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The Effect of Yoga on Wellbeing of Pregnant Women Post Infertility Treatments

By

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A thesis submitted in partial fulfilment of requirements for the degree of Doctor of Philosophy in Health Sciences

University of Warwick, Warwick Medical School

November 2020

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Acknowledgements

It has been a rollercoaster ride for three and half years and it would not have been possible without some very important people. I am indebted to you.

This thesis would not have been possible without the support, encouragement and guidance from my supervisors Professor Sarah Stewart-Brown and Dr Siobhan Quenby. First of all, a thank you to Sarah for accepting my research proposal in its very initial stages and seeing potential in me. Thank you, Siobhan, for bringing the clinician's point of view into this thesis and in helping me achieve a balance. I was blessed to have an amazing combination of supervisors who have helped me build my skills but more importantly mould me towards the correct attitude and thinking required for good research.

I am very lucky to come from a family that always encouraged me to aim higher. I have received unconditional support from them, and they believed in me even when I had lost all confidence in my abilities. Though they are in India and Australia, I always felt their presence and love. My sister, Nishu, was my strongest support system who I could turn to.

A PhD can be a very lonely journey, but I was lucky to have amazing friends. As PhD students, we all understood each other in ways others couldn't. Thank you, Swati, Farah, Ines, Latoya and Muna.

I thank the Warwick Doctoral College for awarding me the Chancellors Scholarship without which I would not have been able to do a PhD, and to the Research Degrees Team at Warwick Medical School for their continuous support while I was in the UK or overseas.

I thank Fernandez Hospital for their support towards conducting the feasibility trial in their hospital.

Last to enter into this journey was my husband, Charlie. He came into my life in the last and most tumultuous stretch of this journey. In the last ten months, he has held me through my happiest days and my breakdowns. Though the whole world is going through the COVID-19 crisis right now, he helped me focus on completing my thesis and did not let me stray off the path. I love you and thank you for everything you have done for me.

Declaration

I hereby declare that this thesis is all my own work except stated otherwise. This thesis has not been submitted for a degree at any other university.

Systematic Review: As my first degree was in India and MSc in the UK was on the subject of Management, my supervisors guided me on writing for medical academic audience in the West. The systematic review chapter presents work that is prepared for a publication co-authored by myself and my supervisors. As a result, my supervisors have had a larger input into the writing of this chapter than into the rest of the thesis. The research underpinning the chapter was undertaken entirely by me with the following exceptions: specific data extraction from papers that required clinical knowledge, identifying intention to treat analysis and extracting information not explicitly presented.

Primary Research: The decision to conduct the trial in India was mine and based partly on pragmatic issues like previous experience and professional connections. For the feasibility trial, the recruitment, data collection and analysis of data was done entirely by me.

For the focus group conducted in the UK, one of my supervisors helped with recruiting doctors and chaired the discussion. Study design, data collection and data analysis were done entirely by me.

Research Training:

I. Understanding Critical Research and Appraisal (Module)
II. Good Consent Practice
III. Using NVivo for Qualitative Research Analysis
IV. Academic Poster Design and Presentation

Thesis Word Count (Chapters 1-13): 62,166

Abstract

Research Aim: To conduct a study evaluating the feasibility of undertaking an RCT on the effects of Yoga on the wellbeing of pregnant women post infertility treatments.

Methods: A mixed methods study starting with a systematic review to identify RCTs of Yoga in pregnancy, examine the successful trial designs, and evaluate existing evidence. A waitlist-control feasibility RCT of Yoga in pregnancy post treatment for infertility was conducted in Fernandez Hospital, India, followed by interviews of all involved in the study. Finally, a focus group with NHS obstetricians.

Results:

a) Systematic Review: 15 trials were reviewed, identifying no evidence of harm from Yoga and potential benefits on a range of mental and physical health outcomes.

b) Feasibility Study: 61 patients contacted, nine gave consent, three attended Yoga sessions. Attendees showed improved wellbeing levels. Reasons for dropout were mental health stigma and relocation.

c) Interviews: eight doctors, two Yoga instructors, three participants and one family member consented. There was little knowledge on the effects of stress on maternal and infant health outcomes. Participants and family believed that exercise should be avoided in pregnancy, and reported problems discussing mental health due to stigma. Patients were afraid of participating in research.

d) Focus Group: UK doctors are aware of the effects of stress on maternal and infant health. There were mixed opinions on Yoga. There is interest in further research on the physiological effects of Yoga on patients. RCTs are the preferred research design.

Conclusion: There is no evidence that Yoga is harmful in pregnancy and some evidence suggesting positive effects on mental and physical health. A full RCT with the post infertility population in India is unlikely to be successful unless the problems identified could be addressed. A three step process ending with a pilot preference trial has been suggested.

Abbreviations

1. ACOG: American College of Obstetricians and Gynaecologists
2. ACTH: Adrenocorticotropic-releasing hormone
3. ADHD: Attention Deficit Hyperactivity Disorder
4. ART: Artificial Reproduction Technique
5. BDI: Beck Depression Inventory
6. BMI: Body Mass Index
7. BSREC: Biomedical and Scientific Research committee
8. CAM: Complementary and Alternative Medicine
9. CBT: Cognitive Behavioural Therapy
10. CES-D: Centre for Epidemiological Studies Depression Scale
11. CH: Chronic Hypertension
12. CPD: Continuing Professional Development
13. CRH: Corticotrophin-Releasing Hormone
14. EBP: Evidence Based Practice
15. EDS: Edinburgh Depression Scale
16. EPDS: Edinburgh Postnatal Depression Score
17. FertiQoL: Fertility Quality of Life
18. FSH: Follicle Stimulating Hormone
19. GA: Gestational Age
20. GDM: Gestational Diabetes Mellitus
21. GHQ-12: General Health Questionnaire
22. GnRH: Gonadotropin-releasing hormone
23. HADS: Hospital Anxiety and Depression Scale

24. HARS: Hamilton Anxiety Rating Scale
25. HDRS: Hamilton Depression Rating Scale
26. HPA: Hypothalamic-Pituitary-Adrenal
27. HPA: Hypothalamus-Pituitary- Adrenal Cortex
28. HRV: Heart Rate Variability
29. ICSI: Intracytoplasmic Sperm Injection
30. IUGR: Intra-Uterine Growth Retardation
31. IUI: Intra Uterine Insemination
32. IVF: In Vitro Fertilization
33. LBP: Lower Back Pain
34. LBW: Low birth weight
35. LH: Luteinizing Hormone
36. LS: Lifetime Stress
37. LSCS: Lower Segment Caesarean Section
38. NHS: National Health Service
39. NPIS: Numerical Pain Intensity Scale
40. OCD: Obsessive Compulsive Disorder
41. OI: Ovulation Induction
42. OR: Odds Ratio
43. PBOS: Pain Behavioural Observational Scale
44. PCOS: Polycystic Ovarian Syndrome
45. pCRH: Placental Corticotrophin-Releasing Hormone
46. PE: Preeclampsia
47. PEQ: Pregnancy Experience Questionnaire
48. PIH: Pregnancy Induced Hypertension

49. PIL: Participation Information Leaflet
50. PPI: Patient and Public Involvement
51. PRF: Pregnancy Related Fear
52. PS: Perceived stress during pregnancy
53. PSI: Pregnancy Symptom Inventory
54. PSS: Perceived Stress Score
55. QIDS: Quick Inventory of Depressive Symptomatology
56. RCT: Randomised Controlled Trials
57. SGA: Small for Gestational Age
58. SPD: Self-Perceive Distress
59. SR: Systematic Review
60. STAI: State Trait Anxiety Score
61. WEMWBS: Warwick Edinburgh Mental Wellbeing Scale
62. WHO: World Health Organization

1 INTRODUCTION

This chapter presents a background to the thesis, the aims and objectives, the structure of this thesis and reasons for my interest in this topic.

1.1 BACKGROUND

There is a reported rise in infertility across the world. India, which is the area of focus in this thesis, has seen a significant rise in reported cases of infertility in the last decade. Research shows that the diagnosis and treatment of infertility has a negative effect on the wellbeing of the couple. Women are especially affected, which potentially leads to further negative effects on maternal and infant health outcomes. I have used the term wellbeing throughout the thesis to refer to the health outcomes of relevance. Wellbeing is the positive end of the health spectrum and more than the absence of disease. It covers health issues like stress and pain in labour which are health problems, but not diseases. The literature on wellbeing focuses mostly on mental wellbeing, as does this thesis. The term is holistic covering physical and social as well as mental health. It covers the physical health topics presented in the thesis relating to obstetric complications and also the social aspects of taking part in trials.

Evidence points towards this population being at risk of deteriorated wellbeing. It is important to study interventions that can effectively manage and ideally improve the wellbeing of infertile women who conceive with the support of infertility treatments.

Yoga is an ancient practice that originated in India. It has been used as a complementary intervention to improve physiological and psychological outcomes in multiple clinical conditions including pregnancy. Prenatal Yoga is a modified form of the original practice. There is research spanning approximately a decade on the benefits of prenatal Yoga on low risk and high-risk pregnancies. However, at the outset of this thesis, there was no research evidence on the benefits of prenatal Yoga on pregnant women who conceived with the help of infertility treatments.

As mentioned above, there is a need to identify interventions to manage and improve wellbeing amongst this population for which there was no evidence of effects of prenatal Yoga. This thesis set out to fill that gap in knowledge.

1.2 AIMS AND OBJECTIVES

The study aimed to evaluate the effect of Yoga on the wellbeing of pregnant women who have undergone infertility treatments. The aim and objectives are stated below:

Research Aim: To conduct a study to evaluate the feasibility of undertaking a large randomised controlled trial of the effects of Yoga on the wellbeing of pregnant women post infertility treatments.

Research Objectives:

1. Review evidence on infertility and its impact on the wellbeing of women, and the effect of maternal wellbeing on the pregnancy, the labour, the infant and the postpartum period.
2. Search and appraise existing literature on pregnancy & Yoga.
3. Evaluate the feasibility of conducting a randomised controlled trial on Yoga and pregnancy post infertility treatments.
4. Explore the perspectives of trial participants and family members on infertility, Yoga intervention, and participation in the trial.
5. Explore expert opinion on perceived benefits and disbenefits of Yoga among the target patient group, and the need for randomised controlled trials.

1.3 STRUCTURE OF THE THESIS

As the project is based on the effect of Yoga on the wellbeing of pregnant women post infertility treatments, the literature review is in two parts. Chapters 2- 3 focus on Objective 1 and reviews existing literature on Infertility, its prevalence and effect on a woman's mental health presenting evidence on the effect of mental wellbeing on pregnancy and postpartum. Chapters 4-6 and 8 review evidence on Yoga, current views of clinicians, benefits and risks during pregnancy and infertility partially achieving Objective 2.

Chapter 7 discusses the paradigms and research frameworks that guided this thesis. Chapter 8 presents a Systematic Review on Yoga and Pregnancy conducted by me and by my two supervisors, achieving Objective 2. Chapter 9 follows presenting the methods and results of the feasibility study conducted in India (Objectives 3 and 4).

Chapters 10 and 11 present the qualitative research undertaken in this thesis (Objective 4 and 5). Chapter 10 focuses on the methods and results of interviews conducted in India and Chapter 11 elaborates on the methods and results of the Focus Group conducted in the UK.

Chapter 12 discusses all the findings from the thesis bringing them together and Chapter 13 concludes this thesis.

