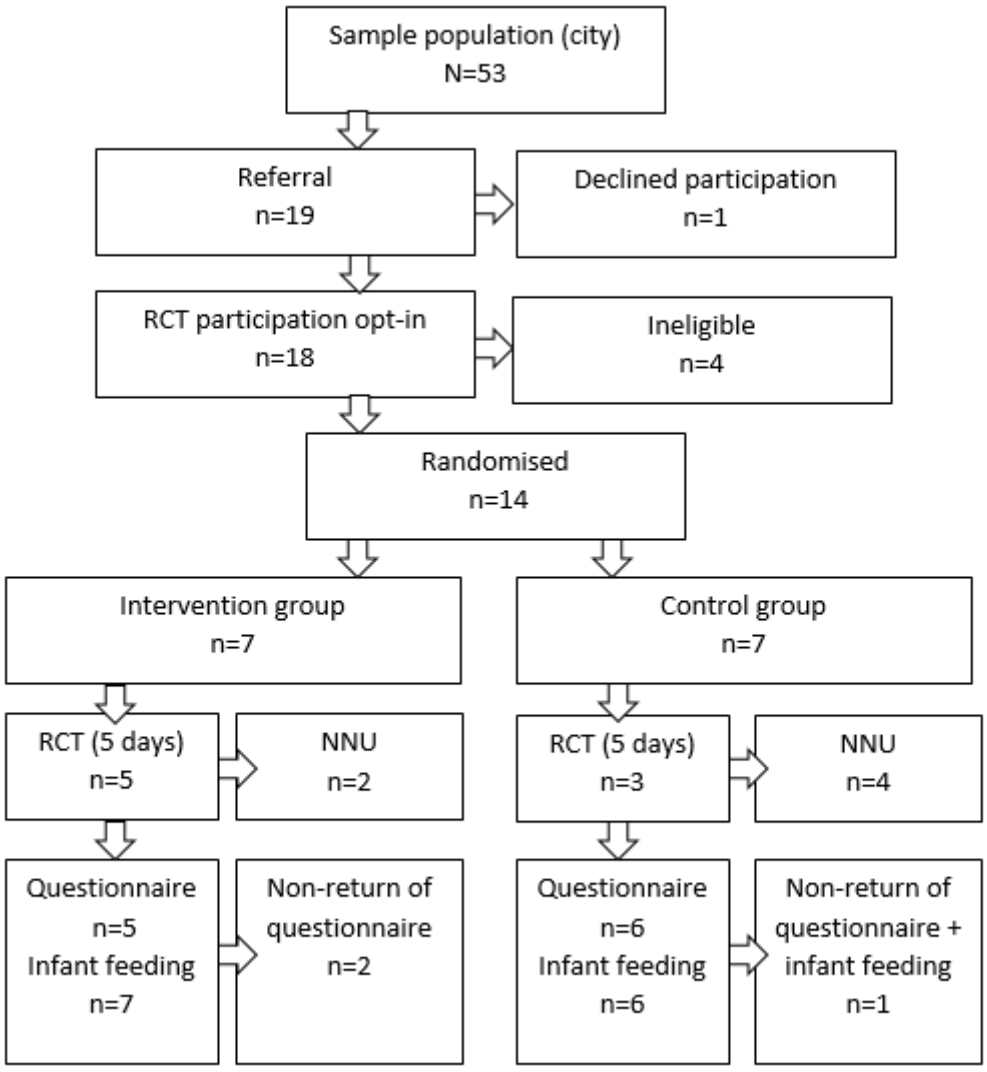
(5) Maternal Satisfaction with Breastfeeding Support

(6) Protocol Fidelity

6.5.1 Recruitment, Completion and Loss to Follow-up Rates

Figure 11 charts the RCT recruitment, completion and loss to follow-up rates from referral until the infant data collection point at the 6th postnatal week. This data enabled an assessment of the demand for the intervention and the retention figures provided an indication of acceptability.

Figure 11: RCT Recruitment, Completion and Loss to Follow-up Rates



6.5.1.1 Recruitment Rate

The caseload of the combined clinic during the trial period was 53 and the gatekeepers referred 19 potential recruits. Of the 19 referrals who returned the reply slip, one woman declined participation following discussion of the research aim and requirements. This resulted in 18 women who opted-in for RCT participation and were eligible dependant on birth outcomes. From this group four became ineligible for continued participation. One woman gave birth prematurely and one other was withdrawn from the study on the recommendation of the gatekeeper. Issues arose regarding illicit substance use and a pre-birth child protection order was put in place prior to the birth of the baby. Amongst the remaining 16 potential participants, non-recruitment occurred in two mother/infant dyads following the birth of the baby. In one dyad, this was due to admission of the baby to the neonatal unit for a medical condition unrelated to withdrawal symptoms. The second mother/infant dyad was lost to study participation following failure of the referral process. The researcher was not contacted when the mother was admitted in labour or post-birth. Of the original 19 women identified as meeting the initial eligibility criteria and who expressed an interest in the study, the eventual number randomised to the RCT was 14.

6.5.1.2 Completion Rate and Loss to Follow-Up

Fourteen mother/infant dyads met the final eligibility criteria. Following randomisation, there were seven mother/infant dyads in the intervention arm and seven in the control arm. During the five-day trial period two infants from the intervention group were admitted to the neonatal unit for pharmacological management. Subsequently, five mother/infant dyads received the full allocation of five intervention sessions. In the control arm, four infants were admitted to the neonatal unit for pharmacological management. Therefore, three mother/infant dyads completed the full five days of comparator care. Although these mother/infant dyads were still eligible to be included in the collection of the RCT data in relation to the post RCT questionnaire and neonatal outcomes. On the 5th day of the trial period, the 14 questionnaires were distributed to the study participants and 11 were

returned. There was a loss of two questionnaires in the intervention arm, with five returned. In the control group, one mother did not return the questionnaire, resulting in six completed questionnaires. Therefore, 11 data sets were completed from the initial group of 14. A follow-up survey on the infant feeding method at 6th postnatal week completed the data collection. There was non-return of one follow-up infant feeding method. Of the 14 infants randomised to the trial there was a resulting loss of 4 items of data used for feasibility evaluation (3x RCT questionnaires and 1x infant feeding method). This was a 71% return, providing an indication of the retention rates of engagement with the study.

6.5.2 Maternal Socio-Demographics and Outcomes

This data provided a comparison of potential confounding variables between the intervention and control cohorts. Statistical analysis was performed although this should be considered in relation to the sample size and the limitations of a feasibility study. Table 29 details maternal socio-demographic characteristics and outcomes.

6.5.2.1 Socio-Demographic Characteristics

Of the RCT participants all were Caucasian and the majority were in a stable relationship (n=12). All were enrolled on an opiate substitution medication programme prior to pregnancy with 13 maintained on methadone and one on buprenorphine.

6.5.2.2 Parity

Parity ranged between 0-8 in the intervention group and 0-4 in the control group, with the median (Md) parity for the intervention group (Md=2) and the control group (Md=1). There were more paragravidum women in the intervention group (n=6) compared to the control group (n= 4).

Table 29: Maternal Socio-Demographic Characteristics and Outcomes

Maternal Characteristic and Outcome	Intervention (n=7)	Control (n=7)	Total (N=14)
Age range (years)			
<20 years (n, %)	0	0	0
20 – 35 years	5 (72%)	4 (57%)	9 (64%)
>35 years	2 (28%)	3 (43%)	5 (36%)
Mean, SD	31.7 ± 4.07	32.4 ± 3.74	32.2 ± 3.53
Parity			
- Primiparous (n, %)	1 (14%)	3 (43%)	4 (28%)
- Parous	6 (86%)	4 (57%)	10 (72%)
Mean, SD	3.1 ± 2.8	1.3 ± 1.5	2.2 ± 2.4
Median	2	1	2
Breastfeeding experience			
- Yes (n, %)	4 (57%)	1 (14%)	5 (36%)
- No	3 (43%)	6 (86%)	9 (64%)
Birth Outcome			
- Spontaneous birth (n, %)	4 (57%)	4 (57%)	8 (57%)
-Instrumental birth	0 (0%)	3 (43%)	3 (21.5%)
- Caesarean section	3 (43%)	0 (0%)	3 (21.5%)

Key: N= total number; n=number in subset; SD = Standard Deviation.

6.5.2.3 Birth Outcomes

Most women achieved a spontaneous vaginal birth (n=8), and this was divided equally between both arms of the RCT. In the intervention group, the remaining three participants underwent an operative delivery whilst the three mothers in the control group experienced instrumental births.

6.5.3 Neonatal Demographics and Outcomes

Table 30 details neonatal characteristics and outcomes.

Table 30: Neonatal Characteristics and Outcomes.

Neonatal Characteristic and Outcome	Intervention (n=7)	Control (n=7)	Total (N=14)	Probability
Gender Male (n, %) Female	 2 (28%) 5 (72%)	 5 (72%) 2 (28%)	 7 (50%) 7 (50%)	
Gestation Range (w+d) Mean, SD	 38+3 – 41+4 40.14 ± 1.21	 36+6 - 41 38.9 ± 1.73	 36+6 – 41+4 39.57 ± 1.55	*p*=0.16 (*ns*)
Birth Weight Range (kg) Mean, SD	 3.0 – 3.9 3.4 ± 0.26	 2.8 – 3.8 3.30 ± 0.35	 2.8 – 3.9 3.3 ± 0.30	*p*=0.31 (*ns*)
Neonatal Unit Yes (n, %) No	 2 (28%) 5 (72%)	 4 (57%) 3 (43%)	 6 (43%) 8 (57%)	*p*=0.59 (*ns*)
Length of Stay Range (d) Mean, SD	 5-24 10.48 ± 7.04	 7-43 19.42 ± 13.02	 5 – 43 14.92 ± 11.09	

Key: w+d= weeks and days; SD= standard deviation; kg= kilograms; *p*=probability; *ns*= not significant; d = days.

6.5.3.1 Gender

There were two male and five female infants in the intervention group whilst the reverse occurred in the control group with five males and two females.

6.5.3.2 Gestational Age

The overall mean gestational age was 39.57 weeks (SD 1.55), with a mean of 40.14 weeks (SD 1.21) in the intervention group and a mean of 38.9 weeks (SD 1.73) in the control group. Results from the Mann Whitney U test

indicated that the difference in gestational age between the two groups was not statistically significant (U=13.500, z=-1.461, p=0.165, r=0.144).

6.5.3.3 Birth Weight

The overall mean birth weight was 3.3kg (SD 0.30), with a mean of 3.4kg (SD 0.26) in the intervention group and mean of 3.3kg (SD 0.35) in the control group. The results from the Mann Whitney U test indicated that the difference between the birth weights in the two groups was not statistically significant (U=16.500, z=-1.024, p=0.318, r=0.306).

6.5.3.4 NAS Severity

Cumulatively, between the intervention and control arms, there were 6 infants admitted to the neonatal unit for pharmaceutical treatment to control the severity of withdrawal symptoms. Opioid replacement was used as the primary therapy for all infants (n=6), secondary therapy of sedation/hypnotic was added in most cases (n=5) and one (n=1) infant required secondary therapy and adjunctant sympatholytic therapy for severe NAS.

In the intervention group two (n=2) infants were admitted to the neonatal unit with four (n=4) infants from the control arm admitted. Result from a Chi Square Test indicated there was no statistically significant relationship between RCT group and admission to the neonatal unit (1.167(x^2) (1, n=14), p=0.592).

6.5.3.5 Duration of Hospitalisation

The increased number of infants who required pharmaceutical management in the control group compared to the intervention group affected the mean length of hospital stay per group. The overall mean duration of length of stay was 14.92 days (SD 11.09), and in the intervention group the mean length of stay of 10.48 days (SD 7.04) with a mean duration of 19.42 days (SD 13.02) in the control group. The results from the Mann Whitney U test indicated that the difference in length of hospital stay between the two groups was not statistically significant (U=11.000, z=-1.735, p=0.097, r=0.83).

6.5.4 Infant Feeding and Neonatal Abstinence Outcomes

Breastfeeding continuation and NAS outcomes were reviewed. Statistical analysis was performed and considered in relation to the limited efficacy inherent of feasibility studies. The data did, however, presented the opportunity to assess whether there was an emerging trend or association between the variables.

6.5.4.1 Breastfeeding Continuation

Table 31 details the infant feeding method in place on the 5th postnatal day and the 6th postnatal week.

Table 31: Infant Feeding Method 5th Postnatal Day/ 6th Postnatal Week

Infant Feeding	Intervention (n=7)	Control (n=7)	Total (N=14)	Probability
5th Day				
- Breast *	7 (100%)	4 (57%)	11	*p*=0.051 (*ns*)
- Formula	0 (0%)	3 (43%)	3	
6th Week				
- Breast	3 (43%)	3 (43%)	6	
- Formula	4 (57%)	3 (43%)	7	
- Unknown	0 (0%)	1 (14%)	1	

Key: ns = not significant

*Breastfeeding defined as the baby feeding from the breast, attempts at breastfeeding and/or expressed breast milk given via bottle.

The intervention group recorded a breastfeeding continuation rate of 100% (n=7) on the 5th postnatal day compared to 57% (n=4) in the control group. Results from a Chi Square test indicated that the relationship between the allocated group and infant feeding method on the 5th postnatal day was nearing statistical significance (3.81(x^2) (1, n=14), p=0.051).

The percentage of breastfeeding continuation on the 6th postnatal week was equal at 43% (n=3) in both the intervention and the control group. This demonstrates no difference between the groups.

6.5.4.2 Infant Feeding Method and Neonatal Abstinence Syndrome

Table 32 details the association between infant feeding method and severity of neonatal withdrawal. Admission to the neonatal unit for pharmacological treatment denotes severe NAS, as mild NAS was managed on the postnatal ward with supportive care.

Table 32: NAS and Infant Feeding Method 5th Postnatal Day

Group	NAS severity	(n/ %)	Breastfeeding	Formula feeding	Probability
Intervention (n=7)	mild	5 (72%)	5 (72%)	0	
	severe	2 (28%)	2 (28%)	0	
Control (n=7)	mild	3 (43%)	3 (43%)	0	
	severe	4 (57%)	1 (14%)	3 (43%)	
Total (N=14)	mild	8 (57%)	8 (57%)	0	*p*=0.055 (ns)
	severe	6 (43%)	3 (21.5%)	3 (21.5%)	

The data demonstrated that for infants who were not admitted to the neonatal unit (n=8), 100% were breastfed on the 5th postnatal day. For those who were admitted to the neonatal unit (n=6), 50% (n=3) were formula fed and 50% (n=3) were breastfed.

Results from a Chi Square test indicated that the relationship between infant feeding method on the 5th postnatal day and neonatal unit admission was nearing statistical significant (5.091(x^2) (1, n=14), p=0.055). This is cumulative data from both arms of the RCT.

One outcome measure collected to denote the severity of neonatal withdrawal was the Finnegan Score (Finnegan *et al.* 1975). However, there were substantial variations in practice noted between users when completing the FS and inconsistency when it was used as an assessment tool for neonatal unit admission. Subsequently, this data set was considered unreliable and was excluded from any analysis.

6.5.4.3 Infant Feeding Method and Length of Hospital Stay

Table 33 gives cumulative details of infant feeding method on 5th postnatal day and length of hospital stay.

Table 33: Infant Feeding Method on 5th Postnatal Day and Length of Hospital Stay.

Infant feeding (n=14)	Length of Hospital Stay Mean (SD)	Probability
Breast (n=11)	10.8 ± 6.73	p=0.022 (*s*)
Formula (n=3)	30 ± 11.78	

The breastfed infants (n=11) had a mean duration of hospital stay of 10.8 days (SD 6.73) and formula fed infants (n=3) had a mean duration of 30 days (SD 11.78). The results from the Mann Whitney U test indicated that the difference in length of hospital stay between the breastfed infants and the formula fed infants was statistically significant (U=2.000, z=-2.270, p=0.022, r=0.023)

6.5.5 Breastfeeding Practice and Outcomes

The first section of the questionnaire enquired about the infant feeding and NAS management offered to the intervention and the control arms. This allowed an assessment of 'standard care' provided to the control group as the intervention comparator, for research purposes. It also gave an

indication of the demand for individual support practices. This can inform future versions of the study. In the intervention group, five (n=5) completed questionnaire were returned and in the control group six (n=6) completed questionnaires were returned. This represented a total questionnaire return rate of 78%.

6.5.5.1 Intervention and Control Group Comparator Care

Table 34 details breastfeeding strategies recommended for BFI facilities (Entwistle 2013). This details the composite replies from 11 questionnaires: intervention group n=5; control group n=6.

Table 34: Intervention and Control Group Comparator Care

BFI recommendations	Intervention (n=5)	Control (n=6)
3) Did a member of staff sit with you for an entire breast feed?	5 (100%)	3 (50%)
4) Did a member of staff observe the start of a breastfeed when you are attaching the baby to the breast?	5 (100%)	6 (100%)

All members in the intervention group (n=5) reported having an entire feed observed including attachment.

Of the control group (n=6) half of the participants (n=3) reported having an entire feed observed but all had the start of a feed, and attachment, observed.

6.5.5.2 NAS Supportive Care

Table 35 details a list of supportive practices aimed at minimising the expression of neonatal withdrawal symptoms. This details the composite replies from 11 questionnaires: intervention group n=5; control group n=6. However, only a partially completed questionnaire was received from the mother of a control group baby who was admitted to the neonatal unit at 3 hours of age. The participant recorded the elements of support which were

relevant, and she had experience of, in the questionnaire. When the number of replies differ, the results are highlighted with an asterisk *.

Table 35: NAS Supportive Care

NAS Supportive Care	Intervention (n=5)		Control (n=5)	
	YES	NO	YES	NO
5) Did your baby have a dummy/pacifier?	1 (20%)	4(80%)	3 (60%)	2 (40%)
6) Were you shown how to express milk?	5 (100%)	0	3 (50%)	3* (50%)
7) Were you in a single room?	5 (100%)	0	3 (60%)	2 (40%)
10) The following things can reduce the symptoms of NAS, were you informed of these? • breastfeeding • provision of breast milk • quiet environment • dimmed lighting • swaddling	5 (100%)	0	5(83%)	1(18%)*

* One infant was admitted to the neonatal unit at three hours of age and therefore there is a variability in the number of responses to some questions. Questions marked with * include six replies.

6.5.5.2.1 Pacifier Use

In the intervention group (n=5) one participant (n=1) responded yes to using a pacifier and four (n=4) reported no. In the control group (n=5) three (n=3) used a pacifier and two (n=2) did not.

6.5.5.2.2 Breast Milk Expression

All the mothers in the intervention group (n=5) were shown how to express and store breast milk, whilst three (n=3) mothers in the control group (n=6) were informed and three (n=3) were not.

6.5.5.2.3 Single Room

All women in the intervention group (n=5) reported being in a single room, for the whole, or majority of their stay. This was not the case for control group (n=5) participants with three (n=3) in a single room, one (n=1) initially in a multi-occupancy room but moved to a single room and one (n=1) remained in a multi- occupancy room for the duration of her hospital stay.

6.5.5.2.4 Support Components

All the women in the intervention group (n=5) reported being informed of supportive strategies whilst in the control group (n=6) one mother (n=1) was only partially informed. She responded that she was not aware that breastfeeding could alleviate withdrawal symptoms.

6.5.5.3 Breastfeeding and NAS Outcomes

Table 36 details common generic difficulties associated with breastfeeding continuation and barriers to breastfeeding an infant experiencing neonatal withdrawal symptoms. Questionnaire replies in this section were returned by five intervention group members and six control group members.

6.5.5.3.1 Generic Barriers to Breastfeeding

In the intervention group two participants (n=2) reported experiencing one or more of the common challenges associated with breastfeeding establishment. Both stated they had an insufficient milk supply and indeed this was the most common problem mentioned with two mothers (n=2) in the control group also experiencing this. Of the intervention participants, both reported that the advice given was to express milk and to have skin-to-skin contact with their baby. In the control group one mother stated that she was advised to drink fluids to increase her milk supply whilst the other did not record what, if any, advice she was given. In the control cohort, there was one report of engorgement, or too much milk, with advice given to massage a little milk to make the breast softer. Another woman mentioned

that she experienced cracked nipples and was informed to rub some milk over the cracks and that there were creams she could buy.

Table 36: Breastfeeding and NAS Outcomes.

Breastfeeding and NAS Outcomes	Intervention (n=5)		Control (n=6)	
	YES	NO	YES	NO
11) Did you have any of the following? • Not enough milk • Too much milk/engorgement • Sore breasts when feeding • Cracked/bleeding nipples	2 (40%)	3 (60%)	4 (67%)	2 (33%)
12) Did your baby have any of the following? • Lost too much weight (greater than 10% of their birth weight) • Unsettled in between feeds • Bringing up milk • Tremors, jittery and easily startled	2 (40%)	3 (60%)	4 (67%)	2 (33%)

6.5.5.3.2 Breastfeeding Barriers associated with Neonatal Withdrawal

The final question of the section related to common neonatal withdrawal symptoms associated with gastro-intestinal (GI) system. Two participants (n=2) in the intervention group recorded that their infant experienced GI symptoms, with both infants requiring pharmaceutical management for severe NAS. Four infants (n=4) in the control group were reported as experiencing GI symptoms, one of which required admission to the neonatal unit. Of the four infants who experienced GI symptoms, three were noted as having excessive weight loss in combination with one other symptom. Two mothers were advised to offer supplementary feeds of formula or expressed breast milk to reverse the rate of weight loss. The third mother reported that she was told her infant had an excessive weight loss but no additional management was recommended.

6.5.5.3.3 Discontinuation of Breastfeeding

Respondents were asked if they were still breastfeeding and for those who were not, could they state their reasons. In the control group, three mothers (n=3) had discontinued breastfeeding and they all mentioned the baby's inability to attach to the breast as a determining factor. This was expressed in terms of 'agitation' by one and as the baby 'too sleepy' by another.

6.5.6 Maternal Satisfaction with Breastfeeding Support

This section of the questionnaire evaluated maternal perceptions of breastfeeding support and their level of satisfaction. Responses were invited regarding improvements. Initially, the respondents were asked to rate their views of breastfeeding support using a Likert scale. This consisted of 5 questions, rated on a Likert scale from 0-10; with 0 being strongly disagree with the statement and 10 being strongly agree. Questionnaire replies in this section were received from five intervention group participants and five control group participants for questions 1 to 4. Question 5* is calculated from the replies of five intervention group participants and four control group participants. Table 37 details maternal perceptions of breastfeeding support and satisfaction.

6.5.6.1 'Staff encouraged me to breastfeed'

This statement received five (n=5) responses from the intervention group and five (n=5) from the control group. The overall mean score in response to this question was 7.7 (SD 2.79). The intervention group recorded a mean score of 9.0 (SD 2.24) and the control group recorded a mean score of 6.4 (SD 2.88). Results from a Mann Whitney U test indicated that the difference was not statistically significant between the intervention and control group ($U=5.000$, $z=-1.671$, $p=0.151$, $r=0.195$).

Table 37: Maternal Perceptions of Breastfeeding Support and Satisfaction

Breastfeeding Support	Intervention Mean (SD)	Control Mean (SD)	Total Mean(SD)	Probability
Staff encouraged me to breastfeed	9.0 ±2.24	6.4 ±2.88	7.7 ±2.79	*p*=0.151 (*ns*)
I asked for help when I needed support	8.8 ±1.09	5.4±3.71	7.1 ±3.14	*p*=0.095 (*ns*)
I always received help when I asked for it	9.2 ±1.3	6.4 ±2.3	7.8 ±2.30	*p*=0.095 (*ns*)
I am satisfied with the support I was given in hospital	9.6 ±0.89	6.8 ±2.17	8.2 ±2.15	*p*=0.056 (*ns*)
I feel confident breastfeeding *	9.0 ±1.73	4.3 ±2.06	6.9±3.06	*p*=0.016 (***s***)

*the mean (SD) for this question is calculated from 9 composite replies (intervention group n=5; control group n=4).

6.5.6.2 'I asked for help when I needed support'

This statement received five (n=5) responses from the intervention group and five (n=5) from the control group. The overall mean score in response to this question was 7.1 (SD 3.14). The intervention group recorded a mean score of 8.8 (SD 1.09) and the control group recorded a mean score of 5.4 (SD 3.71). Results from a Mann Whitney U test indicated that the difference was not statistically significant between the intervention and control group (U=4.000, z=-1.820, p=0.095, r=0.069).

6.5.6.3 'I always received help when I asked for it'

This statement received five (n=5) responses from the intervention group and five (n=5) from the control group. The overall mean score in response

to this question was 7.8 (SD 2.30). The intervention group recorded a mean score of 9.2 (SD 1.3) and the control group recorded a mean score of 6.4 (SD 2.3). Results from a Mann Whitney U test indicated that the difference was not statistically significant between the intervention and control group (U=4.000, z=-1.838, p=0.095, r=0.066).

6.5.6.4 'I am satisfied with the support I was given in hospital'

This statement received five (n=5) responses from the intervention group and five (n=5) from the control group. The overall mean score in response to this question was 8.2 (SD 2.15). The intervention group recorded a mean score of 9.6 (SD 0.89) and the control group recorded a mean score of 6.8 (SD 2.17). The results from a Mann Whitney U test indicated that the difference was nearing statistical significance between the intervention and control group for satisfaction with support given in hospital (U=3.000, z=-2.124, p=0.056, r=0.034).

6.5.6.5 'I feel confident breastfeeding'

This statement received five (n=5) responses from the intervention group and four (n=4) * from the control group. The overall mean score in response to this question was 6.9 (SD 3.06). The intervention group recorded a mean score of 9.0 (SD 1.73) and the control group recorded a mean score of 4.8 (SD 2.06). The results from a Mann Whitney U test indicated a statistically significant difference between the intervention and control group for maternal level of confidence in breastfeeding (U=1.000, z=-2.463, p=0.016, r=0.014).

6.5.7 'What Could Be Improved?'

The final section of the questionnaire invited women to give free text comments to the questions 'What was good about breastfeeding support?', and 'What could be improved?' The responses were analysed using thematic analysis and the coding system and framework is given below followed by a narrative analysis of the outcomes.

THEME	DEFINITION	CATEGORIES	CODES	WORDS/CONCEPTS from QUOTES
Practical Assistance	Practical breastfeeding assistance and enabling maternal skill acquisition.	Practical assistance Enablement	Positioning Skills	showing me different positions helped me latch on
Informational Aspects	Providing information on normal process of breastfeeding and information specific to substance dependency.	Knowledge gaps Information provision	Lack of knowledge	kept me well informed I always thought that milk was just there Plenty of advice and encouragement about breastfeeding
Psychological Influences	Promoting self-efficacy through practical and psychological constructs. Enhancing receptiveness to self-efficacy promotion through conducive environment.	Self-efficacy Verbal persuasion	Encouragement Reassurance Supportive environment	good at reassuring and encouraging encouraging me daily was brilliant The five days was very positive made things feel so simple and natural
Person-centred Approach	Adopting a person-centred approach to support through collaboration and individualised goal setting.	Person specific	Individualised Collaborative Proactive	didn't need any help at all but I was asked if I wanted any. coming to help **me** every morning was ace
Environment and Resources	Resource provision to support breastfeeding. Conducive environment for NAS supportive management	Additional resources Conducive environment NAS supportive care	External stimuli Environment	There was no way I could have dimmed the lights for my baby Impossible to create a quiet environment especially at visiting time (if NAS) to get one of these swaddle blankets.
Intervention Functions	Overarching intervention elements or underpinning principles.	Availability Dedicated	Support worker Proactive Individualised	Extra support of a worker here for me just in case was a great thing (support worker) came to help us she was great
Barriers to Breastfeeding Continuation	Healthcare practices or practitioner actions, attitudes and omissions which negatively impact on breastfeeding continuation	Availability of support Generic practices Poor practice	Lack of staff Irrelevant practice Lack of confidentiality and privacy	midwives on duty are very busy and sometimes can't help not very much advice or information about babies with symptoms of 'NAS' it wasn't very private … discussed confidential matters openly didn't feel comfortable feeding in front of other visitors

6.5.7.1 Narrative Discussion of Thematic Analysis

The replies from the intervention group were all positively framed, as demonstrated by one mother's comment:

> "The support for breastfeeding was really good, no need for improvement"
>
> (*Intervention; breastfeeding Day 5 (D5), formula week 6 (W6))*

Thematic analysis generated five themes associated with the varied and complex breastfeeding challenges of opiate maintained women and the impact of support strategies to address their needs. The main theme included the practicalities of breastfeeding with sub categories of breastfeeding assistance in terms of the technical skills to enable breastfeeding mastery. The second theme incorporated information provision specific to opioid dependence and generic to the normal physiology process of breastfeeding. The third theme concerned emotional support and the influence of psychological factors on breastfeeding perceptions. The fourth theme related to the environmental modifications required to provide NAS supportive care. The final theme did not relate specifically to the research intervention but concerned maternal perceptions of their overall postnatal experience. This theme incorporated the healthcare practices and attitudes indirectly influencing maternal receptiveness to support strategies.

Theme 1: Breastfeeding Practice

This theme concerned the practical aspects of breastfeeding support. It included the availability and access to support services and the perceived quality of the support to meet breastfeeding needs. Participants mentioned the physical difficulties encountered whilst attempting to breastfeed an infant experiencing withdrawal symptoms. Positioning and latching of the baby at the breast was a major concern for many mothers although this is a common problem reported by all demographic groups. This situation was exacerbated in opioid dependence due to the baby's poor sucking coordination and neonatal agitation interfering with feeding ability.

Overwhelmingly, the practical aspects of infant feeding drew most responses from both the intervention and control group:

> "Especially showing me the rugby ball position which I found much easier"
>
> *(Intervention; breastfeeding W6)*

> "Helped me latch on when struggling with different positions"
>
> *(Control; breastfeeding W6)*

Scheduled proactive visits were viewed positively with several participants emphasising the value of additional support. For some this was in response to a perceived lack of availability of ward staff:

> "I was really pleased with the extra support of a worker coming in and helping me as the midwives on duty are very busy and sometimes can't help."
>
> *(Intervention; breastfeeding W6)*

Access to a support worker resonated as a key advantage amongst the intervention group and was considered as a 'safety net' for those who were confident in their breastfeeding ability but felt reassured by the knowledge that a visit from a support worker was guaranteed:

> "Having someone here for me just in case was a great thing."
>
> *(Intervention; breastfeeding W6)*

Theme 2: Information Provision

The provision of information was discussed in relation to advice regarding the normal process of breastfeeding, and this was viewed as an essential component of support:

> "The staff are amazing, patient and kept me well informed."
>
> *(Intervention; breastfeeding D5, formula W6)*

> "I always thought that milk was just there when a baby was born I didn't realise it had to build up so when I was only producing 5 ml I thought it was me but the staff were good at reassuring and encouraging."
>
> *(Intervention; breastfeeding D5, formula W6)*

However, generic advice on breastfeeding lacked sufficient relevance for some respondents. It was suggested that more targeted information on NAS would be beneficial, especially the course and management of withdrawal symptoms. One mother singled this out as a failing of the support given:

> "I have had plenty of advice and encouragement about breast feeding from hospital staff but not very much advice or information about babies with symptoms of 'NAS'."
>
> *(Control; breastfeeding D5, formula W6)*

Theme 3: Psychological Factors

The theme of psychological factors included the provision of emotional support to sustain breastfeeding and the influence of practitioner actions, attitudes and demeanour on maternal perceptions of support.