1.4 PERSONAL INTEREST IN THE TOPIC

My interest in the topic of infertility and Yoga arose from my experience in the maternity sector in India. As a childbirth and breastfeeding educator, and Yoga instructor, I have worked with many women in India across various socio-economic strata.

I have a keen interest in research and teaching. Research on benefits of Yoga is limited and that is how I developed an interest to pursue a PhD in the area of Yoga and maternity. I was accepted at Warwick Medical School and started looking at research opportunities in Yoga and maternity. I identified that research on Yoga and infertility was limited and it gave me an opportunity to add to the existing knowledge. Infertility is on the rise and it was evident that this population faced problems both physiological and psychological.

My education and experience span two industries: management and healthcare. I co-founded an award-winning start-up in India that focuses on improving maternal and infant health outcomes via digital services, home care and building of infrastructure like breastfeeding pods in public places. We have built two mobile apps: Preggo for pregnancy and Kuddls for post pregnancy. The apps provide information and videos, help monitor emotional health, peer to peer forums, an expert question and answer forum, and health trackers. Yoga is a key aspect of the mobile apps and home care services. During service evaluation, we have received positive client testimonials on benefits of Yoga during their pregnancy. They have commented in particular on the reduction of aches and pains, and improved confidence. Women practising after pregnancy have found Yoga beneficial for weight loss. However, there is limited information, potentially biased, and not evidence that will be considered as credible evidence for doctors and midwives.

Clinical research and good quality evidence are understandably required to bring about a change in how midwives and doctors consider Yoga, include it in protocols and advocate it as a potential solution to their patients in order to improve the mental and physical health of pregnant women and their infants.

This thesis sets out to examine the existing evidence and investigate further on the effect of Yoga on wellbeing of women who conceive through infertility treatments. The next chapter presents literature on infertility and its consequences.

2 LITERATURE REVIEW

This chapter provides a context for the thesis presenting information on infertility and its consequences. It aims to show that infertility is common and stressful, as are consequent treatments and subsequent pregnancies. It also looks at studies which investigate the extent to which this stress impacts on fertility and on the outcome of treatment. Further chapters look at the impact of stress on pregnancy outcomes, labour delivery and child health. It is a narrative descriptive review based on systematic searches of databases (MEDLINE, CINAHL, AMED and EMBASE), scanning of bibliographies and identification of relevant papers, together with google scholar searches. The initial searches were conducted in March 2017 followed by a repeat in November 2018 when I started writing this thesis. During the process of writing, google scholar searches with criteria- 2019 to 2020 were conducted to add new literature. Prior to submission in May 2020, a search was conducted to check for any new papers in the field of Yoga and Pregnancy.

2.1 INFERTILITY AND ITS CONSEQUENCES

Infertility, i.e., the inability to have children, affects men and women across the globe. Infertility is defined as the inability to conceive a viable pregnancy after 12 months of regular, unprotected sexual intercourse (heterosexual sex) (World Health Organization, 1991). Another definition states that infertility is a disease of the reproductive system by the failure to achieve a clinical pregnancy post 12 months or more of unprotected sexual intercourse, with no other reason such as breastfeeding or postpartum amenorrhea (Zegers-Hochschild et al., 2009).

Infertility creates a sense of personal suffering and societal repercussions for the couple (Cousineau & Domar, 2007). The World Health Organisation (WHO) has stated that “Infertility is a global public health concern” (Wolrd Health Organization, 1991).

In this chapter, the prevalence of infertility, and the relationship of infertility to stress will be discussed.

2.2 PREVALENCE OF INFERTILITY

It is estimated that globally, one in ten couples struggle with infertility. Rates vary from less than 5% to over 30% in various regions across the world. Countries with previously high fertility rates are showing increasing rates of infertility, a situation termed as “Barrenness amongst plenty” (Balen et al., 1996).

As per Mascarenhas et al., (2012), 48.5 million couples across the world suffer from infertility and prevalence was highest in South Asia, Sub-Saharan Africa, North Africa/Middle East, and Central/Eastern Europe and Central Asia.

As this thesis focuses primarily on India, focus has been given to the prevalence of infertility in India. In India where the primary research for this thesis was conducted, 17.9 million women were reported to be suffering infertility in 2010 (Ganguly & Unisa, 2010) whereas the NHS (2014) reports 3.5 million individuals in the UK are diagnosed with infertility.

Ernst and Young reported (Young, 2015) five years later, there were 27.5 million couples actively seeking infertility treatment in India. 2017 statistics report that 10-15% of the Indian population suffer from infertility and the rates are higher in urban areas (approximately 200.85 million individuals) (Nations, 2017). According to WHO, Infertility becomes a public health concern when it exceeds 15% and India is currently on the borderline which makes research in this area timely and necessary.

This sharp increase in the prevalence of infertility could be for one of two reasons. Either the absolute numbers are increasing or there is an increase in diagnosis and treatment. Whichever the reason, the numbers are high enough to make it a concern.

The United Nations Population Prospects Report (2017) reports a decline in the fertility rate of Indians from 4.97 during 1975-80 to 2.23 during 2015-20 and projects a further decline to 1.86 by 2045-50. 2.2 is considered as optimum replacement level and when it drops below that, a population is projected to decline. In extreme conditions, the WHO (World Health Organization, 1991) states that "Infertility, compounded by pregnancy wastage, infant and child mortality, may lead to depopulation, which poses a serious threat to the social and economic development of the region".

2.3 Relationship of Infertility and Stress

Stress is typically defined as "A stimulus that produces mental tension or physiological arousal" and anxiety arises as a result of the stressor (Cousineau & Domar, 2007). The sections below look at the physiological effects of stress on fertility, whether stress can affect the success rates of infertility treatments, the social and psychological consequences of infertility, how pregnancy after treatments are different and lastly the disclosure of mental health problems to the healthcare professionals.

2.3.1 Physiology

Some of the effects the stress reactions can have on reproduction include interference in gonadotrophin secretion, catecholamine effects on the uterus and fallopian tube, and disturbances in the implantation process (Reading et al., 1989). The Hypothalamic-Pituitary-Adrenal (HPA) Axis and the stress hormones in the body interact with hormones like Gonadotropin-releasing hormone (GnRH), prolactin, Follicle-stimulating hormone (FSH) and Luteinizing hormone (LH) which have a direct influence on fertility and with melatonin, cortisol and endogenous opioids which can interfere with fertility (Campagne, 2006; Hajela et al., 2016; Klonoff-Cohen et al., 2001; Koopman, 2013).

High levels of stress measured by salivary alpha amylase have been reported to be associated with longer time to pregnancy and >2-fold risk of infertility (Lynch et al., 2014). A 29% decrease in fecundity was reported among women in the highest tertial in comparison with women on the lowest tertial of alpha-amylase.

Once treatments begin, common physiological symptoms presented in women with increased levels of stress and anxiety include fatigue, headache, nausea, insomnia and abdominal pain (Volgsten et al., 2008).

2.3.2 Infertility Treatments

Anxiety and stress are common amongst women undergoing fertility treatments due to their state of infertility and, more importantly, the uncertainty of results (Bhat & Byatt, 2016; Cousineau & Domar, 2007; Volgsten et al., 2008). Infertility treatments are a cause for chronic stress as the couple goes through successive cycles of hope and dejection (Domar et al., 1993). Infertility and perinatal loss are together referred to as reproductive trauma. Reproductive trauma occurs in 15% of all women and is often associated with psychiatric disorders or symptoms (Bhat & Byatt, 2016).

Lintsen et al., (2009) discusses three multidimensional sources of stress during an infertility treatment. Firstly, the threat that infertility can be permanent. Secondly, the prospect of the fertility treatment itself. Lastly, the procedural stress of the actual treatment. Infertility assessment and treatment can be one of the lowest points in a woman's life (Freeman et al., 1985).

Veerhaak et al., (2006), Chen et al., (2004) and Volgsten et al., (2008) report that 17%-30% of women visiting infertility clinics show subclinical forms of anxiety and/or depression; especially post unsuccessful treatments. The percentage is much higher than pregnant women in the second trimester (Andersson et al., 2003). A study reported that out of 862 participants in a fertility clinic, approximately 30% of women and 10% of men fulfilled the criteria for depression (Andersson et al., 2003).

Lower stress levels are associated with better fertility in men and women but the evidence on outcomes of fertility treatments is inconclusive. A study on the impact of stress on fecundity indicated that high stress levels can significantly affect chances of conception (Louis et al., 2011). While few studies indicate that stress/anxiety can have a negative impact on fertility treatment outcome (Ebbesen et al., 2009; Gürhan et al., 2009; Karlidere et al., 2008; Klonoff-Cohen et al., 2001; Smeenk et al., 2001), some studies including a meta-analysis of 14 studies (Boivin et al., 2011), indicate that there is no dependant relationship between the outcome of treatments and stress/anxiety levels in women (Anderheim et al., 2005; Campagne, 2006). Smeenk et al., (2001) report that state anxiety scores are better predictors of pregnancy in comparison to depression scores.

Bhat et al., (2016) reinforces the importance of detecting, assessing and treating psychiatric symptoms as infertility or perinatal loss can be caused or perpetuated by these. Continuation of treatment and following the doctor advised care plan is a key factor in successful Artificial Reproduction Technique (ART) treatments and distress is one of the most common reasons given by fertility treatment patients who wish to voluntarily terminate the treatment process (Cousineau & Domar, 2007; Olivius et al., 2004; Rajkhowa et al., 2006). Reducing stress levels can potentially reduce the number of treatment cycles required and affect the coping mechanisms of the couple towards the treatment cycles (Campagne, 2006).

2.3.3 Social and Psychological Consequences

The diagnosis of infertility can have varying degrees of social and psychological consequences. In some cultures, women are ostracised, exiled, face abuse, or divorced as motherhood is the only way to establish their status in the family and community. This can lead to mental distress and isolation (Domar & Seibel, 1990; Hajela et al., 2016; Rutstein & Shah, 2004; Van Balen & Gerrits, 2001). Women are often labelled as the cause of infertility due to the cultural influence of mythology and religion (Hajela et al., 2016; Schiff & Schiff, 1998). In a report by WHO (2001), in some developing countries, women choose suicide over the tortuous life they have to lead due to infertility. Infertility is also perceived as punishment for past sexual indiscretions, abortions or use of contraception (Domar & Seibel, 1990). To ensure that patients stick to treatment regimens and are able to maintain a healthy state of mental wellbeing, healthcare providers need to be sensitive to cultural beliefs of patients during diagnosis and treatment of infertility (Van Balen & Gerrits, 2001).

Freeman et al., (1985) reports that 63% women rated infertility as stressful as divorce when they went through both. A study by Domar et al., (1993) that infertile women have been reported to have global symptom scores equivalent to individuals suffering from cancer, cardiac diseases and chronic hypertension ($p<0.0001$); but lower than chronic pain and HIV ($p<0.02$). It is a report that surprises clinicians and Domar et al., (1993) comment that it is possible that the chronicity of the disorder affects the level of psychological impact rather than the diagnosis itself.

2.3.4 Pregnancy After Infertility Treatments

Pregnancies post infertility treatments are high risk from both an obstetric and a wellbeing perspective. Twin pregnancies, chances of preterm births and caesarean births are prevalent post ART treatments (Adashi et al., 2003; Dhont et al., 1999). A report by Adashi et al., (2003) highlights the risks associated with multiple pregnancies- hypertension, embolisms, urinary tract infections, haemorrhage and fluid overload. Longer periods of rest and hospitalisation are documented among women with multiple pregnancies due to risks of preterm labour. The higher risk of possible physiological issues increase the risk of a constant state of fear amongst the couple.