Participants remarked on the importance of positive reassurance and the encouragement offered by the support worker:

> "The five days was very positive and having someone here for me encouraging me daily was brilliant."
>
> (*Intervention; breastfeeding W6)*

The demeanour of the support worker, such as conveying a relaxed atmosphere, influenced maternal opinion of the usefulness of the

breastfeeding strategies and reduced the degree of anxiety felt. This emphasised the impact of not only what practitioners do but as importantly how they do things in respect of attitudes and non-verbal behaviour:

> "when (support worker) came to help us she was great, she had a wide knowledge and was very laid back, made things feel so simple and natural"
>
> (*Intervention; breastfeeding W6*)

Theme 4: Person-Centred Factors

A person-centred approach focussed on providing individualised and socio-culturally relevant support. Several responses noted the benefit of a dedicated support worker and the positive experience of having time allocated exclusively for them:

> "Knowing someone was coming to help me every morning was ace."
>
> *(Intervention; breastfeeding W6)*

Individualised approach included identifying the level of support required and tailoring daily sessions accordingly:

> "To be honest my baby latched on with no problems at all, so didn't need any help at all but I was asked if I wanted any help."
>
> *(Intervention; breastfeeding W6)*

Theme 5: Environmental Factors

The inability to adopt supportive measures, such as reducing environmental stimuli to limit withdrawal severity, was cited as a negative feature of the postnatal experience:

> "I was on a ward with 4 other lady's & 4 other babies. It was a bit impossible to create a quiet environment especially at visiting time. There is no way I could have dimmed lights for my baby."
>
> *(Control; breastfeeding D5, formula W6)*

Alternatively, a mother in the control group brought her own consolation equipment, reporting that she found these very useful:

> "I only know of swaddling through talking with my community midwife before being admitted to hospital. I would advise anyone whose baby may have symptoms of NAS to get one of these swaddle blankets."
>
> *(Control; breastfeeding D5, formula W6)*

Theme 6: Postnatal Experience

Some participants offered comments about their postnatal experience, although these were not directly related to infant feeding support. These focused on issues of privacy, confidentiality and respectful practice. With the lack of confidentiality, particularly when discussing substance use, highlighted as a major failing. The implications of compromised confidentiality for opiate maintained clients can be devastating in terms of loss of trust, stigmatisation from other services users and fear of being ostracised. It is essential that discussions are conducted in a sensitive manner with a heightened awareness of precautions to safeguard privacy:

> "As I was on a ward with other ladies & baby's I found it wasn't very private and some of the staff were quite "easy" to discuss confidential matters openly without a thought for who might be listening on the other side of the curtains going around the bed."
>
> *(Control; breastfeeding D5, formula W6)*

One mother noted that a change in the clinical environment influenced her breastfeeding experience. She felt confident establishing breastfeeding whilst in a single room on the postnatal ward, before her baby was transferred to the neonatal unit for ongoing management. In this setting, she felt uncomfortable breastfeeding in a general area, and subsequently limited her opportunities to establish breastfeeding:

> "The only negative thing I have about my whole learning to breastfeed experience is that when in the neonatal unit I didn't feel comfortable breastfeeding in front of other visitors, even with the screen it always felt too busy which made me wait until late feeds when it was quiet to feed."
>
> *(Intervention; breastfeeding D5, formula W6)*

Although these comments were not directed at the research study conduct they send a strong message to all HCP to be respectful of the circumstances of others and vigilant as to how actions, or omissions, can have wide ranging consequences. These experiences negatively affected the opinion of this participant of healthcare practices and professionals. This failing in care impeded the establishment of a therapeutic relationship between the mother and HCP. Subsequently, trust and confidence in the system as a whole can be jeopardised, and indirectly, maternal receptiveness to breastfeeding advice.

6.5.8 Protocol Fidelity

The fidelity of intervention delivery was based around the provision of the individual support components of raising awareness of the practical art of breastfeeding, psychological support, provision of environmental modifications and addressing the participant's individual needs. The support workers recorded on the daily assessment log which of these aspects were discussed and in collaboration with the participants set goals around the elements identified as of concern to the mother. Breastfeeding practicalities were observed, discussed and advice given at every visit undertaken. This included breastfeeding technique, positioning, attachment, milk expression and specific challenges such as breast discomfort and neonatal weight loss. Following practical aspects, the provision of environmental modifications and use of consolation techniques were most frequently discussed at the intervention sessions. Psychological support was provided as positive reassurance, praise and acknowledging the commitment and motivation shown by the mothers. As the sessions progressed there was a noted increase in maternal confidence in child-care and the workers recorded that the participants were more 'chatty', 'relaxed', with one mother expressing how much she had enjoyed the daily visits. Towards the end of the intervention period there was also an increase in questions regarding medication, secondary withdrawal and discussion on personal lifestyle and expectations for the future. With two participants, there were lengthy discussions regarding their problems with the ward staff and their resulting feelings of being judged and that their commitment to breastfeeding was doubted. Both participants reported being upset by these interactions and reluctant to ask for breastfeeding assistance at times when the support worker was not available.

In addition to the individual support components fidelity of the intervention was assessed on the ability to implement the logistical elements stipulated in the protocol. The main elements were separate control/intervention areas; first visit within 12 hours of birth; daily session of up to 1 hour and continuity of support worker; single room and maintenance of environmental modifications. For the intervention group the details of which support element were demonstrated or discussed, and a record of this discussion,

were recorded by the support worker on the daily assessment log. These details were collected from the maternal/neonatal postnatal record for the control cohort. Table 38 details the intervention protocol fidelity with the duration of the intervention sessions stated in minutes. Table 39 details the control group conditions.

Table 38: Intervention Group Protocol Fidelity

	FV (hours)	Day 1 (D mins)	Day 2	Day 3	Day 4	Day 5	Duration of trial
2	5	40	60	NEONATAL	UNIT		2 days
3	8	30 S/E	45 S/E	20	40	60	completed
4	17	20	60	20 E	25 E	20	completed
7	6	35	50	50	60	60	completed
8	3	15	10	40	20	25	completed
10	44	S/E/C	45	15	20	40	completed
12	14	20	NEONATAL	UNIT			1 day

Key: FV= time of first visit following birth of baby (in hours); D= duration of session (in minutes). S= single room not available; E= environmental modifications not achieved/maintained; C= no visit or not continuity of care-giver.

Intervention components discussed: P=practical; I=informational; Ps= psychological; Pc=person=-centred; E=environmental.

Green =protocol met; Red= certain protocol conditions not met; Yellow= infant admitted to neonatal unit and trial discontinued.

Table 39: Control Group Protocol Fidelity

Control	Day 1	Day 2	Day 3	Day 4	Day 5	Duration of trial
1	S					completed
5	S	S	S	S	S	completed
6		NEONATAL	UNIT			1 day
9						completed
11			NEONATAL	UNIT		2 days
13	NEONATAL	UNIT				5 hours
14		NEONATAL	UNIT			1 day

Key: S= single room not available.
Green =protocol met; Red= certain protocol conditions not met; Yellow= infant admitted to neonatal unit and trial discontinued.

6.5.8.1 Assessment of Protocol Fidelity

A protocol condition was a separate postnatal ward for intervention and control members, to limit the opportunity for cross-contamination bias. This was found to be unworkable due to the limited availability of single rooms and recruits were transferred to whichever ward could provide a vacant room. However, this protocol recommendation proved to be unnecessary. It became evident, as the study progressed, that due to the number of women recruited it was unlikely that there would be more than one trial participant at any given time and an overlap of study recruits did not occur.
A priority element of the intervention was to maintain continuity of the same dedicated support worker for the five-day duration of the feasibility study. This was logistically challenging but achievable. A limited time-frame was available following randomisation to the intervention group and before the first scheduled visit. An available support worker had to be assigned and the first visit undertaken within 12 hours. Continuity of care-giver was achieved successfully for six of the seven participants. In one case the allocated support worker was unable to attend the first visit due to personal illness and

another support worker was appointed. Subsequently there was a gap of over 40 hours before the initial contact by a support worker was made. The first visit within 12 hours of birth was recommended as it was felt that early contact between the mother and support worker would enable NAS supportive measures to be instigated and the immediate needs of the mother identified. However, in practice, this was not achievable or advantageous. If the first visit was soon after the birth, the mother and/or infant were too tired and not ready to engage. These early sessions appeared to involve introductions and, for some, discussion on consolation techniques. The initial sessions that occurred later tended to have a greater range of components discussed. The support workers verbally reported that they found this a more productive method.

A single occupancy room was deemed as the most suitable accommodation to maintain environmental conditions and afford the participant a level of privacy to openly discuss matters. This proved the main barrier to efficient implementation as securing a room was on on-going problem. During the trial period three mothers were initially roomed in a multi-bedded area, one intervention and two control group participants. A single room became available for two of the women (one intervention/one control) but one control group participant remained in a multi-bedded area for the duration of her hospital stay. When a single room was available, the modifications made were temporary measures and installed and removed relatively simply. The modified cot and consolation equipment were portable and brought to the area as required. For one infant, the use of the cot canopy was restricted, at the request of the paediatrician, due to signs of physiological neonatal jaundice. Direct sunlight can be beneficial in the conjugation of bilirubin in neonatal jaundice, although this practice is historical and is not without consequences. The cot canopy was removed during day light hours on day three and four. For most participants the modifications were achieved and sustained.

The study protocol stipulated that a designated support worker was allocated to deliver the intervention for up to a maximum time of one hour daily. The time frame of one hour was chosen pragmatically and based on the anticipated time required for the support worker to advise on infant feeding and NAS management and collaborate with the mother to set the daily plan.

The objective of recording the individual session time was to allow a more considered estimation for the definitive research trial. It was at the discretion of the mother to dictate the time, duration and indeed the content of the sessions to individualise the approach. It was also important to assess whether one hour was needed, and if so could it be integrated into the existing service without disrupting other staff groups. The daily sessions had to accommodate the inflexibility of hospital routine, such as set meal times and visiting policy. The findings demonstrated that the total time spent in contact with the mother/baby dyad ranged between 2 hours 05 minutes to 4 hours 05 minutes for those who were visited for the full 5 days. The duration of the sessions varied between women and from day to day, with some visits terminating after 15 minutes. There were sessions that lasted for the maximum of 1 hour but this was the exception rather than the norm. In general, the average time spent was considerably less than the allocated one hour.

Part of the intervention recommendation was minimising external stimuli by limiting the noise and activity around the mother/baby dyad. Ward staff were requested to perform cluster care to minimise interruptions, but this was unworkable due to the frequent shift changes. Additionally, several sessions were terminated prematurely due to other HCP or the arrival of family members. Overall, the success of integrating the daily session into the ward routine varied between individuals.

6.6 Chapter Summary

The chapter described the outcomes of the feasibility study. As the purpose was to address the question of 'can this be done', assessing feasibility was the primary aim (NIHR). Secondary considerations included the trend of breastfeeding continuation and the impact of infant feeding method on the severity of NAS. It also provided data to evaluate the research methods for their suitability to assess clinical efficacy in a future trial. Overall, the feasibility study addressed outstanding questions regarding intervention acceptability and fidelity of implementation and enabled an assessment of the deficiencies of the design prior to considering possible modifications.

CHAPTER 7
Discussion, Conclusion and Recommendations

7.0 Introduction

This chapter discusses the key findings of the thesis. This includes the feasibility study outcomes and an assessment of the project's contribution to the existing evidence base. The research strengths and limitations are forwarded in the context of the micro environment of the study and at macro level of government initiatives and global policies. There follows an analysis of the findings in relation to current literature and concludes with recommendations for practice, policy and research.

7.1 Key Findings

There were a number of key influencing factors, identified in Chapter 1 and 2 of the thesis, that governed the direction of the research process and choice of design. These were:

- The potential willingness of the population to engage in research.
- Which support components were necessary and appropriate to include in the intervention.
- Whether a breastfeeding support intervention would be acceptable to the target population and feasible to implement with fidelity.
- The need to derive statistical and structural parameters to inform the development of an adequately powered RCT for future assessment of the clinical efficacy of the intervention and its impact on breastfeeding rates and severity of NAS.

These points were revisited considering the knowledge gained during the research process and the data generated by the feasibility study. This constitutes the key findings of the thesis.

Finding 1: Research Engagement and Substance Dependence

The 'think aloud' recruitment rate and the feasibility recruitment and retention rates demonstrated that the sample population of this study were open to research participation, albeit under the given circumstances. Whilst the specific context may raise issues with generalisability, this finding is supported by several other recent publications focussing on the experiences and needs of this socially marginalised group. The combined weight of this body of evidence challenges the historic view that the substance dependent population are reluctant to engage with research.

Finding 2: Intervention Development

Phase 1 identified practical, informational, psychological, person-centred and environmental issues as influential determining factors in the breastfeeding decisions of opiate dependent women.

These determinants were theoretically underpinned and realised as an applied clinical model designed to support continued breastfeeding. The model incorporated contemporary research evidence and best clinical practice guidelines, whilst acknowledging and responding to the recommendations forwarded by service users and providers. Culturally relevant and subject specific strategies were adopted to optimise receptiveness and acceptability. The main tenet of the intervention was to facilitate breastfeeding knowledge and practice, promote maternal self-efficacy and emotional resilience through a capacity building approach situated within a conducive low stimuli environment.

Finding 3: Feasibility Assessment

The RCT demonstrated that given a suitable location the intervention was feasible to implement and fidelity could be maintained when delivered by dedicated support workers. The design and constituent components of the support intervention were also acceptable to the service users. This shows promise for the practical application of the intervention and provides the opportunity to consider how this model could be implemented either within or by modifying existing resources.

Finding 4: Randomised Controlled Trial Outcomes

The intervention was supportive of continued breastfeeding and on the 5th postnatal day the rate of breastfeeding was nearing statistical significance for the intervention group when compared to the control group. There was a statistically significant difference in the degree of maternal confidence in breastfeeding ability, with the intervention group recording higher levels. Whilst these results must be viewed within the constraints of the limited efficacy of a feasibility study, it does underscore the potential of the intervention to support breastfeeding establishment in this population. Fewer breastfed infants required pharmaceutical management to alleviate NAS symptoms compared to their formula fed counterparts. The relationship between infant feeding method and NAS severity was nearing statistical significance, with breastfeeding associated with a milder expression of neonatal withdrawal. Correspondingly, there was a statistically significant difference between the length of stay for breastfed infants, who recorded shorter hospital durations, than infants who were formula fed. These findings corroborated the existing retrospective reviews of the impact of feeding method on the severity of NAS. Additionally, by utilising an experimental design rather than retrospective chart reviews this work adds a different research perspective to the available literature and makes a valuable contribution to the evidence base.

Finding 5: Research Contribution

The 'think aloud' protocols proved an innovative method and person-based approach to gain participant recommendations for the development of the intervention. This method successfully fulfilled the research objective whilst providing an inclusive and flexible approach which was sensitive to the needs of the cohort. As marginalised groups are frequently under-represented in healthcare research exploring a novel application of an existing and established method raised the possibility of using 'think aloud' protocols for future investigations and with other disengaged groups.

The feasibility study findings offer a timely contribution to the limited knowledge base on breastfeeding support complicated by substance dependence. The intervention elements, those implemented successfully and positively received by participants, can inform the development of targeted breastfeeding support. Equally, the areas deemed as unsuccessful and in need of modification can alert developers to anticipate, adapt or avoid these. Collectively, this presents guidance for stakeholders, policy makers and researchers when planning appropriate services on behalf of this group.

7.2 Strengths and Limitations

Utilising a feasibility design and mixed method approach was considered a strength of the study. Incorporating qualitative and quantitative approaches enabled a comprehensive exploration of the research context from contrasting philosophical and methodological perspectives whilst generating an extensive body of both existing and new evidence. This was of paramount importance given the multi-factorial nature of breastfeeding, the complexities of behaviour change science and the sensitive nature of research with socially vulnerable participants. Integrating differing viewpoints optimised the potential efficacy, relevance and acceptability of the intervention and implementation fidelity. The range of data collected as part of the feasibility study provided substantial data to assess which intervention elements worked, why they worked and in which context. This information can also be used to modify and strengthen the intervention design and offer direction for the next phase of the research.

A strength of the research was its relevance in respect of current global, national and local policies. The promotion and support of breastfeeding to tackle health inequalities is an area of substantial concern and not insignificant investment world-wide. Currently, as a group at risk of health and social inequalities, opioid dependent women and their babies are grossly underrepresented by research which focusses on their unique infant feeding needs. Whilst the historic position of discouraging has been replaced by actively supporting breastfeeding in this cohort, the evidence base has not kept pace with the changing requirements of practice and policy.

This study gives the opportunity to tackle this evidence/ practice /policy gap as research contributing to an increased understanding of the breastfeeding needs of vulnerable groups will enable stakeholders to align strategies appropriately to the specific needs of the community.

National NHS directives advocate placing the individual at the heart of decision-making during management consultations. A fundamental tenet of the intervention was to promote an individualised and holistic approach, situating the mother/infant dyad at the centre of support decisions and minimising the use of ritualistic practices. As part of the daily sessions, and in collaboration, infant feeding goals were set acknowledging the individual capacity of the mother and baby to tackle their identified barriers and limitations. Thus, goals were personalised to the issues which mattered to the women, when they mattered and strategies tailored accordingly.

The 'think aloud' verbal protocols demonstrated the potential of this technique as an interviewing tool with the substance dependent community. Although not all the participants engaged fully with the 'think aloud' procedure, the generated data met the aim of providing recommendations for intervention development. Given this, possibilities remain for the use of 'think aloud' with different phenomenon. Additionally, the successful execution with this population may aid its adoption with other marginalised sectors of society who are disengaged from research participation. This can only enhance professional knowledge of the perspective of disenfranchised groups and lead to services which better serve their needs.

Conversely, the 'think aloud' sessions could also be considered a limitation of the study. This approach used predefined intervention elements as prompts and may have deterred some participants from forwarding their own

recommendations. The findings also leaned heavily towards infant feeding practicalities and environmental modifications with limited discussion regarding psychological components. Conducting semi-structure interviews may have resulted in a more extensive range of opinions, certainly more personalised to the individual. Additionally, the interviewer would have had the opportunity to introduce the concept of psychological support. Subsequently a more robust base for intervention development may have emerged. However, this must be weighed against the documented reluctance of this population to engage with traditional methodologies.

The current literature on the impact of infant feeding method on NAS severity is dependent on clinical observation and retrospective chart reviews. This study demonstrated that it is possible to undertake a randomised trial with this cohort. This may encourage other research groups to consider this methodological approach for a more robust exploration of NAS management. Additionally, as a RCT, the inherent bias-limiting design makes this a valuable contribution to the evidence base, strengthening the current clinical position of promoting and supporting breastfeeding.

Whilst the purpose of a feasibility study, and its sample size, limits statistical significance, the clinical significance of reduced neonatal hospitalisation and prevention of mother and baby separation cannot be discontinued as a primary driver for service improvement or research innovation. Statistical significance is essential in the assessment of efficacy but in healthcare the human elements of patient satisfaction and well-being are equally important and encouraging outcomes.

It is accepted, however, that all research has limitations. Acknowledging these allows an analysis of the work within its contextual constraint and highlights areas which may benefit from further exploration. A limitation of the study was the use of a single site only and the homogeneity of the population. The research project was conducted in one tertiary hospital in Scotland, the participants were recruited from the same clinic and all were of similar socio-economic circumstances. Although the aim was to recruit from both urban and rural areas this was not achievable. Therefore, the research may not be representational of other geographic settings, cultures, demographic groups or where health service provision differs.

The majority of the participants, either the mother or the baby, were still in-patients in the hospital when they were interviewed or completed the questionnaire. The women may have been reluctant to criticise care whilst still in contact with health services. The possibility of social desirable responses, therefore, cannot be discounted.

Additionally, the questionnaire content and construction were reviewed during the 'think aloud' sessions but was not subject to a comprehensive re-evaluation and validation process. Due to this, the possibility exists that some ambiguity of terms or concepts may have affected responses. Formal validation of this questionnaire presents a research opportunity, both to enhance the data collection of this project but also as a tool for use in other studies that aim to evaluate breastfeeding satisfaction and service improvements.

The potential of the expert advisory group was perhaps not exploited fully. As discussed in the thesis it was not possible to convene a series of meetings as per the original protocol. Additionally, the team may have benefitted from inviting key personnel from labour suite and addiction services. A group member to champion the research with labour ward midwives may have improved dissemination of and recruitment to the study. The inclusion of an addiction specialist may have proved insightful into the social dynamics and wider context of the experience of those with a substance misuse disorder. They are key agents in addressing substance use at individual, family and community level and operate within a wide multi-disciplinary arena. Their expertise in interpersonal communication and supportive counselling could have proved an asset whilst considering the training and skill set necessary for delivery of the intervention. Whilst the research measured continued breastfeeding in the initial postnatal period, long-term sustained breastfeeding is the ultimate aim for optimal maternal and infant well-being. As a future objective, the research will consider support beyond the hospital environment and the knowledge and influence of addiction specialists regarding peer and community barriers and the day-to-day experience of the opioid dependent would be beneficial.

The perspective of the support workers of their experience of intervention delivery may have provide a platform to review the usefulness of individual components and feasibility issues. Additionally, whilst the support workers

received a single induction session prior to delivering the sessions they perhaps identified additional training needs during the research. Due to time constraints it was not possible to undertake a formal evaluation of their views during the study period. This omission does limit the comprehensiveness of the feasibility assessment from the position of service providers.

7.3 Discussion

The key research findings detailed above are discussed further to situate these within the existing literature and consider the implications raised by this work for the current evidence base.

7.3.1 Research Engagement and Substance Dependence

Research engagement and the ability to recruit sufficient participants was an area of concern. Poor recruitment rates have been well documented amongst marginalised groups, with the substance dependent population falling into this category (Taylor and Kearney 2005). Additionally, despite data confirming the minimal bioavailability of methadone in breast milk, the limited understanding of this safety profile amongst mothers and practitioners has contributed to inadequate breastfeeding promotion and initiation (Balain and Johnstone 2014). In conjunction, acceptable data collection methods, which are sensitive to the needs of those with substance use disorders, and simultaneously meet research objectives, have challenged previous authors. A key consideration of the study, therefore, was to optimise recruitment and find a research method which was empathetic, inclusive and responsive to participant circumstances.

The pilot RCT target size was not met in the set time allotted although the study did coincide with an unexpected drop in the clinic caseload resulting in a marked reduction in the sample population. It can be argued, however, that the high percentage of those referred who agreed to participate in the study attested to the acceptability of the research aim and methods. Conversely, the women forwarded by the gatekeepers had expressed an interest in the research study and, therefore, were more likely to be

receptive to participation. Additionally, by choosing to enrol on a substitution programme they had actively demonstrated their commitment to engage with health services and behaviour change. This shows a high level of motivation on their part. Pregnancy is also considered a main driver of health promotion for substance dependent women (Fraser *et al.* 2007). This suggests that the participants were proactive and motivated individuals and ergo, more likely to be receptive to the intervention and to persevere with breastfeeding in the face of challenges. For the breastfeeding intervention to be sustainable and have the potential to achieve long-term impact, however, it needs to be effective, relevant and accepted by many the target group, not merely those who are already strongly committed to this aim. Questions must be asked, therefore, whether the generic factors identified in the literature regarding research reluctance were at play or if there were additional barriers inherent of the local setting and group.

It can be assumed from local infant feeding statistics that a predominant reason for non-engagement was that a substantial number of women had already made the decision to formula feed. Formula feeding is the method of choice for disadvantaged groups and despite extensive breastfeeding promotion rates remain well below the general population. Behnke *et al.* (2013) proposed a major factor in the high rates of formula feeding in substance dependence was a lack of accurate information on breastfeeding benefits, affecting both service users and providers. In the study area, the accepted practice was to offer clinic attendees generic infant feeding leaflets, with breastfeeding and opiate maintenance discussed on an individual basis at the discretion of the attending midwife. This ad hoc provision may have been a barrier to breastfeeding promotion in the current study and thus an impact on the number of eligible candidates in the local area. The promotion of breastfeeding in the antenatal period was alluded to during the expert advisory group meeting as an area that would benefit from service improvement. The need for subject specific information, potentially as leaflets or web-sites regarding breastfeeding and substance dependence, has been forwarded in the literature (Balain and Johnstone 2014; Jansson *et al*. 2015). Yet, as demonstrated by the history of health promotion, information is rarely effective if given in isolation and the context of when and where delivered and by whom are all influential factors. Further research is

warranted to review the information needs of the population if breastfeeding management is to be optimised.

Existing literature has discussed the influence of gatekeepers on the response to research shown by the target population. Poor dissemination and recruitment can be the result of gatekeeper misgivings or disinterest regarding the research or a lack of time to introduce the subject during client consultation (Emmel *et al.* 2007). Murphy and Rosenbaum (1999) reported conflict with gatekeepers in their longitudinal survey of the life-view of drug addicts. They found the personal eligibility criteria imposed by the gatekeepers, and which women they approached for research participation, introduced recruitment bias and greatly reduced the referral rate. It has been suggested that gatekeepers may be motivated by non-maleficent, and the belief that the potential vulnerability of this group requires supplementary eligibility criteria above the existing research conditions. This is consistent with midwifery literature describing the paternalistic attitudes of practitioners who act without client consultation in what they perceive as the best interests of women and babies (Bailey *et al.* 2006; Redshaw and Henderson 2012). However, these approaches limit personal autonomy by not ascertaining individual wishes or providing the opportunity for women to make their own decisions. This is an area for scrutiny within the local setting, as the values and prejudices of HCP may have influenced their judgements and actions, including whether they considered it was appropriate to make these decisions on behalf of others. Whilst society may class groups as 'vulnerable', this does not mean that individuals define themselves in this way. A retrospective review of the gatekeeper's research experience and decisions is a possible avenue to investigate their underpinning philosophies.

To overcome perceived recruitment barriers associated with traditional methodologies several authors have employed innovative research methods. Jambert-Gray (2014) explored the transition to motherhood through the medium of art by asking substance dependent women to draw their concept of a good mother and Murphy and Rosenbaum (1999) described their data collection approach as intimate conversations. The current study used the novel approach of 'think aloud' verbal protocols to gain participant design recommendations. This method was conducive to participant sensitivities,

particularly their reluctance for the sessions to be recorded and the anticipated time and physical constraints of early motherhood.
However, as the 'think aloud' method employed predetermined elements as prompts, it could be surmised that this may have restricted consideration of other support measures. A more in-depth exploration of support needs and beliefs might have elicited other infant feeding behaviour determinants. Or, arguably, as the existing literature has demonstrated with the previous use of traditional approaches, it may have restricted recruitment.
Overall, the study recruitment and retention rates would suggest that the local population were willing to participate in research under the given circumstances. These conditions included a flexible and pragmatic data collection method which was responsive to their distinct demands. Both the conduct of the study and the components of the intervention, however, could be strengthened with further research.

7.3.2 Intervention Development

The intervention development process consisted of a comprehensive systematic literature review and 'think aloud' verbal protocols to ascertain breastfeeding behaviour determinants. An expert advisory group provided recommendations on development and implementation strategies.
Collectively, the synthesised evidence suggested that within the context of opioid dependency there was an interdependent relationship between five influencing behaviour determinants. These determinants included breastfeeding skill and knowledge; psychological factors such as self-efficacy and feelings of guilt and responsibility; a person-centred and culturally relevant approach to support and the prevailing environmental conditions. These factors were underpinned with the theoretical principles of behaviour change to optimise intervention efficacy (Conner and Norman 2005).
Evidence and theory integration included aligning the behaviour determinants to theoretical constructs implicated in the mechanism of behaviour change; identifying the appropriate intervention functions aimed at targeting the change process and finally realising these as practical components of a support model (Michie *et al.* 2008; Glasziou *et al.* 2010).

The individual intervention components and implementation strategy are discussed in the following sections.

7.3.2.1 Practical Component

Practical support was an integral part of the intervention. The systematic review found strong evidence to indicate that the availability of practical assistance and advice on the normal process of breastfeeding, that both supported and enabled maternal skill acquisition, was an important factor in breastfeeding continuation (MacVicar and Kirkpatrick 2014). This echoed existing research describing the loss of personal and community breastfeeding awareness and the resulting demand for healthcare services to fill this gap with appropriate support programmes (Chapman and Perez-Escamilla 2012; Thomson *et al.* 2012). The 'think aloud' respondents mentioned the physical difficulties encountered when attempting to breastfeed an infant experiencing withdrawal symptoms, highlighting the need for targeted assistance. Training and education, with an emphasis on the impact of substance exposure, were identified as behaviour change techniques with the potential to address these issues.

The practical elements of the intervention were well-received and proved a key area of support with participants mentioning these as highly beneficial. The daily logs highlighted the importance of gaining maternal technical expertise with the supporters either observing, discussing or providing practical advice as part of every session. This resonates with other literature which intimates that maternal opinion of the adequacy of practical support can be coloured by perceptions of a lack of availability of staff to assist them. Therefore, staff unavailability is frequently cited as a barrier to successful breastfeeding as women feel unsupported and unattended (Redshaw and Henderson 2012). The provision of a dedicated, proactive support worker was considered as a means of overcoming this and participant evaluation attests this.

7.3.2.2 Informational Component

The availability and accessibility of both generic breastfeeding information and that unique to substance exposure was identified as an essential component of supportive practice. The systematic review concluded that inadequate, incorrect and conflicting advice was a common occurrence resulting in maternal confusion, disillusionment with the support provided and a handicap to informed decision-making. Indeed, the impact of poor information provision or poor communication leading to limited understanding has been frequently cited by health services users, and given as a reason for premature breastfeeding discontinuation (Redshaw and Henderson 2012; Lagan *et al.* 2014). A key barrier noted in the 'think aloud' sessions was the absence of relevant advice on the consequences of NAS and impaired maternal concentration which affected the ability to process and retain information. Jansson and Velez (2012) previously reported a lack of professional understanding of, and insight into, the additional and unique support needs of opioid dependent women and Demirci *et al*. (2015) found misinformation from professionals represented a modifiable barrier to successful breastfeeding in this cohort. These studies concluded that generic information was insufficient to tackle the complexity of the situation and whilst practitioners remained ill-informed and ill-prepared a conducive environment could not be fostered in which opioid dependent women felt supported.

A contributory factor to the dissemination of current evidence may have arisen as a consequence of the centralisation of specialist substitution medication services for pregnant women. Dedicated clinics have brought substantial improvements in management but it has limited the contact of other professionals with this cohort, with a resulting loss of expertise (Hall and van Teijlingen 2006). The feasibility study findings reflected this situation with control participants noting that advice on NAS was not proffered on the postnatal ward and they encountered difficulties obtaining information. Accordingly, an experienced support worker, knowledgeable in the challenges of facilitating infant feeding complicated by NAS, was a key aspect of the intervention. Comments passed by participants regarding the informational component were positively framed and intimated that this was an acceptable and useful element of support.

7.3.2.3 Psychological Component

Promoting an emotionally supportive environment, establishing a facilitative relationship and employing strategies to target the psychological factors implicated in infant feeding decisions were core principles on which the intervention was based.

Maternal self-efficacy, and by association verbal persuasion, encouragement and emotional resilience, was identified in the systematic review as a key influence in breastfeeding behaviour. Indeed, the importance of a psychologically supportive environment to counteract the myriad of emotions which impact on breastfeeding has been extensively researched (Dennis 1999; Burns *et al.* 2012; De Jager *et al.* 2013). Emotional support has particular resonance in substance addiction, with the 'think aloud' participants discussing feelings of guilt, responsibility and demotivation and the importance of HCP acknowledging these and demonstrating understanding, empathy and compassion. The intervention cohort described feeling boosted by daily encouragement and maternal anxiety was minimised by reassurance and the positive attitudes of the support workers. The daily logs reflected that participants became increasingly 'chatty' and 'relaxed' with each progressive session and more likely to open discussions on substance use and their lifestyle challenges. However, delivery of the psychological component of the intervention relied on the existing knowledge and expertise of the support worker. Whilst an induction programme was given it was not possible to comprehensively cover a full range of psychologically based therapeutic interventions. There is arguably a requirement to provide instruction around interpersonal communication skills and areas such as counselling and motivational interviewing to enhance the possible efficacy and scope of the intervention.

A facilitative relationship is considered an essential part of supportive practice with the efficacy of this dependent on the perceived authenticity of the connection between the supporter and the mother (McInnes and Chambers 2008; Schmeid *et al.* 2011). Subsequently, negative encounters due to unhelpful actions, attitudes or omissions, can impair the development of a rapport not only between the mother and the HCP involved but also in future interactions with professionals (Cleveland and Bonugli 2014). Similarly, the systematic review demonstrated that stereotyping of

disadvantaged groups, judgemental attitudes and paternalistic actions resulted in rejection of proffered advice. These barriers have been well-evidenced both in respect of the relationship between HCP and the substance dependent population and separately in breastfeeding literature (Maguire 2013; Behnke *et al*. 2013; MacVicar *et al*. 2015). This emphasises the importance of establishing a respectful relationship to optimise the acceptability of emotional support. During the 'think aloud' sessions the respondents considered continuity of a dedicated care-giver as a useful resource as a means of gaining familiarity with the supporter. However, the feasibility study results did not confirm or refute whether this was beneficial to either the perceived efficacy of support or the enablement of a facilitative relationship. This echoes existing research with some studies promoting care-giver continuity as a means of improving maternal satisfaction with support services whilst contradictory views propose that women value the package of care associated with a small team of care-givers following the same philosophy, rather than continuity of the same individual practitioner (Green *et al.* 2000; Freeman 2006; Sandall 2014; Forster et al. 2016). On consideration of the logistics of maintaining fidelity of a single care-giver, and the possibility of a personality clash, it may be as effective and less resource intensive to establish a team of supporters for future trials.