Raoul-Duval et al., (1994) reported that the psychological issues faced by couples conceiving with help of infertility treatments can carry on during pregnancy and has the probability to affect early parenting. While Poikkeus et al., (2014) suggest that the assisted reproduction prepares infertile couples to handle further challenges ahead, Rouhe et al., (2009) suggest that this can increase anxiety about pregnancy and birth.

Pregnant women post ART have significantly greater anxiety regarding health of the child (2012; Hjelmstedt et al., 2003; Slade et al., 1997), survival of the pregnancy, delay telling people about the pregnancy, are anxious regarding threat to the child during process of birth, have negative feelings of childbirth and indicate higher tolerance to medical interventions during birth (McMahon et al., 1997). This group is reported to have a higher level of antenatal complaints (Younger et al., 2015), which is associated with higher rates of hospital admissions for minor problems like a back pain (Bryan, 2000; Hammarberg et al., 2008). A study of 45 couples during their infertility treatment, pregnancy and birth identified that the psychological burden was higher than physical burden and the pregnancy was perceived to be more stressful than the controls with spontaneous conception (Balen et al., 1996; Domar et al., 1993).

McMahon et al., (1997) report that the duration and number of treatments have an effect on higher levels of anxiety. Women who had two cycles or more of treatments show higher levels of anxiety and women who have had just one cycle tend to report suppression of anxiety issues.

While Poikkeus et al., (2014) suggest that the assisted reproduction prepares them to handle other roadblocks ahead, Rouhe et al., (2009) suggest that this can increase anxiety about pregnancy and delivery. In a study by Monti et al., (2009), Edinburgh Postnatal Depression Scores (EPDS) collected at 30-32 weeks' gestation, 1 week after birth and 3 months after birth, reported higher scores in infertility treatment led pregnancies as compared to spontaneous conception pregnancies. The study also reported a significantly higher number of depressed subjects in the treatment led pregnancy group as compared to controls. Women of this group have different psychological needs and coping methods (Balen et al., 1996; Domar et al., 1993).

In the postnatal period, this group of women are vulnerable to low self-esteem and need to be looked after by the caregiver as well as the family and one way to help these women is to have a solid framework of care (physical and emotional) from the antenatal period (Bhat & Byatt, 2016; Jayaprakasan & Kean, 2017).

2.3.5 Disclosure of Mental Health Problems to Healthcare Professionals

Patients at an infertility clinic have a tendency to try and impress clinicians as "good patients" which prevents them from revealing psychological distress to their doctors as there is a fear that treatments may be rejected or postponed (Chen et al., 2004; Volgsten et al., 2008). Women are often afraid to

be perceived as crazy or of being criticized over negative feelings of self (Baram et al., 1988). There is a possibility that results of self-administered questionnaire studies are skewed if women are trying to portray a positive mental state in fear of being rejected treatments. As a result the majority of infertile women experiencing stress and anxiety disorders are undiagnosed and untreated by their healthcare team (Van Balen & Gerrits, 2001; Volgsten et al., 2008).

At the same time, Anderheim et al., (2005) report that IVF patients often enquire about the effect of stress on treatment outcomes due to concerns that their mental health can influence conception rates. Though the evidence is inconclusive, the statement that stress does not have an effect is often used to reassure the couples.

The success rate for infertility treatment is based on the number of viable pregnancies and live births and there is an underlying assumption in medical literature that psychological issues arising from infertility are not comparable to or are as important as more tangible physical health issues affecting pregnancy. The negative psychological impact of infertility is often overlooked and underestimated by obstetricians and midwives because many of the effects are seen after the birth of the baby (See 3.2.3). Patients are often assured by doctors that stress levels do not influence their chances of conception and the other psychosocial effects (Whiteford & Gonzalez, 1995) are not discussed.

Evidence is also mounting that there may be interventions which can reduce stress in infertility and possibly effect clinical outcomes. This has been reviewed in detail in Chapter 6.

Campagne (2006) suggests that stress reduction is a cost-effective and non-invasive method to improve fertility in women. In spite of the equivocal nature of evidence suggesting stress has an impact on fertility and the outcome of treatment, some authors are convinced that because they are inexpensive and non-invasive, preventive and supportive psychological treatments are called for, even ones with only provisional efficacy evidence (Domar et al., 1993; Koopman, 2013; Lintsen et al., 2009).

2.4 CONCLUSION

Infertility is a condition present amongst 10%-15% of the Indian population. India's borderline rates of infertility is a public health issue and a cause for concern. A large population are undergoing diagnosis and treatment for infertility, and the process of diagnosis and infertility treatments have the potential to cause mental health issues.

Stress can impact fertility physiologically and, though evidence is inconclusive, there is a possibility that stress affects success rates of infertility treatments. Infertility has very difficult social consequences that have the potential to adversely affect a woman's mental health potentially putting

her into a vicious cycle of stress and infertility. Pregnancy with help of treatments can lead to fear, doubt and worry. Although there is preliminary evidence that it is possible to reduce stress in patients with infertility, at present healthcare professionals do not seem to be addressing these aspects of infertility adequately.

In the next chapter, the effect a woman's mental health can have on her pregnancy, labour, postpartum period, and her infant will be reviewed.

3 THE EFFECTS OF MENTAL HEALTH PROBLEMS ON PREGNANCY, LABOUR AND THE POSTNATAL PERIOD

The last chapter highlighted the implications of infertility for mental health. It was further discussed that health professionals tend to discount problems related to mental health in contrast to physical health outcomes. This chapter therefore reviews the literature investigating the effect of common mental health problems (stress, anxiety (state and trait) and depression) on pregnancy, labour, the postnatal period and on the development of the infant and child.

Stress, a feeling of discomfort, arises when a stressor (situation or experience) generates feelings of anxiety, threat and fear (Kurebayashi et al., 2012). Depending on individual resilience, stress increases the risk of a variety of illnesses. Individuals with diagnoses of anxiety experience higher levels of threat and fear when faced with a specific stressor than individuals who are not anxious. Anxiety and depression commonly occur together among all age groups and often over time; the presence of one increases the risk of the other (Belzer & Schneier, 2004; Garber & Weersing, 2010). The following sections look at the way mental health problems effect a mother and her baby. The literature covers the effects of stress and the impact of the clinical conditions of anxiety and depression usually in separate publications, but as these conditions are clearly linked, both are reviewed together here.

The prevalence of mental health problems among pregnant women varies between 10-25% in studies across various populations (Burt & Stein, 2002; Marcus et al., 2003; Nonacs & Cohen, 2002). Most studies of mental health in pregnancy report on depressive symptoms and disorders and show that they affect a high proportion of women in all populations. A review by Gavin et al (2005) suggests that 18.4% of pregnant women report depressive symptoms of which 12.7% have an episode of major depression. Prevalence rates of maternal depression may be double among South Asian population as compared to Western societies. (Rahman et al., 2003). Orr et al. (2007) report that in low socioeconomic groups and minority populations, over 40% women suffer from prenatal depression. A study by Lee et al. (2007) reports that 54% of women had antenatal anxiety in at least one trimester. Multiple studies show that anxiety in pregnancy follows a U-shaped curve with higher anxiety levels reported in first and third trimesters as compared to second trimester (Lee *et al.*, 2007; Teixeira *et al.*, 2009).

3.1 EFFECT OF COMMON MENTAL HEALTH PROBLEMS ON A MOTHER'S HEALTH AND ON LABOUR AND DELIVERY

3.1.1 Pregnancy

Studies on the effects of common mental health problems on pregnancy have looked at a variety of outcomes. Elevated first trimester anxiety has been associated with vertigo, low blood pressure, pre-arranged caesarean sections (Fertl et al., 2009), increased nausea, vomiting, prolonged sick leave and higher number of obstetric visits (Andersson et al., 2004). All the above lead to a more difficult pregnancy, increase the cost of care and negatively impact the pregnancy experience of the woman.

Fear is a component of anxiety disorders, often as a response to objects or situations (Shin & Liberzon, 2010) and the Elevated Pregnancy Related Fear (PRF) scale questions are similar to stress/anxiety questionnaires but modified to pregnancy. PRF levels in the first trimester predicted the risk of fatigue, vaginal bleeding, in-patient treatment and eventually levels of surgical deliveries, pregnancy complications and low APGAR scores in the baby (Fertl et al., 2009).

Elevated stress may also play a role in pre-eclampsia (PE), which can in turn lead to preterm birth, hypoxia, growth retardation and, in extreme cases, death. Stress hormones may increase the level of oxidative stress in the maternal blood circulation, and impair the uteroplacental blood flow (Sikkema et al., 2001). The epidemiological evidence for the impact of stress on PE is, however, mixed with four studies establishing risk (1.7 to 2.12 times) (Kurki et al., 2000; Qiu et al., 2009; Rejnö et al., 2019; Yu et al., 2013) and three studies showing no significance (Okoshone et al., 2015; Sikkema et al., 2001; Vollebregt et al., 2008). The latter studies have focused on questionnaire or salivary cortisol in the first or second trimester (<24 weeks) of pregnancy. As preeclampsia is a major cause of maternal and foetal mortality and of pregnancy complications, occurring in 5-7% of pregnancies, further investigation is important.

3.1.2 Labour and Birth

Maternal anxiety and depression have been reported to be associated with fear of childbirth, increased health care service use, higher perception of pain, higher pain reactivity, increased physical distress, painful labour, prolonged labour, request for epidurals, administration of oxytocin, obstetric complications, elective surgical births and low APGAR scores (Alhusen & Alvarez, 2016; Andersson et al., 2003; Andersson et al., 2004; Bayrampour et al., 2015; Kelly et al., 2001; Martini et al., 2010; Rauh et al., 2012; Rejnö et al., 2019; Rhudy & Meagher, 2000; Simkin & Ancheta, 2011; Smorti et al., 2019; Wiklund et al., 2007).

A difficult birth experience, any form of birth trauma or unsatisfying labour and birth can impact the mother and the effects of childbearing experiences can last a lifetime, creating a strong impact throughout the woman's life and subsequent pregnancies (Ehrlich, 2004; Simkin et al., 2016).

3.2 FOETAL DEVELOPMENT

3.2.1 Foetal Growth, Gestation and Birth Weight

Growth and development of the foetus may also be influenced by the psychological state of the mother (Mulder et al., 2002). Maternal stress can play a role in compromising embryonic and foetal growth and in some cases predict recurrent spontaneous abortions (Neugebauer et al., 1996; Rondo et al., 2003).

Studies in the USA (Diego et al., 2009; Edwards et al., 1994; Field et al., 2004; Orr et al., 2002; Steer et al., 1992), Brazil (Rondo et al., 2003), Sweden (Liu et al., 2016), Korea (Chang et al., 2014) and the UK (Rice et al., 2010) assessing indices at birth among infants of prenatally depressed mothers in comparison with controls report shorter gestation period, restricted foetal growth and/or lower birth weight.

Women with panic disorders (with or without clinical treatment) have been observed to have a higher risk of babies being born with lower birth weights as well as preterm birth and maternal anaemia (Bánhidy et al., 2006; Wasser, 1999). Banhidy et al., (2006) report that pregnant women with panic disorders have a 0.4 week shorter gestation ($p=0.02$) and a larger proportion of preterm births (17.1% vs 9.1%).