7.3.2.4 Person-centred Component

The intervention promoted a person-centred approach with the explicit aim of identifying and acknowledging maternal wishes and needs and working together to realise these. The systematic review noted the importance of care tailored to individuals and this affirmed previous research by Schmeid *et al.* (2011) which suggested that HCP should discuss the personalised breastfeeding aims of the woman and her family, and in collaboration facilitate ways in which to achieve these. Similarly, MacGregor and Hughes (2010) proposed that healthcare services must be responsive to the needs of the individual whilst Lagan *et al.* (2014) reported maternal disillusionment with prescriptive practices and routinized care. Neither the intervention nor the control group commented on the impact of individualised or generic strategies to support breastfeeding. For the intervention cohort, the key

theme resonating from the person-centred focus of the support model was the reassurance of knowing that a dedicated support worker was available each day and this time was allocated exclusively to them.
Part of a person-centred approach included consideration of the implications of substance dependence and modifying actions or attitudes to limit maternal distress. One control participant reported the lack of privacy when discussing substance addiction with HCP. Situations compromising confidentiality can be devastating for substance dependent clients in terms of stigmatisation from other services users, fear of being ostracised and a loss of trust in healthcare providers (Chandler *et al.* 2013). Thus, it is essential that discussions are conducted in a sensitive manner with a heightened awareness of the need to take precaution to safeguard confidentiality and privacy. Conversely, the impact of internalised stigma and low self-confidence can result in women being 'over-sensitive', as reported by one respondent, and misconstruing the actions of practitioners. This consolidates the recommendation that supporters receive training in interpersonal and communication skills to be both attuned to the nuances of verbal and non-verbal behaviour and respond appropriately.

7.3.2.5 Environmental Component

The 'think aloud' sessions demonstrated that maternal understanding of supportive management was variable and strategies were inconsistently applied. Therefore, installing and maintaining environmental modifications to minimise external stimuli were an integral part of the intervention. Additional resource included consolation equipment and personnel with the specialist knowledge and expertise to facilitate mothers to respond appropriately to the infant's behavioural cues (Velez and Jansson 2008). The respondents noted that if neonatal supportive management was not practiced, or not possible for those in a multi-bedded area, there was a marked increase in the expression of neonatal withdrawal symptoms with infants displaying adverse neuro-behaviour. This compromised the ability to physically breastfeed and thus undermine maternal confidence in her ability to adequately nourish her child.

The physical feeding difficulties associated with NAS have consistently been reported as a major determinant of breastfeeding discontinuation (Wachman 2014; Jansson and Velez 2015). The role of the support worker involved practical assistance to minimise the technical challenges of uncoordinated feeding patterns but also to collaborate with the mother in a capacity building approach to facilitate her awareness of the infant's internalised and externalised signs of withdrawal. The mother is in the privileged position of exclusively attending to her infant and sustained involvement can enable a therapeutic relationship for both (Pritham *et al.* 2013).

7.3.3 Feasibility Assessment

Testing the feasibility of the intervention was a primary aim of the study. This encompassed the ability to delivery and maintain fidelity of the protocol stipulations; integration into the existing service and acceptability by service users and providers. The main challenges to successful implementation were limiting the traffic of hospital personnel in the study area and the availability of a single room. Introducing cluster care was proposed as a means of reducing the number of disturbances but this was only partially successful as it was not consistently communicated between ward personnel. Enhanced dissemination of the research protocol may have led to improved compliance with this. As an initial research study this was a new and different approach from the normal routine and it can be proposed that with further trials it could be integrated as the acceptable norm. Placing a 'do not disturb' sign was contemplated as a deterrent to repeated interruptions but the women were reluctant to do this. The reasons for their hesitance were not clearly established but it may relate to the fear of being 'singled out' or identified as opioid dependent, resulting in discrimination by other hospital users. Alternatively, during the 'think aloud' protocols, several mothers mentioned their reticence to inconvenience staff or add to the existing workload. This underpins the assumption that internalised stigma and low self-regard contribute to opioid dependent women devaluing their own worth. Either of these factors may explain why the participants felt the signs were inappropriate.

There were ongoing difficulties securing a single room within the existing hospital facility. A single room should be standard management for this cohort, but this was not adhered to in 3 of the 14 participants thereby limiting supportive care measures. Whilst the unavailability of single accommodation may be a casualty of outdated hospital environments it could imply a lack of practitioner awareness of the importance of minimising external stimuli for this group (Jansson and Velez 2011). Previous literature has surmised that allocating resources to the substance dependent mother and baby is not considered a priority compared to the requirements of other hospital users (Maguire. 2014). It has long been recognised that negative attitudes and approaches to substance dependent families exist within the health service (Corse *et al.* 1995; Gerace *et al.* 1995; Raeside 2003). Yet, despite the acknowledgement of attitudinal and organisational concerns regarding the management of this population, unsupportive practices continue to be reported in the contemporary literature (Maguire 2013; Balain and Johnson 2014). On consideration, it is fair to conclude that the most suitable environment in which to deliver the intervention is open to speculation. Contradictory views were expressed by service users and providers regarding single versus multi-bedded area for the intervention delivery and the feasibility study highlighted that the problem goes beyond this. Whilst the current study was undertaken in a hospital perhaps this type of facility is not appropriate for the changing needs of contemporary healthcare in this instance. The potential of future trials implemented in other settings should be explored, perhaps within designated mother and baby units with dedicated staff attuned and responsive to the distinct needs of this cohort.

A suggested criterion for feasibility assessment was the response of service users and providers to the intervention (Bowen et al. 2009). Yardley *et al.* (2015) stressed the value of investigating the beliefs, attitudes and situation of the people who deliver and use an intervention as a means of evaluating its acceptability and relevance. Hoddinott (2015) also identified service providers as a primary source of information on the subtleties of practice implementations. There are likely to be inherent structures within institutions which dictate clinical practices and attitudes, and these may not be openly apparent to those you are not directly involved. As an accepted member of

the organisation the support workers were in a privileged position of being aware of the main influences and influencers of the endemic culture (Wells *et al.* 2012). This afforded them the knowledge to predict and react to possible barriers. However, due to resource constraints the views of the support workers were not formally evaluated and this limitation weakens the conclusions drawn. There is the prospect to interview the support workers prior to future testing of the intervention. Additionally, the worker's perspective of the knowledge and expertise required to confidently and competently undertake their role could be explored. The scope to provide instruction around communications skills and neonatal developmental care are all potential considerations for future versions of the intervention. These training options could expand the comprehensiveness and efficacy of the intervention and impact on service provider satisfaction.

The feasibility study did not aim to integrate the intervention model wholly into existing services as the dedicated support workers were employed by the research team. However, as resource allocation must be a consideration for future stages of the research, the time required to deliver the intervention was monitored to inform economic costings allocation. Acknowledging the need to optimise finite resources, exploring the possibility of an equitable breastfeeding support service should be considered. This could focus on those with a substance use disorder as they stand to benefit more from additional and specialist services than the general population. This may prove a more affordable approach to the delivery of targeted interventions within existing services.

7.3.3.1 Assessment of Research Methods

The feasibility study allowed an assessment of the applicability of the research methods and outcome measures to evaluate clinical efficacy in a future trial. The Finnegan Scoring system was found to be neither a reliable indicator of the degree of NAS nor a robust data collection method. Concerns have been raised in previous literature regarding inter-rated reliability of the FS and its appropriateness to assess withdrawal severity in the constantly changing environment of poly-drug use (D'Apolito *et al.* 2014;

Osborn *et al.* 2010a). Pharmaceutical therapy or admission rate to the neonatal unit were both more accurate reflections of neonatal withdrawal.

7.3.4 Randomised Control Trial Outcomes

The RCT found that in the intervention group continued breastfeeding was more likely on the 5th postnatal day compared to the control group. This suggested that the purpose of the intervention to enable mothers to sustain breastfeeding during the height of the neonatal withdrawal period was achieved. However, the review of infant feeding status at the 6th postnatal week showed that an equal number of infants were breast or formula feeding at this time point. It is difficult to speculate on the significance of these figures, in relation to the long-term impact of the intervention, as statistics from the general population also demonstrate a substantial drop off in breastfeeding rates by the 6th postnatal week (McAndrews *et al.* 2012).

The RCT indicated an association between infant feeding method and the severity of NAS. Although it is well-evidenced that breastfeeding and the provision of breast milk have a positive impact on neonatal outcomes, with a shorter duration of hospitalisation and a reduced need for pharmacological treatment, this has not been consistently observed across all studies (Abdel-Latif *et al.* 2006; Isemann *et al.* 2011; McQueen *et al.* 2011(a); Pritham *et al.* 2012; Logan *et al.* 2013; O'Connor *et al.* 2013). These findings are based on reviews of neonatal documentation and their reliability must be considered in light of the inherent flaws of retrospective research methods where the ability to control or review confounding variables is limited and data is subject to the veracity and accuracy of others (Tashakkori and Teddlie 2010). The small scale RCT provided a robust method of assessment due to its strict randomisation process and bias limiting design (Creswell 2014). The inferences that can be taken from a feasibility study, however, are restricted by the pragmatic sample size and limited efficacy (Bowen *et al.* 2009). Nonetheless, the data demonstrated that the need for pharmaceutical management was nearing a statistically significant difference between the formula fed infants and the breastfed infants. This both supports and strengthens the retrospective reviews and this RCT can be considered as a valuable contribution to expand the evidence base. It is

imperative, however, that further prospective research, particularly research designs from the higher levels of the hierarchy of evidence, is conducted. Evidence based practice, by definition, needs evidence and it is essential that research attention moves away from its preoccupation with chart reviews and prioritises more robust methodologies.

7.3.5 Research Contribution

A key contribution to research is the unique use of 'think aloud' verbal protocols in this population. The approach was well received and two women expressed the view that it had been cathartic to have someone express an interest in their opinion. This echoes comments from previous research where respondents have benefitted from discussing their experience as a debriefing exercise (Hoddinott and Pill 1999; Redshaw and Henderson 2012). This may be especially significant for substance dependent women as the positive contribution they can make for others through research engagement may provide a form of validation of their self-worth (Demirci *et al.* 2015; Jansson and Velez 2015).

With the current emphasis on initiatives to promote health and social equalities, the substance dependent population must be a direct focus of these. There is much to gain from sustained research investment to increase awareness of the challenges faced by those affected by substance dependence. As an already marginalised group, who suffer exponentially from negative media and social preconceptions of stereotypical drug abusers, accurate depictions are required to redress the balance (Seddon 2008). The informality and adaptability of the 'think aloud' approach provides an option for securing their engagement with research, and with a comprehensive understanding of a phenomenon stakeholders and practitioners can maximise the suitability of services. To continue to underserve this population in terms of a paucity of robust evidence on which to base practice is to marginalise them further and increase their disadvantage within society.

7.4 Conclusion

There are well-recognised practical, psychological and institutional challenges to successful breastfeeding for substance dependent women, yet very little research attention has been devoted to explore ways in which to overcome these barriers (Jansson and Velez 2011, Asti *et al.* 2015). With this paucity of evidence on which to base practice, poor rates of breastfeeding will continue with the culmination of adverse maternal and neonatal outcomes (Boxwell 2010; Wachman *et al.* 2010; Balain and Johnstone 2014). Thus, this thesis recounts the initial steps of a programme of research aimed at developing and testing the feasibility of a complex healthcare intervention to support breastfeeding for the substance exposed mother and baby.

Phase 1 generated a comprehensive base of evidence with the findings suggesting that a complex and interdependent combination of practical, informational, psychological, person-centred and environmental factors influenced breastfeeding decisions. An applied intervention support model was developed by identifying theoretically derived behaviour change techniques, grounded in the findings, which aimed to specifically target these determinants.

In Phase 2 the intervention was assessed in a feasibility study. Predominantly, the intervention was delivered with a high degree of fidelity, although some elements would benefit from modification to optimise and enhance the design. Individual intervention components were well received and complemented each other to offer holistic support for the substance exposed mother and the baby. Acknowledging the limited efficacy inherent of feasibility studies, there was an identified trend towards successful continuation of breastfeeding amongst the intervention group. Additionally, breastfed infants were less likely to require pharmaceutical treatment with a corresponding shorter duration of hospital stay compared to their formula fed counterparts. The RCT also provided data to derive an effect-size estimate, power and sample size calculation for a future statistically powered clinical efficacy trial. These findings strengthen the existing knowledge base and show promise as the basis for future research.

The unique challenges of research engagement with the substance dependent community were addressed by the innovative and original use of 'think aloud' protocols. This was a unique application of this method which

proved to be responsive and sensitive to their needs whilst meeting the research objectives. This also enabled a person-centred approach to intervention development by eliciting the perspectives of those with personal experience of the situation thus optimising relevance and acceptability of the model.

Research with, rather than on, those with substance use disorders has seen an exponential growth in recent times as the importance and ethicality of affording marginalised groups an equal voice has gained momentum. With this recognition comes the need for appropriate methodologies to explore and report their experiences accurately and faithfully. The use of 'think aloud' protocols as an alternative approach from traditional interview techniques offers an opportunity for this, and as demonstrated in previous substance misuse literature, innovative and pragmatic strategies may be the norm for this group (Murphy and Rosenbaum 1999; Jambert-Gray 2014). The use and success of the 'think aloud' sessions endorse the originality of this study and this contribution to existing research knowledge is a key strength of the thesis.

The scope of influence of this subject extends across global, national and international directives, with the possible benefits of supporting breastfeeding for the substance exposed mother and baby impacting health, social and psychological outcomes. Furthermore, the implications for improved short and long-term resource utilisation should not be underestimated in these times of fiscal austerity. Given the consequences of not supporting breastfeeding in this vulnerable group it is imperative that sustained research investment is forthcoming to challenge the current, unsatisfactory, clinical situation.

7.5 Recommendations

The thesis findings derived recommendations in respect of research, clinical practice and policy. The research considerations focus on further development of the intervention, implementation modifications and refinements to the research methods. As this is anticipated as a long-term project these recommendations are iterative and not viewed as exhaustive.

7.5.1 Research Recommendations: Intervention and Implementation

Inclusion of Addiction Specialists

Including members of the addiction service in the expert advisory group would extend the scope and depth of professional experience and knowledge available. These clinicians may also provide a link between the hospital environment and the community setting particularly as one of the long-term aims of the project should be that of sustained breastfeeding.

Inclusion of Labour Suite Representative

Including a representative from labour suite in the expert advisory group would facilitate dissemination of the research project within that clinical area. This may lead to improvements in the recruitment of participants and during the referral process of those already recruited to the study.

Perspective of Intervention Support Workers

Verbal feedback was obtained from the support workers following the intervention sessions but this was not formally recorded or analysed. Future trials could be enhanced with a retrospective and comprehensive review of the support workers experience of the actual implementation of the intervention on a day-to-day basis.

Perspective of Healthcare Professionals

Exploring the views of other staff groups who were, or might be, affected by the service change presents the opportunity to consider inherent issues of staff dynamics, hierarchical structures within clinical practice and individual beliefs and prejudices. The attitudes and behaviours of practitioners were highlighted as an area of contention and therefore an understanding of the origins of these is warranted. Negative attitudes may have an adverse impact on the provision of care with the potential of HCP demonstrating an avoidance approach, diminished personal engagement or lack of empathy towards this client group.

Breastfeeding Experience of Substance Dependent Women

A noted limitation of the initial development phase was the approach of the 'think aloud'. Suggesting support components using predetermined prompts potentially restricted the comprehensiveness of the evaluation. Additionally, there was minimal discussion on the socio-cultural and psychological aspects of support compared to practical components. A more in-depth investigation of the experience of breastfeeding and support from the perspective of substance dependent women is recommended.

Data Collection Tools: Finnegan Neonatal Scoring System

The feasibility study demonstrated that significant differences existed between operators when using the Finnegan Scoring system to assess NAS. For the purpose of the research outcomes, the FS was found to be an unreliable indicator of the severity of neonatal withdrawal due to the subjectivity of the scoring system and user variability. It is proposed that in a future trial the need to instigate pharmaceutical therapy should be used as the outcome measure as this proved a more accurate reflection of the severity of NAS.

7.5.2 Clinical Practice Recommendations

Neonatal Abstinence Syndrome Supportive Management

There was disparity amongst some HCP regarding supportive measures to alleviate NAS and a noted reluctance to discuss substance use with women. This omission in clinical practice may be reflective of a lack of understanding of the current evidence regarding the management of the substance exposed neonate. Whilst it is acknowledged that the available literature on this topic can be contradictory supportive care is best practice and considered 'gold standard'. Therefore, educational resources and awareness sessions of the recommended guidelines should be available for all staff groups who encounter substance exposed clients. However, the success and expedience of integrating directives into daily practice is a highly debated area. A conducive environment is required to underpin receptiveness to service changes and facilitating this may need to be the primary focus to ensure appropriate staff attitudes and behaviours towards this population.

Promotion of Breastfeeding in Substance Dependence

Universal strategies aimed at promoting breastfeeding may not be appropriate to engage or sufficiently inform opioid dependent women. The study findings noted maternal disengagement from breastfeeding advice and practices if these were not relevant to the challenges of feeding an infant experiencing NAS. Additionally, the participants were reluctant to access the existing provisions of generic breastfeeding leaflets or attend pre-birth classes open to the general public. It can be argued that the limited and ad-hoc promotion of the specific benefits of breastfeeding in substance dependence was a contributory factor in the level of study recruitment.

The use of targeted strategies may be more effective to raise awareness of the additional advantages of breastfeeding in this cohort and thus encourage promotion. As indicated in the literature women are more receptive to personalised programmes and subsequently are more likely to

demonstrate self-efficacy and continued breastfeeding. As the available evidence on breastfeeding promotion and substance dependence has predominantly been generated from clinical observation and professional opinion further research exploring the maternal perspective is warranted. This could focus on ascertaining the informational needs of this group and the most appropriate and accessible modes of delivery.

7.5.3 Healthcare Policy Recommendations

Targeted Breastfeeding Support

The provision of an equitable breastfeeding support service, with a focus on those who may benefit the most from additional and specialist services may be warranted. Rather than providing generic services to all a more individualised approach could be more responsive to the level of need displayed by specific groups, and prove a more affordable approach to the delivery of targeted interventions. The substance dependent population should be considered as a cohort with specific and bespoke needs. This approach has the potential to improve health and well-being outcomes and optimise finite resources.

7.6 Thesis Overview

The thesis is considered as the initial step of a research project to develop, test, refine and assess the clinical efficacy of a healthcare intervention to support the substance exposed mother and baby to sustain breastfeeding. The feasibility study addressed several key uncertainties regarding the willingness of this cohort to engage with research, the ease and fidelity of intervention implementation and the acceptability of the support model. In this respect the research study has achieved its aim and objectives. Collectively, the successful development and testing of the intervention feasibility and the applicability of the research methods to determine future clinical efficacy offers the opportunity and the means to both continue with and enhance this initiative further. Given the limitations inherent of a feasibility study it is proposed that the subsequent steps concentrate on the suggested intervention modifications, with possible development work focussing on staff attitudes and actions, prior to piloting work. It is anticipated that the research may require several stages of testing and modifications before a statistically powered randomised control trial can be conducted.

This study provided an original contribution to existing research by increasing awareness of the additional and unique needs of the substance exposed mother and baby during the acute stage of neonatal withdrawal. The support model has the potential to address the current deficiencies in the knowledge base and clinical practice, with far reaching consequences for improved health, psychological and economic outcomes at individual, institutional and societal level.

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APPENDIX 1

COMPREHENSIVE SYSTEMATIC LITERATURE REVIEW PROTOCOL

MACVICAR, S. and WILCOCK, S., 2013. The effectiveness and maternal satisfaction of interventions supporting the establishment of breast-feeding for women from disadvantaged groups: a comprehensive systematic review protocol. *The JBI Database of Systematic Reviews and Implementation Reports,* 11(8), pp. 48-63.

The effectiveness and maternal satisfaction of interventions supporting the establishment of breast-feeding for women from disadvantaged groups: a comprehensive systematic review protocol

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Review question/objective

The review question is 'how effective are and what is the level of maternal satisfaction with interventions supporting breast-feeding establishment for women considered 'disadvantaged' due to socio-demographic characteristics'?

Specific quantitative and qualitative objectives are:

1. Describe the interventions available to support the establishment of breast-feeding for women from disadvantaged groups

2. Assess the effectiveness of support interventions for women from disadvantaged groups as determined by the establishment of breast-feeding in the early postnatal period

3. Explore the maternal satisfaction of women from disadvantaged groups in relation to their views and perceptions of the usefulness and acceptability of interventions supporting the establishment of breast-feeding in the early postnatal period

Systematic review operational definitions are:

Breast-feeding: establishment of breast-feeding will be defined as feeding an infant by breast or predominantly feeding expressed breast milk by gastric feeding tube.

Postnatal period: for this review the early postnatal period will be considered as up to seven days following delivery.[1] This is to coincide with the expected establishment of lactogenesis.

Disadvantaged groups: for the purpose of this review disadvantaged groups will be classified as populations who are at increased risk of health inequalities due to specific socio-demographic characteristics.[2] These are determined as residing in areas of socio-economic deprivation; low income; under 20 years of age; substance dependent or eligible for the special supplementary nutrition program for Women, Infant and Child (WIC) in the United States of America (USA).

Support: any intervention provided to women from disadvantaged groups to facilitate establishment of breast-feeding/lactation and may include but not limited to practical, motivational, informative or educational assistance.

Background

Breast-feeding is considered the optimum method of infant nutrition and there is a considerable body of evidence supporting the health and psychological advantages it confers on both mother and baby.[3] Short term health benefits for the infant include passive immunity, protection against infections and a lower incidence of sudden infant death syndrome. Infants who are not exclusively breast-fed for the first six months of life are more likely to experience gastric, respiratory, ear and urine infections. Where there is a predisposing family history there is an increased incidence of developing atopic disease. Studies on long-term outcomes demonstrate that breast-fed babies are less likely to suffer from obesity, high cholesterol or type-2 diabetes in adulthood. For women, the potential outcome of breast-feeding includes reduction in breast and ovarian cancers and a lesser prevalence of postmenopausal osteoporosis.[3-6] Within a health/social context, an improvement in short and long-term morbidity and mortality states reduces the financial burden on health care resources.

Recognition of the impact of exclusive and prolonged breast-feeding on the inherent well-being of populations has resulted in global strategies to increase breast-feeding rates in both developing and developed countries.[7] In 1992, the World Health Organization (WHO) and United Nations International Children's Fund (UNICEF) launched the Baby Friendly Hospital Initiative (BFHI), to promote, protect and support breast-feeding.[8,9] This program works with health service providers to implement best practice in midwifery care and BFHI accreditation indicates that the facility offers a high level of skill, knowledge and support for breast-feeding.

Since committing to BFHI, breast-feeding initiation in the United Kingdom (UK) has gradually increased but statistics show that there is considerable attrition within the first week following birth.[10] Additionally, some groups demonstrate substantially lower breast-feeding rates compared to national averages.[11] Studies identify women residing in areas of socio-economic deprivation, teenagers, smokers, substance dependent and those with lower educational attainment as less likely to establish lactation.[12-14] National figures demonstrate an average initiation rate of 81% across all population groups decreasing to 66% of women breast-feeding at days seven to ten following delivery. However, in areas of greatest deprivation, 60% of women initiate breast-feeding but this declines to only 31% within the first post-partum week.[11] These mother and infant dyads also have a greater prevalence of health inequalities due to the effects of an intergenerational cycle of poor nutrition and detrimental lifestyle choices.[15,16] Subsequently, UK public health initiatives targeting an increase in breast-feeding amongst socio-economically disadvantaged women have become a priority objective.[17,18]

The National Institute for Health and Clinical Excellence (NICE) recommends that breast-feeding promotions for disadvantaged groups should utilize the best package of support interventions, be informed by the views of the service users and address the diverse needs of the target population.[17] However, within health care literature the 'best package' of breast-feeding interventions remains undetermined and the concept of 'support' has not been clearly defined.[19,20] Three Cochrane reviews have investigated the effectiveness of various components for the initiation and prolongation of breast-feeding, concluding that the studies evaluated demonstrated inconsistent results or findings originated from single studies only.[21-23] Renfrew et al.[23] reviewed 'Support for Healthy Breastfeeding Mothers with Healthy Term Babies' comparing different breast-feeding interventions with standard maternity practices. When studies were analysed together, all forms of extra support, whether educational, motivational or delivered by peers or professionals, had a positive impact on feeding duration. However, the authors were unable to distinguish the effectiveness of individual components, the most appropriate method of delivery or the most conducive setting from the reported evidence. This review included studies on women from disadvantaged groups but they were not the primary focus. It was recommended that further research concentrating on those mother/infant dyads at risk of health inequalities due to socio-economic disadvantages, should be considered. Additionally, a deficiency across all studies in reporting maternal perceptions and acceptability of the support interventions was identified.

The general view within existing health care literature is that support may encompass practical, informative, emotional, motivational and network/relational elements. [20] Schmied *et al.* conducted a meta-synthesis on the breast-feeding support interventions which women perceived as supportive.[24] Practices judged positively were described as 'authentic' and 'facilitative', whilst unhelpful or detrimental interventions were considered as 'disconnected' and 'reductionist'. Mothers commented that the development of a trusting, continued relationship which was encouraging and affirmative of their ability, was most conducive to breast-feeding prolongation. Interactions which were fragmented, lacking in rapport or where staff were either over-zealous about breast-feeding or offered conflicting advice, negatively influenced a woman's personal confidence. The type of support directly impacted on the mother's perception of her self-efficacy to successfully breast-feed and unsupportive actions resulted in a loss of confidence and subsequent feeling of being undermined, confused and guilty. Demirtas reviewed qualitative studies on breast-feeding support for women of all socio-demographic groups, reporting that low-income women needed much more support, confidence-building and reassurance than affluent women.[25] It was also noted that these women had less ability to cope with common breast-feeding problems such as nipple pain, latching difficulties and perceived insufficient milk supply. These findings were corroborated by MacGregor and Hughes in their review of breastfeeding experiences of teenagers and low-income mothers.[14] The authors reflected that barriers and negative misconceptions of breast-feeding were inherent of the „bottle-feeding culture"[16] which has developed within many socio-economically deprived communities. Overall, the

recommendations of these reviews are that health care professionals must adopt more explicit and cultural specific interventions to overcome these issues.

There has been extensive research conducted on initiation and prolongation of breast-feeding and the strategies adopted to enhance these.[26] Yet, considerably fewer studies investigate the establishment of breast feeding in the early post-partum period despite the high attrition rates during this time.[27] Furthermore, studies focusing exclusively on the breast-feeding experiences of women considered disadvantaged, and therefore at greatest risk of health inequalities, are under-represented within this body of evidence.[28,29] Consequently, there is a lack of clarity on the most appropriate strategies to support breast-feeding establishment during the early postnatal period, particularly interventions which are effective and acceptable to disadvantaged women.[2,23] This review aims to identify the best available evidence in this regard.

Keywords
breast-feeding; disadvantaged; perceptions; postnatal; support

Inclusion criteria

Types of participants

The quantitative and qualitative components of this review will consider studies that include disadvantaged women who have elected to breastfeed. Eligible studies are those researching women who would be considered disadvantaged due to socio-economic-demographic characteristics. These include women who are of low income, from areas of socio-economic deprivation, under 20 years of age, substance dependent or eligible for the special supplementary nutrition program for WIC in the USA. Studies which include disadvantaged groups in their research on the general population of breast-feeding women, but they are not the explicit focus of the study, shall be excluded due to the potential moderating effect on the reported data. Subgroups with low breastfeeding initiation due too ethnic, cultural or specific religious practices, and therefore not representational of other disadvantaged women, shall be excluded. Types of intervention(s)/phenomena of interest

The quantitative components of the review will consider studies that evaluate the effectiveness of professionally led practices designed to support breast-feeding establishment during the early postnatal period for women from disadvantaged groups.

The phenomena of interest for the qualitative component of the review will be the perceptions and experiences of women from disadvantaged groups of professionally led breast-feeding support provision and their expressed level of satisfaction with the intervention.

Breast-feeding support interventions may include or take the form of:
- informative and /or educational
- practical
- motivational.

The intervention may be either a combination of all/some of the support elements or delivered as a single intervention.

The intervention will be professionally led and delivered in an in-hospital setting by one or more of the following: - midwife
- midwifery support worker
- nurse/neonatal nurse
- breast-feeding support worker
- lactation consultant.

Interventions delivered by peer/lay councillors or requiring continued support/supervision outside the early postnatal period will be excluded.

Types of outcomes
This review will consider studies that include the following outcome measures:

(1) Effectiveness of the intervention to support the establishment of breast-feeding/lactation within the early postnatal period, as determined as fully fed at the breast or receiving predominantly breast milk by gastric feeding tube.

(2) Level of maternal satisfaction as determined by the views and perceptions of disadvantaged women on the usefulness and acceptability of the intervention to support breast-feeding establishment in the early postnatal period.

Types of studies
The quantitative component of the review will consider both experimental and epidemiological study designs including randomized controlled trials, non-randomized controlled trials, quasi-experimental, prospective and retrospective cohort studies, case control studies, case series and analytical and descriptive cross sectional studies for inclusion.

The qualitative component of the review will consider studies that focus on qualitative data including, but not limited to, designs such as phenomenology, grounded theory, ethnography, action research and feminist research.

Search strategy
The search strategy aims to find both published and unpublished studies, in the English language only and published from 1992 to March 2013. The commencement date of 1992 was chosen as in this year WHO/UNICEF launched the Baby Friendly Hospital Initiative recommending practices to globally increase breast-feeding rates. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe articles. A second search using all identified keywords and index terms will then be undertaken

across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies.

The databases to be searched include: AMED, ASSIA, CINAHL, Campbell Collaboration, Cochrane Library, EMBASE, EThOS, Internurse, Intermid, Maternity and Infant Care, Midirs, MEDLINE, SAGE and Web of Science/Knowledge.

Initial keywords for the search will be:

breastfeeding OR breast-feeding OR lactation
AND
support OR intervention
AND
disadvantaged
deprivation
low-income OR "Women Infant and Child (WIC)
teenager OR adolescent
substance dependent OR substance misuse OR „Neonatal Abstinence Syndrome"

Assessment of methodological quality

Quantitative papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JB MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Qualitative papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Qualitative Assessment and Review Instrument (JBI-QARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data collection

Quantitative data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

Qualitative data will be extracted from papers included in the review using the standardized data extraction tool from JBI-QARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

Data synthesis

Quantitative papers will, where possible be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square and explored using subgroup analyses based on the different quantitative study designs included in this review. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Qualitative research findings will, where possible be pooled using JBI-QARI. This will involve the aggregation or synthesis of findings to generate a set of statements that represent that aggregation, through assembling the findings (Level 1 findings) rated according to their quality, and categorizing these findings on the basis of similarity in meaning (Level 2 findings). These categories are then subjected to a meta-synthesis to produce a single comprehensive set of synthesized findings (Level 3 findings) that can be used as a basis for evidence-based practice. Where textual pooling is not possible the findings will be presented in narrative form.

Conflicts of interest

No conflict of interest noted.