However, systematic reviews and meta-analyses provide contradictory evidence on maternal anxiety and depression as a cause of preterm birth (Accortt et al., 2015; Rose et al., 2016; Staneva et al., 2015). The evidence is stronger for anxiety than for depression. Some researchers believe that maternal stress should be considered as one of the clinical conditions that contribute to the cascade of events that leads to preterm birth, and high levels of the stress hormone CRH and ACTH have been reported in women who spontaneously gave birth prematurely (Hobel et al., 1999; Leung et al., 1999; Mancuso et al., 2004). But the evidence is not clear cut.

When adjusted for gestational age, Chang et al (2014) suggest that the link between birth weight and depression could be the impact of depression on the gestational age at birth. In a study of 720 pregnant women in rural Bangladesh, post adjustment for potential confounders, depression and anxiety were significantly associated with LBW infants (<2.5kgs) but no significant difference was reported in preterm births (Nasreen et al., 2010). The head circumference of the newborn babies of

depressed and anxious women was significantly lower than their counterparts. Head circumference is a key indicator of growth, and a symptom of many potential syndromes or disorders in the baby.

3.2.2 Foetal Heart Rate Variability

Patterns of foetal heart rate variability have been used as indicators of foetal wellbeing and central nervous system development including maturity of the autonomic nervous system (Groome et al., 1994) and there is evidence that these are influenced by maternal depression. When foetal developmental outcomes associated with prenatal depression were compared to those of foetuses in non-depressed controls, focusing on fetoplacental integrity and central nervous system development, it was reported that during the baseline period, the foetal heart rate was higher in foetuses of depressed mothers (Allister et al., 2001). When an external stimulus was presented, foetuses of both groups demonstrated an expected increase in heart rate. The foetuses of the control group demonstrated greater acceleration in presence of an external stimulus and faster return to baseline. Foetuses of depressed mothers were slower to react to external stimuli and recorded a 3.5-fold increase in time to return to the baseline; these findings were attributed to alterations in the hormonal environment of the mother. In this study Infants of prenatally depressed mothers were born with lower resilience to stress.

3.2.3 Infant and Child Behaviour

There is convincing evidence that foetal exposure to maternal depression, anxiety and stress has adverse consequences for a child's neuro, cognitive and behavioural development (McMahon et al., 2013).

Neonates of prenatally depressed and anxious mothers spend significantly less time awake and alert, and more time crying and fussing in comparison controls (Diego et al., 2005; Van den Bergh, 1990). It is trait anxiety rather than state and pregnancy-specific anxiety which is the predictor of infant temperament. It may be however, that women who conceive with infertility treatments are protected from these effects as they consider themselves lucky to have the infant. McMahon et al., (2013) in a study of 462 women, record that ART women reported less difficult infant temperament ($p<0.001$) as compared to spontaneous conception counterparts. Infants of prenatally depressed mothers also had a significantly higher risk of diarrhoeal infection, poor growth and were less likely to be immunised on time than infants of women in the control group (Rahman et al., 2004).

Neonates of mothers with elevated cortisol levels in second and third trimesters had a larger infant cortisol response to a heel-stick procedure and a slower rate of recovery (Davis et al., 2011). A previous study reported that maternal cortisol at 30-32 weeks was significantly related to negative infant reactivity but early pregnancy and postpartum cortisol levels were insignificant (Davis et al.,

2007). Evidence points towards a possibility that infants of prenatally stressed/anxious/depressed mothers are more likely to be fussy, cry a lot and have higher cortisol levels.

Maternal anxiety disorders in pregnancy seem to have a long lasting effect on the infant, being associated with offspring anxiety disorders like social phobia, agoraphobia, generalised anxiety disorder, obsessive-compulsive disorder and posttraumatic disorders (Martini et al., 2010). Mother–child pairs (n=992) from a representative community sample of the prospective-longitudinal Early Developmental Stages of Psychopathology (EDSP) study were studied and the offspring outcomes were measured at baseline of 14-17 years of age and for a further 2, 4 and 10 years.

Self-perceived distress (SPD) during pregnancy was associated with Attention Deficit Hyperactivity Disorder (ADHD) in the child but not specifically offspring anxiety. Human and animal studies have indicated the adverse effect of stress on neuronal development of the foetus which may develop into multiple types of behavioural pathology as the child grows into an adult (Weinstock, 2001). Maternal stress is associated with a range of negative cognitive and emotional outcomes in children like ADHD, anxiety and language delay (Talge *et al.*, 2007).

Studies of the relationship between maternal mental health problems and mental health problems in the offspring raise the question of genetic links. One study of IVF pregnancies is particularly important in this respect. Rice et al., (2010) showed a significant association of prenatal maternal stress on child antisocial behaviour in IVF pregnancies with both their own gametes (p=0.0001) and donor gametes (p=0.02). This study also showed prenatal stress to be associated with offspring anxiety in related (p=0.001) and unrelated mothers (p=0.01). These findings show that the putative effects of maternal mental health problems on child mental health problems cannot be transmitted by genetic mechanisms alone. In contrast, in the same study maternal prenatal stress was only linked to ADHD in the child in related mothers (p=0.001).

High levels of parenting stress can be predicted by pregnancy-specific anxiety and trait anxiety during pregnancy but not state anxiety (Huizink et al., 2017). They have also been associated with undesirable outcomes like parental depression, less effective parenting, and behavioural problems and developmental delays in the children (Neece *et al.*, 2012).

Epidemiological evidence such as covered here can suggest causality but not prove it. Evidence of biological plausibility strengthens the argument that the associations are causal.

3.3 THE BIOLOGICAL PLAUSIBILITY

In the human body, exposure to stress activates the Hypothalamus-Pituitary- Adrenal Cortex system (HPA axis) which leads to the release of corticotrophin-releasing hormone (CRH),

adrenocorticotropic-releasing hormone (ACTH), cortisol and (nor)adrenaline (Davis et al., 2011; Mancuso et al., 2004; Mulder et al., 2002). The idea that high levels of stress affect the reproductive system has biological plausibility as the endometrium, ovaries and myometrium have abundant CRH and cortisol receptors. CRH synthesised by the placenta, i.e., Placental CRH (pCRH), determines the duration of pregnancy. The pCRH levels rise at the end of pregnancy and just before birth of the baby. Detection of a stress signal from the maternal environment by the foetal/placental unit conveys a message that there is threat to survival leading the placenta to produce higher levels of pCRH to shorten gestation and leave the malignant environment (Sandman et al., 2006). This can compromise the survival of the foetus.

Variation in levels of maternal hormones (CRH, ACTH, pCRH) can be early indicators of changes in maternal stress levels (Austin & Leader, 2000; Mulder et al., 2002; Wadhwa et al., 2001). In addition, maternal stress can affect the foetus through reduction of the blood flow to the baby (Mulder et al., 2002).

In Section 3.2.2, evidence has been shown that prenatal depression affects the development of the foetal stress response, and infants of depressed mothers are born with less resilience to stressors, leading to long term effects on their mental health. Prenatal depression also predicts postpartum depression and this may affect the mother for years after delivery. (Alhusen & Alvarez, 2016; Davalos et al., 2012).

3.4 CONCLUSION

Overall, the evidence presented in this chapter strongly suggests that maternal mental health problems in pregnancy should be of concern to health care providers caring for pregnant women. Maternal stress increases the risk of minor health problems in pregnancy and spontaneous abortion. It also shows that mental health problems are associated with an increased use of health services in pregnancy and more difficult labours resulting in more surgical births. The evidence relating to more serious adverse pregnancy outcomes like preeclampsia, preterm delivery and low birth weight is suggestive but not proven. The evidence is strongest for the long-term consequences of maternal mental health problems on the developing infant and child, with good quality studies showing a clear relationship with neuro, cognitive and behavioural development. Mental health problems in pregnancy predispose a mother to parental stress which has an ongoing detrimental effect on child development.

Maternal mental health problems tend to occur in families with other stressors and social and economic factors which also affect the growth and development of the infant and progress of the

pregnancy. However, it may be that mental health problems are more amenable to intervention than other factors and that such interventions can improve the chances of positive birth outcomes even in disadvantaged families. This thesis set out to examine the possibility that prenatal Yoga is one of the interventions that could have this effect.

4 YOGA: ORIGINS, APPROACHES AND HEALTH BENEFITS

4.1 ORIGINS OF YOGA

Yoga is an ancient practice that originated in India thousands of years ago. The etymology of the word "Yoga" comes from an old language called Sanskrit. In Sanskrit Yoga means "union" or "to join" (Shearer, 2010; Taylor, 2003). Feuerstein (2002) states that the term Yoga refers to a large body of precepts, attitudes, values and techniques developed in India over 5000 years.

Patanjali codified the original Hindu texts written in 2000 B.C.E. into Yoga Sutras in 200 C.E (Feuerstein, 2002). As per Patanjali's Yoga Sutra, "Yoga is the control of the fluctuations of the mind". A well rounded practice of Yoga is reported to result in creating holistic health through the union of body, mind and spirit (Taylor, 2003). The ultimate goal of Yoga was originally to be a guide for wholeness, happiness and wellbeing (Feuerstein, 2003). The postures, chanting and meditation, which are commonly presented as Yoga today, are only a small portion of the complete ancient practice.

Yoga focuses on controlling the fluctuations of the mind with the physical body as a tool of practice (Feuerstein, 2002). Yoga sessions encourage body awareness and help recognize tension areas in an emotional as well as physical way. It helps create a sense of self-control and self-efficacy (Javnbakht et al., 2009). Psychologically, Yoga is considered as an introspective and meditative activity (West et al., 2004). When the power of mind is harnessed, the physical outcomes are flexibility, posture, balance, strength and overall enhanced physical health (Feuerstein, 2002; Iyengar, 2007).

Yoga has evolved out of Hindu, Jain and Buddhist religious traditions in India but makes no dogmatic demands of belief (Taylor, 2003). It is a common misconception that the practice of Yoga is linked to a specific religious belief. However, whilst Yoga is a spiritual practice, it has been adapted to be used by people of all religions across the world. Unlike the original practice, some modern practices of Yoga, particularly those now taught in the Western world are not grounded in spiritual development or path to transcendence. These approaches focus on physical and psychosomatic components of the practice (White, 2009).

The postures of a Yoga practice are designed to stretch and strengthen the muscles to keep the joints and spine flexible and strong, massage the internal organs for better functionality and circulation, improve immune functioning, sleep, hand-eye coordination and for somatic awareness (Feuerstein, 2003; Field, 2011).

4.2 TYPES OF YOGA

There are over 40 reported styles of Yoga in the scriptures. Hatha Yoga, developed in 1000 C.E. is the most common form of Yoga (Feuerstein, 2002). Hatha is a combination of Asanas (Postures), Pranayama (Breathing) and Meditation/Relaxation. There are many forms of Hatha Yoga being practiced today- Ashtanga, Iyengar, Kundalini, Bikram, Sivananda and Ananda (Feuerstein, 2003; Taylor, 2003; White, 2009). Basic Hatha Yoga is most popular followed by the variations given below in Table 1. Basic Hatha Yoga is the form used in the majority of clinical trials and research studies.