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Appendix I: Appraisal instruments

QARI appraisal instrument

JBI QARI Critical Appraisal Checklist for Interpretive & Critical Research

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Is there congruity between the stated philosophical perspective and the research methodology?	☐	☐	☐	☐
2. Is there congruity between the research methodology and the research question or objectives?	☐	☐	☐	☐
3. Is there congruity between the research methodology and the methods used to collect data?	☐	☐	☐	☐
4. Is there congruity between the research methodology and the representation and analysis of data?	☐	☐	☐	☐
5. Is there congruity between the research methodology and the interpretation of results?	☐	☐	☐	☐
6. Is there a statement locating the researcher culturally or theoretically?	☐	☐	☐	☐
7. Is the influence of the researcher on the research, and vice- versa, addressed?	☐	☐	☐	☐
8. Are participants, and their voices, adequately represented?	☐	☐	☐	☐
9. Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	☐	☐	☐	☐
10. Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	☐	☐	☐	☐

Overall appraisal: ☐ Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

MAStARI appraisal instruments

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	☐	☐	☐	☐
2. Were participants blinded to treatment allocation?	☐	☐	☐	☐
3. Was allocation to treatment groups concealed from the allocator?	☐	☐	☐	☐
4. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
5. Were those assessing outcomes blind to the treatment allocation?	☐	☐	☐	☐
6. Were the control and treatment groups comparable at entry?	☐	☐	☐	☐
7. Were groups treated identically other than for the named interventions	☐	☐	☐	☐
8. Were outcomes measured in the same way for all groups?	☐	☐	☐	☐
9. Were outcomes measured in a reliable way?	☐	☐	☐	☐
10. Was appropriate statistical analysis used?	☐	☐	☐	☐
	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was study based on a random or pseudo-random sample?	☐	☐	☐	☐
2. Were the criteria for inclusion in the sample clearly defined?	☐	☐	☐	☐
3. Were confounding factors identified and strategies to deal with them stated?	☐	☐	☐	☐
4. Were outcomes assessed using objective criteria?	☐	☐	☐	☐
5. If comparisons are being made, was there sufficient descriptions of the groups?	☐	☐	☐	☐
6. Was follow up carried out over a sufficient time period?	☐	☐	☐	☐
7. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
8. Were outcomes measured in a reliable way?	☐	☐	☐	☐
9. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

		Yes	No	Unclear	Not Applicable
1.	Is sample representative of patients in the population as a whole?	☐	☐	☐	☐
2.	Are the patients at a similar point in the course of their condition/illness?	☐	☐	☐	☐
3.	Has bias been minimised in relation to selection of cases and of controls?	☐	☐	☐	☐
4.	Are confounding factors identified and strategies to deal with them stated?	☐	☐	☐	☐
5.	Are outcomes assessed using objective criteria?	☐	☐	☐	☐
6.	Was follow up carried out over a sufficient time period?	☐	☐	☐	☐
7.	Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
8.	Were outcomes measured in a reliable way?	☐	☐	☐	☐
9.	Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

Appendix II: Data extraction instruments

QARI data extraction instrument

JBI QARI Data Extraction Form for Interpretive & Critical Research

Reviewer _____ Date _____

Author _____ Year _____

Journal _____ Record Number _____

Study Description

Methodology

Method

Phenomena of interest

Setting

Geographical

Cultural

Participants

Data analysis

Authors Conclusions

Comments

Complete Yes ☐ No ☐

Findings	Illustration from Publication (page number)	Evidence		
		Unequivocal	Credible	Unsupported

Extraction of findings complete Yes ☐ No ☐

MAStARI data extraction instrument

JBI Data Extraction Form for Experimental / Observational Studies

Reviewer _____ Date _____

Author _____ Year _____

Journal _____ Record Number _____

Study Method

RCT ☐ Quasi-RCT ☐ Longitudinal ☐

Retrospective ☐ Observational ☐ Other ☐

Participants

Setting

Population

Sample size

Group A _____ Group B _____

Interventions

Intervention A

Intervention B

Authors Conclusions:

Reviewers Conclusions:

Study Results

Dichotomous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

Continuous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

APPENDIX 2

IBriS STUDY PARTICIPANT DOCUMENTATION

EXPERT ADVISORY GROUP

- Letter of Invitation (HCP)
- Letter of Invitation (Lay Representative)
- Opt-in Form
- Consent Form
- Participant Information Leaflet (HCP)
- Participant Information leaflet (Lay representative)

THINK ALOUD SESSIONS

- Letter of Invitation
- Opt-in Form
- Participant Information Leaflet
- Consent Form

FEASIBILITY STUDY and RCT

- Letter of Invitation
- Opt-in Form
- Participant Information Leaflet
- Consent Form
- Questionnaire
- Daily assessment log
- HV Cover Feeding Review

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Aberdeen
AB25 2ZL
Tel: 01224 438444
Email: tracy.humphrey@nhs.net

IBriS Trial

Interventions supporting Breastfeeding in Substance dependency

Dear Colleague,

We would like to invite you to participate in a research project as a member of an expert advisory group. We are conducting a project on breastfeeding support for women who attend the substance misuse service clinic at Aberdeen Maternity Hospital. The project title is the IBriS trial – Interventions supporting Breastfeeding in Substance dependency. The chief investigator for the trial will be Sonya MacVicar, an Advanced Neonatal Practitioner currently seconded to Robert Gordon University as a doctoral student (e-mail s.macvicar@rgu.ac.uk ; tel xxxxxxxxxxx).

Methadone use in pregnancy results in Neonatal Abstinence Syndrome and breastfeeding can alleviate the severity of this condition due to the consolation effect of feeding and the transfer of methadone in the breast milk. The rate of successfully establishing breastfeeding in this group is low due to maternal, neonatal and institutional factors. The aim of the research project is to design a breastfeeding support intervention for methadone maintained women and test its feasibility, acceptability and effectiveness.

The research project consists of two phases – phase one is developing and informing the breastfeeding intervention based on the views of service users and providers; phase two is a pilot randomised controlled trial of the intervention. We would like to invite you to be a member of a joint expert advisory group of health care professionals and lay representative. The preliminary programme is for the advisory group to meet on 2-3 occasions lasting approx. 1 hour. The meeting will be directed by a chairperson and minutes and observations will be taken.

I want to emphasise that your participation as a member of the advisory group is entirely voluntary. All data from the trial will be kept confidential and your identity protected.

Please contact me if you have any questions about the study. I have enclosed a participant information sheet and opt-in form for your review. If you choose to discuss the study, please sign and date the opt-in form and return it in the envelope provided.

Yours sincerely,

Professor Tracy Humphrey
Clinical Professor of Midwifery

Room 6

SCHOOL OF NURSING AND MIDWIFERY
ROBERT GORDON UNIVERSITY•ABERDEEN

NHS Grampian

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Tel: 01224 438444
Email: tracy.humphrey@nhs.net

IBriS Trial

Interventions supporting Breastfeeding in Substance dependency

Dear Participant,

We would like to invite you to take part in a research project. We are conducting a trial on breastfeeding support for women who attend the combined pregnancy/substance misuse clinic at Aberdeen Maternity Hospital. The project title is the IBriS trial – Interventions supporting Breast-feeding in Substance dependency.

When women have been prescribed methadone during pregnancy their baby may develop Neonatal Abstinence Syndrome (NAS), this describes a range of withdrawal symptoms such as unsettled and crying, jitteriness and poor feeding. Breastfeeding can lessen the symptoms of NAS and reduce time spent in hospital but it can be difficult for a baby with NAS to latch onto the breast and feed properly. The study aim is to design and evaluate in-hospital breastfeeding intervention for substance dependent women during the first 5 days after birth. This is the time when a baby develops early NAS and when both mother and baby will be in hospital.

We are interested in your views of breastfeeding support and what you think of the proposed study. We would like to invite you to be a member of a joint advisory group of health care professionals and lay representative. The preliminary programme for the advisory group is to meet on 2-3 occasions lasting approximately 1 hour. The group will consist of managers, clinicians and specialists from obstetric, neonatal and midwifery departments of the hospital and lay representative from the community. The meeting will be directed by a chairperson and minutes and observations will be taken.

We want to emphasise that your participation in this study is entirely voluntary. All data from the trial will be kept confidential and your identity protected.

We have enclosed a participant information sheet and opt-in form for your review. Please read the form and feel free to contact me if you have any questions about the study. If you choose to agree to discuss the study, please sign and date the opt-in form and return in the envelope provided.

Your participation will be greatly appreciated.

Yours sincerely,

Professor Tracy Humphrey
Clinical Professor of Midwifery

IBriS Trial

Interventions supporting Breastfeeding in Substance dependency

I have read the invitation letter and agree to meet with the researcher to discuss participating in the above study. I understand that I can opt out of the study at any point without giving a reason.

Please sign the opt-in form below and return in the envelope provided. A member of the research team will contact you in the near future.

Name……...

Preferred contact details……

Preferred time of contact ……...

I agree to being contacted by a member of the research team to discuss participating in the above project.

Signature……...

Date…….

SCHOOL OF NURSING AND MIDWIFERY
ROBERT GORDON UNIVERSITY•ABERDEEN

NHS Grampian

CONSENT FOR ADVISORY GROUP PARTICIPATION

IBriS Trial

Interventions supporting Breastfeeding in Substance dependency

Identification Number for this trial: ☐☐☐☐☐

Lead Researcher: Sonya MacVicar, Robert Gordon University, Aberdeen. tel: 07730954247 E-mail: **s.macvicar@rgu.ac.uk**

Please initial box

1. I confirm that I have read and understand the participant information sheet dated 23/08/13 (version.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

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

3. I agree to notes being taken during the group meeting ☐

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

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

Who has reviewed the study?

This research has been approved by North of Scotland Research Ethics Services, NHS Grampian Research and Development and Robert Gordon University School of Nursing and Midwifery Ethics Review Panel.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally details can be obtained by contacting the individuals below.

To participate in this study, please compete the attached opt-in slip and return it in the envelope provided. Thank you in advance.

Further Information /Contact details

If you have questions about the study, please contact:

Research academic supervisor
Professor Tracy Humphrey e-mail t.humphrey1@rgu.ac.uk tel: 01224 262615
Research clinical supervisor
Dr Medhat Ezzat e-mail m.ezzat@nhs.net tel: 01224 552660
Chief Investigator
Sonya MacVicar e-mail s.macvicar@rgu.ac.uk

SCHOOL OF NURSING AND MIDWIFERY
ROBERT GORDON UNIVERSITY•ABERDEEN

NHS Grampian

IBriS Trial

Interventions supporting Breastfeeding in Substance dependency

Dear Health Care Professional

You are invited to participate in a research study as part of an expert advisory group to inform the development of a breastfeeding intervention for substance dependent women. The title of the research project is 'IBriS Trial – Interventions supporting Breastfeeding in Substance dependency'. Please take time to read the following information. Ask us if there is anything that is not clear or you would like more information. Take time to decide whether or not you wish to take part. You will be given this information leaflet and signed copy of the consent form should you decide to participate.

What is the purpose of the study?

This research aim is to design and test the feasibility of an in-hospital intervention to support methadone maintained women to successfully establish breastfeeding in the first 5 days after birth. The research project has two phases (1) developing an evidence based theory informed intervention in conjunction with service users and stakeholders (2) pilot randomised controlled trial to evaluate feasibility, acceptability and effectiveness.

Why have I been invited?

As a local expert/ clinical lead in substance misuse services we would like your informed opinion on the feasibility of the proposed support intervention.

Do I have to take part?

No, participation is entirely voluntary. You are free to withdraw at any time, without giving a reason. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form.

Expenses and payments

There will be no expenses paid for taking part

What will I have to do?

The preliminary programme is for the advisory group to meet on 2-3 occasions, with sessions lasting approximately 1 hour. The group will consist of managers, clinicians and specialists from obstetric, neonatal and midwifery departments of the hospital and lay representative from the community. The meeting will be directed by a chairperson and minutes and field notes/observations will be taken.

What are the possible benefits and disadvantages of taking part?

The information you provide may help to improve the service offered to future mothers and babies. There are no anticipated risks of taking part in the research.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information will be handled in confidence. All information collected during group meetings will be anonymised, pseudonyms used and the transcript will be coded without using details which could identify you. The transcript will be kept in a locked drawer and destroyed once the study is completed.

What will happen if I don't want to carry on with the study?

You may withdrawal from the advisory group at any time, without giving a reason**.**

What will happen to the results of the research study?

The main findings from the research study will be published as a doctoral thesis. Comments made during group sessions may be used but you will not be identified in any publications unless you have given your consent. You may request a summary of the report by contacting the research team on the numbers listed below.

Who has reviewed the study?

This research has been approved by North of Scotland Research Ethics Services, NHS Grampian Research and Development and

Robert Gordon University School of Nursing and Midwifery Ethics Review Panel.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally details can be obtained by contacting the individuals below.

To participate in this study, please compete the attached opt-in slip and return it in the envelope provided. Thank you in advance.

Further Information /Contact details

If you have questions about the study, please contact:

Research Supervisor
Professor Tracy Humphrey e-mail t.humphrey1@rgu.ac.uk
Tel: 01224 262615

Chief Investigator
Sonya MacVicar e-mail s.macvicar@rgu.ac.uk

SCHOOL OF NURSING AND MIDWIFERY
ROBERT GORDON UNIVERSITY•ABERDEEN

NHS Grampian

IBriS Trial

Interventions supporting Breastfeeding in Substance dependency

Dear Participant

You are invited to participate in a research study as part of an expert advisory group to inform the development of a breastfeeding intervention for methadone maintained women. The title of the research project is 'IBriS Trial – Interventions supporting Breastfeeding in Substance dependency'. Please take time to read the following information. Ask us if there is anything that is not clear or you would like more information. Take time to decide whether or not you wish to take part. You will be given this information leaflet and signed copy of the consent form should you decide to participate.

What is the purpose of the study?

Methadone use during pregnancy can result in Neonatal Abstinence Syndrome (NAS). NAS describes the withdrawal symptoms a baby may have in the weeks after birth. Breastfeeding can reduce the symptoms of NAS but it can be difficult for a baby with NAS to latch onto the breast and feed properly. The purpose of this study is to provide and assess breastfeeding support offered to mothers maintained on methadone.

Why have I been invited?

As a community member with experience of breastfeeding a baby experiencing NAS we would like your informed opinion on the proposed support intervention.

Do I have to take part?

No, participation is entirely voluntary. You are free to withdraw at any time, without giving a reason. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form.

Expenses and payments

There will be no expenses paid for taking part

What will I have to do?

The preliminary programme is for the advisory group to meet on 2-3 occasions, with sessions lasting approximately 1 hour. The group will consist of managers, clinicians and specialists from obstetric, neonatal and midwifery departments of the hospital and lay representative from the community. The meeting will be directed by a chairperson and minutes and field notes/observations will be taken.

What are the possible benefits and disadvantages of taking part?

The information you provide may help to improve the service offered to future mothers and babies. There are no anticipated risks of taking part in the research.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information will be handled in confidence. All information collected during group meetings will be anonymised, pseudonyms used and the transcript will be coded without using details which could identify you. The transcript will be kept in a locked drawer and destroyed once the study is completed.

What will happen if I don't want to carry on with the study?

You may withdrawal from the advisory group at any time, without giving a reason**.**

What will happen to the results of the research study?

The main findings from the research study will be published as a doctoral thesis. Comments made during group sessions may be used but you will not be identified in any publications unless you have given your consent. You may request a summary of the report by contacting the research team on the numbers listed below.

IBriS Trial

Dear Participant,

We would like to invite you to take part in a research study. We are conducting a project on breastfeeding support for women who attended the substance misuse service clinic at Aberdeen Maternity Hospital. The project title is IBriS Trial: 'Interventions supporting Breast-feeding in Substance dependency'.

When women have been prescribed methadone during pregnancy their baby may develop Neonatal Abstinence Syndrome (NAS), this describes a range of withdrawal symptoms such as unsettled and crying, jitteriness and poor feeding. Breastfeeding can lessen the symptoms of NAS and reduce time spent in hospital but it can be difficult for a baby with NAS to latch onto the breast and feed properly. The study aim is to design and evaluate in-hospital breastfeeding intervention for substance dependent women during the first 5 days after birth. This is the time when a baby develops early NAS and when both mother and baby will be in hospital.

We are interested in your views and experience of breastfeeding support and what you think of the proposed intervention. We would like to invite you to take part in a face to face interview to discuss this in more detail. The interview will not take longer than 30 minutes and will be conducted at a time and place suitable for you.

We want to emphasise that your participation in this study is entirely voluntary. All data from the trial will be kept confidential and your identity protected.

We have enclosed a participant information sheet and opt-in form for your review. Please read the form and feel free to contact me if you have any questions about the study. If you choose to agree to discuss the study, please sign and date the opt-in form and return it to a member of staff.

Your participation will be greatly appreciated.

Yours sincerely,

Ms Liz Grant
Specialist Midwife
Aberdeen Maternity Hospital
01224 554516

IBriS Trial

I have read the invitation letter and agree to meet with the researcher to discuss participating in the above study. I understand that I can opt out of the study at any point without giving a reason.

Please sign the opt-in form below and hand it to a member of staff. A member of the research team will contact you in the near future.

Name…….

Preferred contact details…….

I agree to being contacted by a member of the research team to discuss participating in the above project.

Signature…….

Date…….

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NHS Gr Grampian

CONSENT FOR PARTICIPANT INTERVIEW

IBriS Trial

Intervention Supporting Breastfeeding in Substance dependency

Identification Number for this study: ☐☐☐☐☐

Lead Researcher**:** Sonya MacVicar, Post Graduate Research Student, Robert Gordon University, Aberdeen. Tel: xxxxxxxx, E-mail: s.macvicar@rgu.ac.uk

Please initial box

1. I confirm that I have read and understand the participant information sheet dated 23/08/13 (version.2) for the above study and have had the opportunity to 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 a reason ☐
3. I agree to notes being taken during the interview ☐
4. I agree to take part in the above study ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature

_____	_____	_____
Researcher	Date	Signature

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed by North of Scotland Research Ethics Service and the School of Nursing and Midwifery Research Ethics Panel, Robert Gordon University**.**

What if there is a problem?

If you have concerns about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally details can be obtained by contacting the individuals below.