Table 1: Variations of Hatha Yoga (Feuerstein, 2003; Taylor, 2003)

Variations of Hatha Yoga (alphabetical order)	**Description**
Ananda	Slow, gentle movements, affirmations, meditation and specialised breathing exercises.
Ashtanga	One of the most intensive forms of Yoga. It is very athletic with swift movements between poses. Usually followed by people with wide experience of Yoga. Not suitable for therapy.
Bikram	Commonly known as "Hot Yoga". A standard sequence performed in a room heated up to 100-100-degree Fahrenheit. Very demanding on the body and not suitable for many. Not suitable for therapy.
Iyengar	Second most commonly performed form of Yoga. This uses a host of props and supportive structures like blocks, straps, bags, cushions and chairs to perform the Yoga poses. Excellent for therapy and rehabilitation.
Kundalini	Postures, breath control, chants and meditation used to awaken the inner energy of the body.
Power	Very athletic and aerobic exercise-based format of Yoga. Useful for weight loss. Unsuitable for therapy and rehabilitation
Restorative	Gentle practice for sustained relaxation. Supportive props are occasionally used. Useful for a wide range of medical conditions.
Sivananda	Series of 12 Yoga postures including chants, relaxation and breathing

4.3 PREVALENCE OF YOGA PRACTICE

There are over 10,000 Yoga teachers in the UK and between 20,000-30,000 Yoga classes are taught per week (Finder UK, 2020). As the average size of a class is 15 people, it is estimated that 300,000 to 460,000 people are attending classes every week. It is estimated that 20 to 30 million people in the United States (US) practice some form of Yoga (Taylor, 2003) and schools in the US are increasingly using Yoga to help their students manage stress and influence behaviour and wellbeing (White, 2009). There are no published figures on number of people practising Yoga in India. News articles state that there is a rise in individuals practising Yoga, but no numbers are recorded.

The prevalence of the practice is relevant as it translates into awareness about the practice and its variations and benefits among the general public. The higher the prevalence, the easier it will be to recruit participants for research work in this field.

4.4 YOGA AS A COMPLEMENTARY APPROACH TO CLINICAL MEDICINE

Uebelacker et al., (2010) suggests that the holistic goal of Yoga in promoting physical and mental health while being spiritually and socially conscious appeals to both patients and providers who are concerned about the symptom-reduction based methods of psychopharmacology.

There is reasonable evidence from controlled trials that Yoga practice is beneficial for common mental health problems. A systematic review of 16 trials by Balasubramaniam et al., (2013), showed moderate quality evidence supporting potential acute benefit for Yoga in depression, as an adjunct to medication in schizophrenia and ADHD, and low quality evidence supporting benefit of Yoga for sleep issues. Another systematic review of eight studies on Yoga and anxiety reported positive findings for use of Yoga in Obsessive Compulsive Disorder (OCD), snake phobia, examination anxiety, anxiety neurosis and psychoneurosis out of which only the OCD study is reported to be of good quality (Kirkwood et al., 2005).

Yoga offers promise to the field of eating disorders as its mind-body therapy approach promotes greater self-awareness and greater acceptance of the body (Balasubramaniam et al., 2013; Frisch et al., 2006; Neumark-Sztainer, 2014).

Yoga has also been shown to be of potential benefit in a wide range of clinical conditions. The results of eight Cochrane reviews on the effect of Yoga have been briefly summarised below:

I. Asthma: There is moderate quality evidence that Yoga improves quality of life and alleviates symptoms of asthma. High quality RCT's are required to study its effect on lung function and medication usage (Yang et al., 2016).
II. Coronary Heart Disease: No studies matched inclusion criteria (follow up duration of 6 months or more). High quality RCT's are required (Kwong et al., 2015).
III. Prevention of Cardiovascular Disease: There is limited exploratory evidence from short-term studies with moderate-low quality of favourable effects on diastolic blood pressure, cholesterol and triglycerides, HDL and uncertain effects on LDL (Hartley et al., 2014).
IV. Breast Cancer: In comparison to no therapy, Yoga helps in improving quality of life, sleep disturbances and reducing fatigue. Yoga was also reported to be better than psychosocial or educational interventions like counselling in reducing fatigue, anxiety and depression. There is low quality evidence indicating that Yoga is as effective as other exercise interventions and can be used as an alternative (Cramer et al., 2017).
V. Stroke Rehabilitation: There is potential for Yoga to be part of a patient centred stroke rehabilitation program. However, more evidence is required to establish clear effectiveness as a treatment plan (Lawrence et al., 2017).
VI. Non-Specific Lower Back Pain: Low-moderate evidence that Yoga in comparison to non-exercise controls result in small to moderate improvements at three and six months. It is uncertain whether Yoga with other exercise or Yoga alone is better for non-specific lower back pain. Long-term outcomes need to be researched (Wieland et al., 2017).
VII. Epilepsy: Possible beneficial effect in control of seizures have been reported in a study of 50 participants from two trials. Yoga was reported to be better than no intervention or other interventions. No difference was reported between Yoga and Acceptance and Commitment Therapy. No reliable conclusion was reported for uncontrolled epilepsy and further research is required to evaluate efficacy of Yoga for refractory epilepsy (Panebianco et al., 2017).

The recurrent themes in these reviews are the lack of high quality RCT's, but also that Yoga may be effective at improving quality of life in patients with long term medical disorders.

4.5 SAFETY OF YOGA

Safety is always a concern amongst clinicians where complementary therapies are concerned. No studies have reported adverse outcomes or harm to the patients post Yoga. These include patients who would be considered high risk e.g., Psychiatric/Mental health, Cancer, Epilepsy, Asthma, Stroke. No harms have been reported in low-risk patients or prevention studies either. The culmination of evidence in a wide range of populations from multiple trials across the world make it very unlikely

that that the properly supervised practice of Yoga can cause harm. In regard to the latter, all the above trials provided the Yoga interventions through a certified Yoga instructor with appropriate credentials.

4.6 CONCLUSION

Yoga, an ancient form of exercise and therapy originating in India, is today common across the world. The strongest evidence for the beneficial effects of Yoga is on mental health, but there is also reasonable evidence that Yoga is helpful for various disorders and chronic illnesses. Yoga is potentially an attractive complementary therapy approach to support clinical intervention as a part of patient care plans.

As this project focuses on effect of Yoga in pregnant women, the next chapter focuses on research on Yoga and Pregnancy

5 YOGA AND PREGNANCY

5.1 INTRODUCTION

Prenatal Yoga is a modified form of the original practice. It focuses on physically and emotionally strengthening the woman's body and mind, to carry the baby to term and have a comfortable birth. The asana/postures focus on strengthening and stretching the pelvic area, helping to support excess weight on the back and build strength in the arms to carry the infant after birth. Prenatal Yoga is slow in motion and focuses on breath work and internal awareness. The postures practiced are different in the different stages of pregnancy.

Prenatal Yoga sessions are thought to relax and calm the mother, increase her self-confidence and self-esteem. Yogic postures minimise common pregnancy symptoms like nausea and constipation and ease the tension around the cervix and birth canal (Jiang et al., 2015). Pranayama or the breathing exercises, ensure adequate oxygen flow through the body; it also increases the confidence in the mother that she has the power within herself to go through pregnancy and birth (Bhattacharya, 2019). Yoga, when continued postnatally, enables restoration of body and relieves the stress in the upper back and breasts after childbirth (Anbu & Swaminathan, 2019).

The American College of Obstetricians and Gynaecologists (ACOG) does not yet recognise prenatal Yoga as an adequate exercise program in pregnancy (Ferreira et al., 2018). No statements have been made about Yoga in pregnancy by either the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK, or by the National Institute of Health (NIH) in India. Positive recognition by these clinical bodies that Yoga is a valuable exercise program in pregnancy would have two key outcomes. Firstly, it will aid researchers in Yoga to widely study the effects of the practice in women. Secondly, it will encourage clinicians to educate themselves on the practice and its potential benefits on their patients. Currently, research on prenatal Yoga is still in its nascent stage.

This chapter examines the qualitative literature relating to women's experiences of the benefits of Yoga in pregnancy. It also presents a synopsis of published research using quantitative methods other than randomised controlled trials. The latter literature is addressed in Chapter 8, which presents a systematic review of RCTs of Yoga in pregnancy.

5.2 QUALITATIVE STUDIES REPORTING WOMEN'S EXPERIENCE OF YOGA IN PREGNANCY

Qualitative studies on Yoga and pregnancy have reported a set of themes that throw light onto why pregnant women take up Yoga, the perceived benefits, and how women actually feel during and after the sessions. Three studies were conducted in the US and one was conducted in Australia. Two studies were based in a community health centre setting (Kinser & Masho, 2015b; Kinser & Masho, 2015d), one in an urban hospital (Kinser et al., 2019) and one in a women's health clinic (Doran & Hornibrook, 2013). The number of participants in these studies varied between 14 and 19. Although a range of ethnicities is represented, the majority identify themselves as Hispanic or Black. Some themes are common between all the studies and some highlight new aspects. The six themes are discussed in the following sections.

5.2.1 Feelings of Stress/Depression prompted interest in Yoga

In focus groups conducted by Kinser and Masho (2015d), women talked about their mental state being their primary motivation to join Yoga. The women felt stress and depression were pervasive problems in pregnancy and they believed that Yoga could help them feel better.

In interviews by Doran and Hornibrook (2013), women talked about being in a state of chronic anxiety or stress before joining their class and that leaving the house for these sessions were key to them feeling better. "I couldn't get off the couch for a month", "I cried for several months", "I feel like depression is harder to talk about than physiological symptoms" were some of the statements used by the women.

Women from the study by Kinser and Masho (2015d) believed that the benefit of Yoga came from the mind-body approach for self-care. It was a space in their day which was dedicated to themselves and their babies. "Yoga was my saving grace because I go in and let go", "felt relaxed afterwards", "It was an opportunity that allowed me to get away from the madness that was…." were the phrases used by women.

In the focus group by Kinser and Masho (2015b) participants perceived Yoga as helpful for stress, even those who had never practiced before. A statement made was "I think it would bring on a happier pregnancy and a healthier baby. Like, I'm so stressed out, so I'm going to a Yoga class."

5.2.2 Preparation for birth/ Physical Benefits

Women report a feeling of greater physical strength and lower discomforts with Yoga practice. "I was getting stronger even though I was getting bigger. Each week I felt myself getting into more positions more comfortably because we had been doing them repetitively" was a statement from the Kinser

and Masho (2015d) focus group. Some participants from the Kinser and Masho (2015b) group believed that Yoga helped with back pain during pregnancy and that Yoga will help them in labour.

Women from Doran and Hornibrook (2013) interviews reported similar feelings of strength and stability. “Yoga is great…. does all this empowering stuff where you visualise yourself as a really strong woman… like a warrior kind of thing” was one of the statements used by the women to explain their feeling of preparation for birth. Though women did not consider Yoga as a practice that fitted with traditional exercise, they reported increased confidence regarding physical activity after Yoga sessions which led to a larger amount of time spent in physical activities (Kinser et al., 2019). In these studies, the decision to join Yoga sessions was made from a place of active self-management of emotions and feelings.

5.2.3 Connecting with the baby

Women from the Doran and Hornibrook (2013) interviews talked about being able to form a deeper connection to the baby in utero through the reflective practice of Yoga. It is an early start to the bonding process that continues after the birth of the baby.

5.2.4 Building connections/Sharing Stories

Women felt that the Yoga classes provided them with a safe space to be themselves and yet have a supportive community experiencing similar problems. A participant from the Kinser and Masho (2015d) focus group stated that “I think the community aspect in general is very helpful in dealing with stress and depression”. Another participant who used a DVD to practice Yoga most of the time stated that her relationship with her partner improved. Participants from Kinser and Masho (2015b) believed that Yoga sessions helped combat isolation and were a great support system.

Women identified the Yoga class as a safe space to share their previous birth stories, learn from other mothers and feel nurtured (Doran & Hornibrook, 2013). “In this group, pregnancy was normalised”, “My little pocket I got every week where I could enjoy being pregnant…” were some statements from the interviews.