Further information and contact details

Chief Investigator
Sonya MacVicar
PhD research student
Robert Gordon University
Aberdeen
xxxxxxxx

Research Supervisor
Professor Tracy Humphrey
Clinical Professor of Midwifery
Robert Gordon University/NHS Grampian
Aberdeen
01224 262615

SCHOOL OF NURSING AND MIDWIFERY
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NHS Grampian

IBriS Trial

Interventions supporting Breastfeeding in Substance dependency

Introduction

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the study is being done and what it would involve for you. One of our team will go through the information sheet and answer any questions you have**.** We suggest that this should take about 10 minutes. Talk to others about the study if you wish. Ask us if there is anything that is not clear. You will be given this information leaflet and a signed copy of the consent form should you decide to take part in the study.

What is the purpose of the study?

Methadone use during pregnancy can result in Neonatal Abstinence Syndrome (NAS). NAS describes the withdrawal symptoms a baby may have in the weeks after birth. Breastfeeding can reduce the symptoms of NAS but it can be difficult for a baby with NAS to latch onto the breast and feed properly. The purpose of this study is to provide and assess breastfeeding support offered to mothers on methadone.

The study is in two parts; the first stage is to find out what type of support would help methadone maintained mothers establish breastfeeding. The second part is to provide and assess a breastfeeding support package.

Why have I been invited?

We are recruiting 4- 6 women who were prescribed methadone during pregnancy and who breastfed their baby. We would like you to tell us about your experience of breastfeeding while you were in hospital. We would also like to ask you what you think of the breastfeeding support package proposed in this study.

Do I have to take part?

No, it is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. This will not affect the standard of care you or your baby receive.

What will I have to do?

The interview should take 20- 30 minutes and you will be asked questions about breastfeeding your baby. Your comments will be written down and read back to you at the end of the session. You can then check if what has been recorded is correct.

Expenses and payments

There will be no expenses paid for taking part

What are the possible benefits and risks of taking part?

The information you provide may help to improve the breastfeeding support given to future mothers and babies.

There are no anticipated risks of taking part in the research. If you do not wish to answer a particular question or decide to withdraw from the study let the researcher know and the interview will stop.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

All information which is collected during the interview will be anonymised and the transcript will be coded without using details which could identify you. The transcript will be kept in a locked drawer and it will be destroyed once the study is completed.

What will happen to the results of the research study?

The information you give during the interview will be used to develop a breastfeeding support intervention for methadone maintained mothers. The complete study will be published as an academic study in 2015. Comments that you make during interview may be used but you will not be identified in any publications unless you have given your consent. If you wish a summary of the final study, please contact the research team using the numbers listed at the end of this information sheet.

IBriS Trial

Dear Participant,

We would like to invite you to take part in a research project. We are conducting a trial on breastfeeding support for women who attend the combined pregnancy/substance misuse clinic at Aberdeen Maternity Hospital. The project title is the IBriS trial – Interventions supporting Breast-feeding in Substance dependency.

When women have been prescribed methadone during pregnancy their baby may develop Neonatal Abstinence Syndrome (NAS), this presents as a range of withdrawal symptoms such as jitteriness, difficult to settle and poor feeding ability. Breastfeeding can lessen the symptoms of NAS and reduce time spent in hospital but it can be difficult for a baby with NAS to latch onto the breast and feed properly. The study aim is to design and evaluate in-hospital breastfeeding intervention for substance dependent women during the first 5 days after birth. This is the time when a baby develops early NAS and when both mother and baby will be in hospital.

We would like to invite you to take part in a randomised control trial for women on methadone who intend to/ or may want to breastfeed their baby. If you agree to take part in the trial, and once your baby is born, you will be given either routine hospital support to establish breastfeeding or you may be given routine support and additional help from a research team member. On day 5 following your baby's birth you will be asked to fill out a short questionnaire. The trial will finish on day 5.

We want to emphasise that your participation in this study is entirely voluntary. All information from the trial will be kept confidential and your identity protected.
We have enclosed a participant information sheet and opt-in form for your review. Please read the form and contact me if you have any questions. If you choose to discuss the study, please sign and date the opt-in form and give it to a member of staff.

Your participation will be greatly appreciated.

Yours sincerely,

Ms Liz Grant
Specialist Midwife
Aberdeen Maternity Hospital
01224 554516

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NHS Grampian

IBriS Trial

Intervention supporting Breastfeeding in Substance dependency

I have read the invitation letter and agree to meet with the researcher to discuss participating in the above study. I understand that I can opt out of the study at any point without giving a reason, without my medical care or legal rights being affected.

If you would like to obtain further information the researcher's contact details are given below or discuss the study with a member of clinic staff.

Sonya MacVicar
Post Graduate Research Student
Robert Gordon University
e-mail: s.macvicar@rgu.ac.uk

Please sign the opt-in form below and hand it to a member of staff. A member of the research team will contact you at your next clinic appointment if you wish to participate in the study.

Name…….

Contact details (if wished) tel or e-mail

…….

Next clinic date……

I agree to being contacted by a member of the research team to discuss participating in the above project.

Signature…….

Date…….

CONSENT FOR RANDOMISED CONTROL TRIAL
IBriS Trial

Identification Number for this study: ☐☐☐☐☐

Lead Researcher**:** Sonya MacVicar, Post Graduate Research Student, Robert Gordon University, Aberdeen, AB10 7QG. Tel: xxxxxxxxx, E-mail: s.macvicar@rgu.ac.uk

Please initial box

1. I confirm that I have read and understand the participant information sheet dated 23/08/13 (version.2) for the above study and have had the opportunity to 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 a reason, without my medical care or legal rights being affected ☐

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

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

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

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed by North of Scotland Research Ethics Service and the School of Nursing and Midwifery Research Ethics Panel, Robert Gordon University**.**

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally details can be obtained by contacting the individuals below.

Further information and contact details

Chief Investigator
Sonya MacVicar
PhD research student
Robert Gordon University
Aberdeen

Research Supervisor
Professor Tracy Humphrey
Clinical Professor of Midwifery
Robert Gordon University/NHS Grampian
Aberdeen
01224 262615

SCHOOL OF NURSING AND MIDWIFERY
ROBERT GORDON UNIVERSITY•ABERDEEN

NHS Grampian

IBriS Trial

Introduction

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet and answer any questions you have**.** We suggest that this should take about 15 minutes. Talk to others about the study if you wish. Ask us if there is anything that is not clear. You will be given this information leaflet and a signed copy of the consent form should you decide to take part in the study.

What is the purpose of the study?

Methadone use during pregnancy can result in Neonatal Abstinence Syndrome (NAS). NAS describes the withdrawal symptoms a baby may have in the weeks after birth. Breast-feeding can reduce the symptoms of NAS but it can be difficult for a baby with NAS to latch onto the breast and feed properly. The purpose of this study is to provide and assess breastfeeding support offered to mothers maintained on methadone.

Why have I been invited?

We are recruiting approximately 20 women who are prescribed methadone and who may wish to breastfeeding their baby while they are in hospital.

Do I have to take part?

No, it is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

What will I have to do?

After your baby is born and you decide to breastfeed, you will be randomly allocated into one of two groups. Random allocation means that a computer programme decides whether you are in the control group or the intervention group, you cannot ask to be in a particular group. If you are in the control group, you will receive routine hospital care to help establish breastfeeding. If you are in the intervention group, you will be given routine hospital care and additional support from research team members. The support worker will visit each day, for up to 1 hour, for 5 days and offer support with any breastfeeding issues you may have. On day 5 both groups will be asked to complete a short questionnaire on your views of the support you received. The trial ends on day 5.

Expenses and payments

There will be no expenses paid for taking part.

What are the possible benefits and risks of taking part?

Previous research does suggest that support can help to prolong the duration of breastfeeding and that feeding can reduce the withdrawal symptoms felt by the baby. There are no anticipated risks of taking part in the research. You can withdraw from the study at any point and this will not affect the care you receive.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information which is collected during the study will be anonymised and any details which could identify you removed. The data collected will be kept in a locked drawer and it will be destroyed once the study is completed.

What will happen to the results of the research study?

The data collected during the trial will be used for an academic study; a summary may be published in nursing journals or presented at conferences. Any comments that you make in the questionnaire may be used but you will not be identified in any publications. If you wish a summary of the final report please contact the research team using the numbers listed at the end of this information sheet.

SCHOOL OF NURSING AND MIDWIFERY
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NHS Grampian

IBriS Trial

This questionnaire is anonymous and confidential.

Study Identification Number: | | | | | |

Date……..……...……...

This is about you and your baby (Please circle your answers)

1. Is this your first baby? Yes No

2. Did you give breast milk to any of your other children? N/A Yes No

This is about your stay in hospital (Please circle your answers)

3. Did a member of staff sit with you for **an entire breast feed**? Yes No

4. Did any member of staff observe the **start of a breastfeed** when you are attaching the baby to the breast Yes No

5. Did your baby have a dummy? Yes No

6. Were you shown how to express milk? Yes No

7. Were you in a single room? Yes No

8. Are you still breastfeeding your baby? Yes No

9. If you are no longer breastfeeding, can you tell us why?

The following things can reduce the symptoms of NAS, were you informed of these (please tick box)

	YES	NO
Breastfeeding		
Breast milk		
Dim lighting		
Quiet environment		
Swaddling		

These questions are about breastfeeding.

Did you have any of the following: -

	YES	NO	What were you advised to do?
Not enough milk			
Too much milk/engorgement			
Sore breasts when feeding			
Cracked/bleeding nipples			

Did your baby have any of the following -?

	Yes	No	What were you advised to do?
Lost too much weight (greater than 10% of birth weight)			
Unsettled between feeds			
Bringing up milk			
Tremors, jittery and easily startled			

How do you feel about the breastfeeding support you received?

On a scale of 0-10, where 0 means strongly disagree and 10 means strongly agree, how do you rate the following statement (Please circle your answer)

1. Staff encouraged me to breastfeed

Strongly disagree ***Strongly agree***

0 1 2 3 4 5 6 7 8 9 10

2. I asked for help/buzzed when I needed support

Strongly disagree ***Strongly agree***

0 1 2 3 4 5 6 7 8 9 10

3. I always received help when I asked for it

Strongly disagree ***Strongly agree***

0 1 2 3 4 5 6 7 8 9 10

4. I am satisfied with the support I was given in hospital

Strongly disagree ***Strongly agree***

0 1 2 3 4 5 6 7 8 9 10

5. I feel confident breastfeeding

Strongly disagree ***Strongly agree***

0 1 2 3 4 5 6 7 8 9 10

What was good about breastfeeding support? What could be improved?

Please add any comments

We would like to know how you are feeding your baby at 6 weeks of age. Do you give your permission for us to contact your health visitor at 6-8 weeks and ask about feeding only? Yes No

Thank you for taking part.
If you place the completed questionnaire in the envelope provided the researcher will collect it.

IBriS Trial

Study Identification Number: | | | | | |

Date/time…….

Infant's age at visit ……..……..……..…

Birth weight/ daily weight…….…….

	Breastfeeding only	Breastfeeding and EBM	Breastfeeding and EBM and formula	Formula only
Feeding since birth/last 24 hours				

If formula introduced

Age when formula introduced

Reason for supplementation

Who introduced/suggested supplementation?

Breastfeeding Support Intervention

Intervention element	Comment/details
Practical Support (breastfeeding technique and NAS) latch/position Frequent feeding Potential problems (discuss and reassure) Breast/nipple discomfort Infant unsettled Expressing breast milk	
Psychological Support Motivation/praise Positive reinforcement Maternal self-efficacy	
Environmental measures Reduce stimuli (lights/noise/disturbances) Pacifier use Containment	
Individualised Support maternal objectives specific needs/goals	
Daily assessment plan Review last 24 hours Plan next 24 hours	

Duration of session……minutes

Interruptions/barriers to session

Discussion/comments

Time arranged for next visit…….

Support worker…….

Signature……....

Room 6

Dugald Baird Centre
Aberdeen Maternity Hospital
Aberdeen
AB25 2ZL
Tel: 01224 438444
Email: tracy.humphrey@nhs.net

IBriS Trial

Interventions supporting Breastfeeding in Substance dependency

Dear Colleague,

We would like to ask for your assistance in a research project. We are conducting a project on breastfeeding support for women who attend the substance misuse service clinic at Aberdeen Maternity Hospital. The project title is the IBriS trial – Interventions supporting establishment of breastfeeding for women who are substance dependent.

Methadone use in pregnancy results in Neonatal Abstinence Syndrome and breastfeeding can alleviate the severity of this condition due to the consolation effect of feeding and the transfer of methadone in breast milk. The rate of successfully establishing breastfeeding in this group is low due to maternal, neonatal and institutional factors. The aim of the research project is to design a breastfeeding support intervention for methadone maintained women and test its feasibility, acceptability and effectiveness.

We are gathering follow-up data on trial participants regarding their breastfeeding status at 6 weeks postnatal. It is anticipated that the participant detailed overleaf will attend the postnatal/ Health Visitor clinic at your surgery. It would be greatly appreciated if you could complete the enclosed questionnaire and return it in the envelope provided.

Please contact me if you have any questions about the study.

Yours sincerely,

Professor Tracy Humphrey
Clinical Professor of Midwifery

IBriS Trial

The following patient participated in the research study – IBriS Trial and has given her permission for details of her infant feeding status at 6 weeks to be collected.

Patient's name……

Infant's name…….…….

Infant's DOB…….

Expected date of attendance at clinic……

IBriS Trial

This questionnaire is anonymous and confidential.

Study Identification Number: | | | | | |

Date……..……...……...

Status	Please tick
Patient no longer at this practice	
Patient did not attend clinic	
Exclusive breastfeeding at 6 weeks	
Mixed -breast and formula feeding at 6 weeks	
Formula feeding only at 6 weeks	

If you could return the completed questionnaire in the envelope provided, please.
Thank you for your assistance.

APPENDIX 3

EXPERT ADVISORY GROUP: TERMS OF REFERENCE

Expert Advisory Group

Terms of Reference

1. Background

IBriS Trial is the result of a joint PhD studentship between RGU and NHS Grampian to undertake an applied piece of research in a national and local priority area that is meaningful for services and clinical practice. In collaboration with key stakeholders it was agreed that the focus of the research would be to contribute towards the strategic goal of increasing breastfeeding rates, specifically within the area of substance misuse services, whilst reducing health inequalities.
The research aim is to design evidence informed, theory based intervention to support methadone maintained women to breastfeed and conduct a pilot randomised controlled trial to test whether the intervention is feasible, acceptable to mothers and effective in establishing breastfeeding.

2. Role/Remit of Group

The role of the advisory group is to inform the development of the breastfeeding support intervention incorporating the needs of service users and providers whilst acknowledging the constraints of local resources.

3. Membership

The composition of the advisory group will include representation from obstetrics, neonatology, midwifery and specialist services for substance misuse at Aberdeen Maternity Hospital and a lay representative from the community. Others may be invited to attend on an ad hoc basis in relation to specific topics. Members can resign from the group by formally writing to or emailing the Chair.

3.1 Members include:

XXXX Neonatologist (chair)
XXXX Obstetrician
XXXX Midwife
XXXX Feeding Midwife
XXXX Midwife
XXXXX Midwife
Lay representative

3 Ex-officio members:

XXXX Neonatal
XXXX Child Health

4. Quorum

A quorum (number of members who need to be present before business can continue) will be one third of the group membership.

5. Attendance by members

Members will be expected to attend at least 50% of meetings per annum.

6. Attendance by others
Members of the advisory group can co-opt for others to attend the meeting when appropriate.

7. Role/remit of Group Members
The role of the advisory group member is to:

- Attend and actively participate in the group meetings
- Liaise and consult with the groups or professionals that they represent, reporting on the activities of the advisory group and providing feedback.
- Contribute to IBriS Trial advisory group activities.
- Undertake necessary work outside of the meetings in a timely way as required.
- Participate in any consultation exercises.
- Champion the work that the group produces.

8. Accountability and reporting arrangements
The advisory group will be accountable and report to the Chair.

9. Frequency and recording of meetings
The advisory group will meet 2 to 3 times during the trial period, which shall not be longer than 1 year. Additional meetings may be arranged to support the effective functioning of the research project if necessary.
An agenda will be sent to members no later than one week ahead of a scheduled meeting. Unapproved notes/minutes of the meeting will be taken and sent to members no later than two weeks after a meeting has been held. These will be considered for approval by the group at the next meeting.

10. Monitoring effectiveness
A final report will be produced at the end of the project describing the work of the advisory group.

11. Review
The advisory group will confirm its terms of reference at the initial meeting and thereafter as necessary.