5.2.5 Different from mainstream/ compared to other options

In all the studies, women identified Yoga as very different from mainstream care or other options. It was consistently mentioned in the focus group by Kinser and Masho (2015d) that group antenatal classes did not provide the same benefits as Yoga classes. Participants felt bored and disengaged in the antenatal sessions where they were expected to sit and listen. One participant stated, “I felt like we were all there because we felt like we had to be there…. I did not feel like the same community at all [as I felt in Yoga]”. A woman from the Doran and Hornibrook (2013) study reported that “Yoga

enabled me to have a connection with my body and child.. which is really important and really overlooked in the mainstream medical side of obstetric care".

5.2.6 Cost and Duration of Sessions

Women felt that antenatal Yoga was worth the financial investment. The participants had part-time or full-time jobs and at least a college degree. A participant from Kinser and Masho (2015d) stated "It was worth it. I will eat ramen for dinner. I have to go to my Yoga class."

Some women from the Kinser and Masho (2015b) group expressed concern about being taught by an instructor who is not pregnant and may not understand physical limitations that pregnant women have. However, the majority of women expressed that the sessions should not end at 12 weeks. They would like it to extend throughout pregnancy and into the postpartum period for health benefits and the community feeling. In another study where Yoga was offered for 30 minutes, the women expressed disappointment with short sessions and stated they desired longer sessions (Kinser et al., 2019). In the same study, women reported to be comfortable in attending sessions because it was in a safe environment and the clinicians were aware and supporting their participation.

5.2.7 Summary

Though there are a limited number of qualitative studies, they show that women perceive many benefits of Yoga during pregnancy such as increased self-esteem, strength, stability, connection with the baby and shared positive feeling during classes. The American studies showed that women actively seek out Yoga and prefer it to other forms of exercise, which could be linked to the popularity, availability and accessibility of Yoga classes in the USA. Along with being regarded as a gentle practice, women felt a sense of novelty about it. There is a need for larger numbers- both in number of studies and number of participants. This qualitative evidence is consistent with results of the quantitative studies reported in the following section in terms of suggestive benefits and provide valuable evidence that Yoga is a potentially beneficial adjunct to standard care.

5.3 QUANTITATIVE NON- RCT STUDIES OF YOGA IN PREGNANCY

The literature on Yoga in pregnancy includes surveys of attitudes to Yoga in pregnancy among pregnant women and among health care providers. It also includes uncontrolled and controlled but nonrandomised studies which suggest beneficial effects on pregnancy and labour discomforts, gestational diabetes and hypertension, mental health and physiological indicators of stress. A wide range of outcomes with different approaches and measures have been used in these studies making meta-analyses impractical.

5.3.1 Attitudes to Yoga in Pregnancy Among Pregnant Women and Healthcare Providers

A survey of 422 women in the US on exercise and Yoga during pregnancy reported that 65% of respondents believed that Yoga could be beneficial, 40% had attempted it pre-pregnancy, 44% considered it somewhat difficult, 65% would take it up if they had access to it and 55% were more likely to join if provided by a healthcare provider (Babbar & Chauhan, 2015).

In a service evaluation of free Yoga classes, Westbury (2019) reports that patients found the classes to be beneficial and felt the breathing and relaxation exercises were invaluable. They believed the group setting helped make friends and build a support network. High-risk pregnant women in Boston reported that women with Yoga experience were likely to be older, more likely to be college graduates and white in ethnicity. Willingness to participate in Yoga was significantly dependent on educational level and the authors recommended educational initiatives for patients with no Yoga experience to increase participation in prenatal Yoga (Deshmukh et al., 2019; Wang et al., 2005b). This study presents a different picture from the qualitative research in the USA where the majority of women were Hispanic or Black. Although qualitative research does not purport to be representative, together these studies suggest that Yoga is popular across ethnicities in the West.

There was no literature on attitudes of obstetricians and midwives towards Yoga in pregnancy. Two studies reported on attitudes towards complementary and alternative medicine (CAM) in pregnancy. A survey of 230 Obstetricians and Midwives in Australia reported a possible benefit of offering CAM to their patients (Gaffney & Smith, 2004). 14% of doctors considered it as a threat to clinical medicine. Over 90% of doctors and midwives felt a need to know more about it to be able to advise their patients. 72% of the obstetricians and 30% of midwives agreed for the need for more scientific reports on benefits of CAM. Another survey of 104 care providers in the US reported that 36% would recommend neither medication nor CAM for low back pain in pregnancy and 11% said they would recommend a combination CAM and medical treatments. 52% would recommend only CAM and 1.5% only medicine (Wang et al., 2005b). Significantly higher numbers of midwives recommend CAM compared to physicians and prenatal nurse educators.

5.3.2 Physical Health

Women who practice Yoga have reported a reduction in physical discomforts of pregnancy from baseline to post intervention (Beddoe et al., 2009) including in the third trimester. (Sun et al., 2010)

A significant decrease in back and leg pain, change in gait speed, improvement in Pregnancy Symptom Inventory (PSI) scores and less pregnancy complaints were observed in women after attending Yoga classes (Holden et al., 2019; Pont et al., 2019b). Among healthy nulliparous women, the ones who started Yoga practice in the second trimester have reported significantly less

interrupted sleep (Hayase & Shimada, 2018) and lesser sleep disturbances at night as compared to women who start a Yoga practice in the third trimester, suggesting better outcomes if Yoga is introduced early in pregnancy (Beddoe et al., 2010b). Hayase & Shimada (2018) further report on a decrease of alpha amylase levels attributed to less interrupted sleep after Yoga. Alpha amylase is a recognised biomarker of stress.

A study on antenatal women already diagnosed with Gestational Diabetes Mellitus (GDM) reported that the levels of mean fasting blood glucose, postprandial blood glucose and mean HbA1C were significantly lower in the Yoga group (Youngwanichsetha et al., 2014). Occurrence of PIH was reported to be lower in women practising Yoga among both high and low risk groups (Narendran et al., 2005).

Increased self-efficacy in active and second stage labour, shorter first stage of labour, lower average length of total labour (5 hours and 45 minutes), higher maternal comfort and lower scores of self-reported labour pain, lower requirement of induction and analgesics, higher number of normal vaginal births, lower caesarean sections and improved maternal-foetal attachment post birth have been reported among the Yoga groups in other studies. (Bolanthakodi et al., 2018; Muzik et al., 2012; Pont et al., 2019a; Sun et al., 2010; Westbury, 2019). A significantly lower occurrence of IUGR was reported in the Yoga group in a further study (Narendran et al., 2005)

5.3.3 Mental Health

5.3.3.1 Stress and Stress Markers

Regular Yoga practice has been reported to reduce stress and anxiety levels in individuals by modulating the stress response system internally (Sengupta, 2012). Yoga practice has been reported to reduce serum cortisol levels immediately after a Yoga session and in the long term (Beddoe et al., 2009; Bershadsky et al., 2014; Kusaka et al., 2016; West et al., 2004; Yadav et al., 2012). A significant reduction in perceived stress among the Yoga group was reported in one study (Bhartia et al., 2019). Another study (Hayase & Shimada, 2018) reporting non- significance in perceived stress reported a significant decrease in salivary alpha amylase immediately after Yoga practice. This study suggests that alpha amylase may be a more sensitive indicator of actual bodily stress than self-report using validated scales.

Bhartia et al., (2019) investigated the effects of twelve weeks of Yoga therapy on Heart Rate Variability (HRV) and reported a decrease in low frequency band power, an increase in high frequency band power and a reduction in the LF/HF ratio. An increased LF/HF ratio indicates an

individual's sympathetic nervous system dominance, in other words, a fight or flight state. Reducing the LF/HF ratio can lead to a calmer state of mind.

Similarly, a prospective longitudinal study reported higher Heart Rate Variability (HRV) during the night and late night (28-31 weeks' gestation) and significantly higher variability between morning, afternoon and late night (36-40 weeks' gestation) in a group of women in a Yoga group in comparison to controls (Hayase & Shimada, 2018). Heart rate variability indicates psychological resiliency and behavioural flexibility, reflecting an individual's capacity to self-regulate and effectively adapt to changing social or environmental demands

Together the above evidence suggests that Yoga can play a valuable role in stress reduction.

5.3.3.2 Anxiety & Depression

Yoga interventions have been reported to significantly reduce scores on the State Trait Anxiety Inventory (STAI) in low risk mothers (Beddoe et al., 2009; Vieten & Astin, 2008) and prenatally depressed mothers (Field *et al.*, 2013a), Becks Depression Inventory (BDI) (Muzik et al., 2012), Hamilton Anxiety Rating Scale (HARS) (Yulianti et al., 2018), Hamilton Depression Rating Scale (HDRS) (Yulianti et al., 2018) & Centre for Epidemiological Studies Depression Scale (CES-D) (Field *et al.*, 2013a).

The antenatal Edinburgh Postnatal Depression Scale (EPDS) scores are considered as a predictor of postnatal depression and Muzik et al., (2012) reported a significant reduction in EPDS scores of psychiatrically at-risk antenatal mothers post a Yoga intervention in a pilot study. Among prenatally depressed mothers, in another pilot trial, Yoga decreased depressive symptoms by an average of 4.4 points on the Quick Inventory of Depressive Symptomatology (QIDS) and 5.5 on EPDS over a period of 10 weeks (Battle et al., 2015).

In a pre-post assessment, significant increases in mean scores of optimism, power and wellbeing were reported between baseline and post intervention assessments in pregnant women participating in a Yoga intervention (Reis & Alligood, 2014).

5.4 SAFETY OF YOGA DURING PREGNANCY

Both qualitative and quantitative non-RCT literature adds to knowledge about the safety of Yoga in pregnancy. Non-randomised controlled trials (Sun et al., 2010), Cohort (Hayase & Shimada, 2018; Polis et al., 2015a; Rampalliwar et al., 2013; Sillero Quintana et al., 2012), Observational studies (Gavin et al., 2018; Kawanishi et al., 2016; Narendran et al., 2005), Case-control studies (Bershadsky et al., 2014; Javnbakht et al., 2009), Quasi-experimental studies (Shim & Lee, 2012), Comparative

studies (Field *et al.*, 2013a), Pilot studies (Battle et al., 2015; Beddoe et al., 2010a; Muzik et al., 2012; Nguyen-Feng et al., 2014; Vieten & Astin, 2008), Feasibility studies (Beddoe et al., 2009), Pre-Post Assessments (Kusaka et al., 2016; Pont et al., 2019a; Reis & Alligood, 2014), Systematic reviews (Curtis et al., 2012; Gong et al., 2015; Kirkwood et al., 2005), Qualitative reviews (Sharma & Branscum, 2015), Literature reviews (Babbar & Shyken, 2016; Ferreira et al., 2018; Jiang et al., 2015; Mitchell, 2010; Rakhshani et al., 2015; Sengupta, 2014), Descriptive Qualitative (Kinser & Masho, 2015a), Exploratory Qualitative (Campbell & Nolan, 2016; Doran & Hornibrook, 2013; Kinser *et al.*, 2019; Kinser & Masho, 2015c), Non Randomized cross sectional study (Polis et al., 2015c), and Surveys (Babbar & Chauhan, 2015; Battle et al., 2010; Cramer et al., 2015; Wang et al., 2005a) have reported that when learnt & practised with a qualified teacher, Yoga has no harmful effects on the mother and baby. A survey of women with previous Yoga experience reported that they believed that Yoga is safe in pregnancy (Deshmukh et al., 2019).

These findings from a wide range of studies are supported by a cohort study (Polis et al., (2015a), which evaluated pre and post non stress tests, maternal heart rate, temperature, pulse oximetry and foetal heart rate. During the Yoga postures, vital signs, pulse oximetry, uterine tocometry and foetal heart rate were evaluated. All the tests were reported as normal in all participants in the cohort. No participants reported a reduction in foetal movements, occurrence of contractions, leakage of fluid or any vaginal bleeding in a 24 hour follow up.

Gavin et al., (2018) followed the study by Polis with an observational study that monitored maternal and foetal heart rate throughout a 50 minute Yoga session. Maternal heart rate significantly increased during Yoga in comparison to rest, meditation and recovery. Foetal heart rates fluctuated minimally, and no significant decelerations were observed. There were no statistically significant differences among Yoga, rest, meditation and recovery on the foetal heart rates. Uterine activity was significantly greater during Yoga practice.

5.5 CONCLUSION

Together these studies suggest that Yoga is viewed favourably by women in pregnancy in the USA and that participation would be increased by provision in the health services. The lack of studies from other parts of the world may indicate lack of research interest in this topic or lack of interest by pregnant women. Among pregnant women who practice Yoga, the practice is perceived as helping relieve stress, bond with the baby and enabling a self-care routine. Some women in the West are choosing Yoga as a method of active self-management of their discomforts. Women who do not have knowledge or experience of Yoga would be more open to if recommended by their care providers.

There is promising evidence on the physical, physiological, emotional and social benefits of Yoga during pregnancy and the way in which they are improving maternal and foetal health outcomes. No studies have reported any adverse effects from the Prenatal Yoga interventions. Care providers play a strong role in encouraging patients to try new things, suggesting that professional education about these benefits and lack of harms from prenatal Yoga would increase uptake of this practice.

In the next chapter, Yoga and Infertility will be explored.

6 YOGA AND INFERTILITY

The literature examining the impact that mental health problems like stress and depression can have on conception rates in infertile couples was discussed in Chapter 2. The studies identified provided no more than suggestive evidence with some studies reporting negative results. The belief that stress does influence conception rates however remains common among infertile couples. It is also common amongst practitioners of Yoga who have developed special protocols to offer Yoga to infertile couples (Khalsa, 2003).

Like prenatal Yoga, which is a modified form of hatha Yoga, fertility Yoga is a form that is specifically designed to assist couples in improving their fertility levels. Different positions and postures in Yoga are believed to create pressure on specific endocrinal glands and stimulate optimal hormonal secretion. In the case of infertility, women can be advised on specific poses that target the pelvic area to increase vascularity and aid in conception (Yadav & Chaudhari, 2017). Forward bending poses are promoted to stimulate the second chakra also known as the primary energy centre of the body in Yogic literature, that controls the flow of energy through the spine affecting the sexual organs (Myss, 2013). Khalsa (2003) highlights that from the Yogic perspective, conception occurs when the woman is in a state of receptivity and our body goes into the state of receptivity when we feel safe, calm and relaxed.

In terms of psychological health, both meditation and Yoga are believed to empower women undergoing fertility treatments by increasing clarity of mind, regulating the body chemistry, maintaining body balance, alleviating the physical discomforts and developing a sense of patience to complete the treatment instead of terminating it (Khalsa, 2003).

A small number of studies have been undertaken to examine the impact of Yoga on a variety of outcomes in infertile couples. This literature is addressed below.

6.1 THE EFFECT OF YOGA ON MENTAL HEALTH AND CONCEPTION

A broad review of 87 papers by Darbandi et al., (2017) on Yoga, Pregnancy and Fertility, reports that Yoga can increase the success rates of ART by improving the psychological and physiological state of men and women. The interventions lasted between six to twenty weeks across five continents (details not specified). The review concluded that Yoga could reduce pain, depression, anxiety, rates of assisted delivery and improve foetal outcomes. However, as there is no quality assessment of the studies reviewed, it is difficult to draw firm conclusions on the suggested benefits.

An RCT in India by Nayar et al., (2017) reported that women who underwent three months of Yoga (30 sessions) before undergoing frozen embryo transfer had significantly higher pregnancy rates, clinical pregnancy rates (presence of a foetal heartbeat at 6-7 weeks of pregnancy) and reduction in depression and anxiety on the Hamilton Depression and Hamilton Anxiety Scales respectively. The latter results are consistent with the results of a pilot study of 120 women (45 Yoga group and 75 control; self-selected) awaiting IVF treatment which showed a significant reduction in STAI, GHQ-12 and EDS in the yoga group (Valoriani et al., 2014) compared to control. A point to note is that the Yoga group had higher EDS and GHQ-12 scores at baseline, suggesting that women who are already distressed are more open to Yoga intervention. It has been reported that patients often report feeling stronger, more powerful and confident about their body after a Yoga practice (Kochhar et al., 2017).

Comparing the two studies above- Nayar et al., (2017) and Valoriani et al., (2014), the former recruited individuals with at least five years of primary infertility and failed IVF cycles, whereas the latter recruited individuals who were starting on their first IVF cycle. The results suggest that Yoga as an adjunct to treatment can be beneficial to all couples seeking infertility treatment.

A prospective study by Oron et al., (2015) of 49 patients attending a Yoga intervention while awaiting IVF treatment, reported a significantly higher mean Core FertiQoL score after participating in the study, as compared to before, a reduction in the mean anxiety score and a reduction in depression scores. Post completion of the intervention, in terms of satisfaction with the intervention, on a scale of 1 to 5 (5 being the highest), the mean average score was 4.6 ± 0.6. The score on planning to continue Yoga while undergoing treatment was 4.4 ± 0.9. Due to the low number of participants, more research would be needed to confirm the results. However, the latter score is relevant from a long-term perspective. If research studies or small adjunct programs can get women started on Yoga programs, they are likely to continue post completion of the intervention/program while also benefitting from improved wellbeing, potentially higher chances of pregnancy, and improved maternal and infant outcomes highlighted in Chapter 5.

Another prospective feasibility study by Jasani et al., (2016) of 79 women undergoing infertility treatment (55 Yoga and 24 control; self-selected groups) reported that after a six week Yoga program, the Yoga group had a 20% reduction in mean state anxiety scores in comparison to the control group and a 12% reduction in trait anxiety scores. Jasani et al., (2016) suggest that reducing the anxiety and depression levels of women undergoing treatments can potentially help in ensuring they complete the prescribed treatment and not dropout midway due to psychological reasons. It is to be noted that when patients were allowed to self-select groups, there was a higher number in the Yoga group as opposed to the control group.

Another key study in this topic was reported by Hajela et al., (2016), where 300 women (160 intervention, 140 control) were enrolled and mental health screening, counselling, Yoga and meditation were offered. In the intervention group, 50.5% women reported positivity as compared to 27% in the control group (p=0.008). All the cases with positive pregnancy outcome showed reduction in anxiety, depression and infertility related stress in the study group.

A preliminary report on an ongoing study on difference in impact of in-person vs online Yoga classes among infertility patients indicates a significant reduction in anxiety scores for both Yoga interventions but no significant difference between the interventions (Martini et al., 2017).

Existing research on infertility and Yoga suggest three key findings: firstly, there is reported benefit from Yoga irrespective of the years the couple have been trying to conceive, secondly distressed women are more likely to sign up for a Yoga intervention and thirdly that improving mental wellbeing can potentially help in treatment adherence and higher clinical pregnancy rates.

6.2 Attitudes Towards Complementary Medicine

A cohort study of 428 couples seeking fertility treatment in the USA (Smith et al., 2010) reported that a positive attitude towards complementary and alternative medicine (CAM) use and a belief that adopting healthy habits improves chances of conception, was linked to usage of CAM. Each 5-year increase in a woman's age was associated with a 28% increase in the odds of using CAM. Couples with an annual household income >$200,000 were 2.8 times more likely to use CAM in comparison to couples with an annual household income <$100,000. As Yoga is considered as one of the options under CAM, this study highlights the socio-economic demographic and attitudes of individuals who are likely to be open to Yoga interventions.

6.3 Conclusion

Although the evidence on the role of stress in conception in infertility is equivocal, Yoga practices have been developed to specifically address infertility and are believed to work in part by reducing stress.

The research that has been published supports the belief that Yoga can be beneficial to both conception rates and mental health in infertile couples, but the number and quality of the studies are low. Because infertility is so common, and because Yoga is inexpensive and safe, more research on the benefits of Yoga in this group is needed.

7 RESEARCH METHODOLOGY

7.1 INTRODUCTION

In the previous chapters, existing research on Yoga in Pregnancy has been reviewed and critiqued. This chapter highlights the research methodology, their strengths and weaknesses and my reasons for choosing the methods used in this thesis. The paradigms, philosophies, importance of evidence-based methodologies in health research, and the primary research design developed have been discussed.

7.2 RESEARCH PHILOSOPHY AND PARADIGMS

The two main research philosophies are deductive and inductive approaches (Liamputtong, 2010). In the deductive approach, the researcher starts with general ideas, develops a hypothesis and tests it. In the inductive approach, the research begins with observations, develops ideas and formulates theories/hypotheses for further testing on the basis of further observations.

Positivism and Interpretivism are the two main research paradigms. The first is most associated with the deductive approach and the second with an inductive approach. Positivism is a paradigm that assumes a single objective reality that can be ascertained by the senses and tested subject to the laws of scientific methods (Bowling, 2014). The results are regarded as facts and believed to be undistorted by the value judgement of the researcher. Positivists do not measure the meaning of situations to individuals as they cannot be measured in a scientific and objective manner. Positivist methods aim to minimise the influence of the researcher and measurement instruments. (Liamputtong, 2010). Positivists tend to follow deductive research philosophies by developing hypotheses and testing them which is almost always quantitative. The main criticism of positivism is that it emphasises verifiable facts and does not give importance to the underlying mechanisms and/or their meanings to the individual.

Interpretivism integrates human interest into research design. As per Myers (2008) , 'Interpretive researchers assume that access to reality is only through social constructions such as language, consciousness, shared meanings and instruments." Interpretivism emphasizes qualitative analysis over quantitative analysis and follows an inductive approach. The disadvantage is its subjective nature, room for bias and lack of generalisability since it is heavily dependent on personal viewpoints and values.

Positivism and interpretivism are opposites of each other and sometimes there is a need to move to a third approach called pragmatism. As per Saunders (2009), "Pragmatics recognise that there are many different ways of interpreting the world and undertaking research, that no single point of view can ever give the entire picture and that there may be multiple realities." In pragmatism, the research question is the determinant of the research philosophy. It can combine both positivist and interpretivist views within the scope of a single research.

Innovative healthcare research combines the different perspectives into a single research approach (known as mixed methods) while respecting the distinct philosophical origins from where they are derived (Bowling, 2014; Morgan, 2007).

7.3 EVIDENCE BASED PRACTICE

Evidence-based practice (EBP) is the foundation of healthcare today. It was developed to improve healthcare by enabling the best use of research. EBP is a conscientious, explicit and judicious use of the best available evidence for clinicians to take decisions on their patients' health (Sackett et al., 1996). Originally EBP was limited to disseminating the findings of RCT's but subsequently extended to other research designs. Although Sackett (1996), the author of the term EBP, says that EBP is not restricted to randomised controlled trials (RCTs), rather that it is about identifying the best external evidence that answers the question. A hierarchy of research evidence has been developed that places RCT's at the top of EBP (Waters & Doyle, 2002), prioritising deductive and positive approaches.

EBP has made an important contribution to clinical knowledge by highlighting the importance of bias in uncontrolled studies and the value of systematic reviews and meta analyses as a means of synthesising research free of bias (Padgett, 2011).

7.3.1 Systematic reviews

Systematic reviews are thus at the heart of EBP (Stevens, 2001). They are useful in summarising the results of large numbers of studies addressing the same research question and in understanding the similarities and differences amongst them (Cook et al., 1997). These reviews represent the best way for clinicians to understand and use the latest research to provide the best care for their patients (Cook et al., 1995). A systematic review of literature prevents researchers from re-inventing the wheel and allows them to create a project based on solid existing evidence.

Like the name suggests, systematic reviews follow a systematic process, are comprehensive in identifying and evaluating literature, and objective in the interpretation of data (Chalmers & Altman, 1995). The research question is clearly defined, the inclusion criteria set, and all relevant studies are

included. Systematic reviews aim to minimise bias and errors in the reporting of data. By undertaking critical appraisal according to well recognised schema like the Delphi checklist (Verhagen et al., 1998) and Jadad Score (Moher et al., 1995), a systematic review aims to give more weight to the results of high quality studies and less weight to the results of poorer quality studies.

A systematic review methodology can be applied to any research methodology including qualitative research. However, most systematic reviews aim to provide a synthesis of the results of RCT's. The review appraises the quality of research in the studies included and synthesizes the outcomes. The two most common methods of synthesis are meta-analysis and narrative synthesis. Meta-analysis is conducted when there are sufficient similar quantitative outcome measures. However, when there are limited numbers or very diverse outcomes, meta-analysis is not feasible and narrative synthesis is used. Narrative synthesis does not precisely quantify effect sizes but looks into effectiveness against a range of outcomes (Boaz et al., 2002).

Systematic reviews are now regarded as an essential stage in the preparation of an RCT. They set the stage for the trial by establishing whether the proposed trial has been undertaken before and what similar trials have found.

7.3.2 Randomised Controlled Trials (RCT's)

Randomised controlled trials (RCTs) are known as the most powerful and revolutionary tool of medical research. "Best evidence" in medicine most often means RCT's (Petticrew, 2013) and they play a key role in healthcare strategies (Machin & Fayers, 2010). This is because in uncontrolled studies you cannot tell if the population who had the pill/intervention might have got better anyway. In non-random controlled trials you cannot tell whether the pill/intervention group got better than the non-pill group because they were different in some way. Only by randomly allocating participants blindly to control or intervention, can you be relatively sure that both intervention and control groups are similar both in terms of variables that you know about and in terms of those that influence outcomes that you don't know about.

New interventions are assessed using RCT's when, after reviewing existing evidence, it cannot be established with certainty that the intervention causes net harm or benefit (Machin & Fayers, 2010; Matthews, 2006; Threlfall et al., 2014). This practice has its roots in biomedicine where practising professions need to offer evidence-based interventions and abandon ineffective or harmful ones. RCT's can only answer questions where quantitative questions are applicable (Jadad & Enkin, 2008) and that they can only be rigorously applied in certain circumstances. In an RCT, the quantitative change in outcomes in the intervention group is compared with the quantitative change in outcomes in the control group using statistical methods like regression analysis.

The need for RCTs in different situations is however debated (Petticrew, 2013; Threlfall et al., 2014). In their book, Jadad & Enkin (2008) highlight that in the 21st century the complexity of healthcare issues are rising and RCTs do not always give the most important or trustworthy results because they are based on the reductionist paradigm of a single specific cause and a single specific treatment for disease. Academics working in health promotion declared over 20 years ago that, in their field, RCTs are, in most cases, "inappropriate, misleading and unnecessarily expensive"(Evaluation & World Health Organization. Regional Office for, 1998; Stewart-Brown et al., 2011) and an increasing group of healthcare practitioners now question if RCT's can provide definitive answers to what works in complex and dynamic health issues and solutions (Victora et al., 2004). .

Health practitioners, especially in the field of public health, often work in settings where RCTs are difficult or impossible to carry out (Waters & Doyle, 2002).The research environment is complex as interventions involve communities, and public health promotion is based on the notion of effectiveness, plausibility and timelines. Rigorous RCT design in a public health scenario requires well-funded attention.

The random allocation of participants into experimental and control groups itself may reduce the effectiveness of the intervention in a study. Because the effectiveness of an intervention, especially in preventive care, is largely dependent on the active participation of the patient influenced by their treatment preferences (Black, 1996; Stewart-Brown et al., 2011) RCT's may be difficult to set up even in regular healthcare settings, as there is often professional resistance. Professionals may be resistant to change and can be reluctant to offer the new treatment/intervention to their patients or to compare their service to that of others (Black, 1996). Small numbers of referrals can make an RCT impossible with a long and expensive trial period (Greenfield, 1989). Other underlying practicalities like difficulty in randomising and low compliance rates can add to the problems of running a trial (Jadad & Enkin, 2008; Petticrew, 2013).

Researchers need to acquire a better understanding of when RCTs can and cannot be done and to identify research approaches that can provide necessary evidence when RCTs are not appropriate (Petticrew, 2013; Threlfall et al., 2014).

Even with all their drawbacks and challenges in terms of implementation, RCTs remain the gold standard of evidence in medical literature today and remain dominant in terms of developing healthcare strategies and process decisions. As RCTs are expensive and require large teams and long timelines, the first step in the process is to conduct a feasibility study to understand if an RCT can be successfully conducted. Feasibility trials identify roadblocks and solutions, consider how the intervention is accepted by the participants being targeted, assess financial viability, and determine whether the trial could show significant benefit to the population at large.

7.3.3 Feasibility Studies

The goal of a feasibility study is to produce findings that aid in determining whether an RCT can be conducted in a particular topic in the suggested study design. The National Institute for Health Research (2019) defines feasibility studies as "pieces of research done before a main study in order to answer the question 'Can this study be done?'. They are used to estimate the important parameters that are needed to design the main study."

Some examples of parameters as set out by NIHR include:

a) Willingness of participants to be randomised

b) Willingness of clinicians to recruit participants

c) Characteristics of proposed outcome measures

d) Follow up rates, response rates, adherence

e) Time needed to collect and analyse data

The feasibility study helps to ensure research projects can be completed successfully and is also a key way to advance interventions that have a high probability of efficacy (Bowen et al., 2009).

7.4 QUALITATIVE RESEARCH

As per Green & Britten (1998), qualitative evidence represents best evidence when research questions are focused on understanding meaning and interpretations. Qualitative research offers an insider rather than an outsider perspective; it is person-centred, holistic, contextual to the situation and in-depth rather than broad (Green & Thorogood, 2018; Padgett, 2011). Qualitative research flourishes analytically on differences and discrepancies (Morgan, 1993). When testing feasibility of interventions, it is key to understand the attitudes and opinions of the people involved.

Padgett (2011) states five situations where qualitative research is required:

1. Exploration of a topic that is nascent and requires insider perspective.
2. Topics that are sensitive and contain emotional depth.
3. Researcher aims to capture experience from the perspective of the people who live it and create meaning from it.
4. There is a need to deep dive into the "black box" of practice, programs and interventions.
5. Unanswered questions arise from quantitative research, which calls for qualitative insight.

Qualitative studies, most often do not follow a predictable step-by-step format and hence offer the opportunity for creativity and decision making on an ongoing basis (Padgett, 2011). Quantitative

evaluations help to establish if something works but qualitative evaluation helps understand how and why a program succeeds or fails (Green & Thorogood, 2018; Greene & Caracelli, 1997). Quantitative measurement with standardised tools is limited in the study of the deep emotional reactions and experiences of participants. Quantitative research has its limitations when the study is focusing on complex, dynamic and changeable phenomena such as are seen in the process of learning a new skill or in personal development (Faltermaier, 1997).

7.4.1 Qualitative Research Methods

There are several different approaches to gathering data in qualitative studies. Interviews and focus groups are the most common. Other methods include observation of participants in natural settings and document analysis.

7.4.1.1 Interviews

There are three different types of interviews conducted in qualitative research- unstructured, semi-structured and structured (Liamputtong, 2019). Unstructured interviews take place with few or no prepared interview questions. The conversation progresses like a normal conversation concerning the research topic. It is comparatively difficult as multiple rounds of interviews may be needed to answer the research question and the interviewer needs to be well trained as they are expected to probe participants to extract required data.

Semi structured interviews have an interview guide to help guide the researcher. It involves conversational aspects, but it is mainly a guided conversation between researcher and participant. The semi-structured aspect allows the researcher to probe for additional details when needed. This format gives flexibility to the researcher and multiple rounds of interviews will not be required. An interview guide is prepared which consists of guiding questions and domains that the interviewer aims to draw out. Some questions are prepared in advance and some will be probes to lead the participant to go into more detail on the topic.

Structured interviews strictly adhere to the use of an interview guide and only those questions are asked. There is a lack of opportunity for the researcher to probe for more information if needed. This method is useful when there is a comprehensive list of targeted questions to be answered.

Interviews are scheduled in advance, take place in a private and comfortable setting, and require preparation (Padgett, 2011). In-depth interviews have a performative quality where the players enact their roles and the recorder captures the drama (Salmon, 2007). The interviewer takes the role of an enabler and creates a free-flowing environment for the interviewee to speak. For some interviewees, a question will get them to open up and talk. However, most need to be probed in order to achieve

the depth required. Probes are used to go deeper, go back, clarify, steer and contrast information. Probes are important to get beyond rehearsed answers and pre-fabricated accounts (Oakley & Women, 1981; Salmon, 2007).

Interviews can be undertaken with the general public or with specific groups, i.e., patients with a specific condition, mothers of young children, or healthcare providers. The latter maybe labelled as expert interviews. These can add a top-down insider perspective to the research (Nader, 1972). Such interviews require additional planning and foresight for two reasons. Firstly, interviewees are busy professionals and may believe they have less to gain from talking to a researcher. Secondly, they might believe they have a lot to lose despite assurance of confidentiality. For example, a comment made on the behaviour of a colleague may pass through the team and create an uncomfortable working environment. Questions for the experts need to draw on their unique perspectives and be tailored to achieve the maximum use of time.

7.4.1.2 Focus Groups

Focus groups are a form of group interviews that generate data through the communication of the research participants (Kitzinger, 1995). It has been used to explore people's knowledge and experiences, and to understand why people think the way they do. Focus groups are well suited to studying opinions and decision-making processes (Bloor, 2001) and have been used in healthcare as a preliminary work for larger studies by assessing views of experts in the subject, validating interventions and research designs (Kirchberger et al., 2009). A focus group with experts may enhance the expert's knowledge through the sharing of understanding of research evidence and the different approaches and opinions among a group of peers (Barbour, 2008). Focus groups help the researcher tap into the multiple forms of daily communication used by participants like body language, jokes, arguments and anecdotes which often remain untapped by other data collection techniques (Kitzinger, 1995). Additionally, it highlights sub cultural values and group norms which makes it particularly sensitive to cultural variables. Although it is more difficult to set up in comparison to individual interviews, it is faster than conducting multiple interviews and provides richer data.

A focus group is always conducted by a moderator with varying degrees of control over the conversation (Denzin & Lincoln, 2005). In a structured format, there is a clear agenda, and the moderator ensures that the conversation sticks to the pre-prepared flow. In an unstructured format, the discussion is free flowing and works well when the discussion is exploring general issues, for example, how the group feels about a new policy change.

A debrief is a meeting that is held after the focus group to discuss every aspect of the session. The contents of the discussion are summarised and the key messages of confidentiality of the discussion

are reiterated (Sim & Waterfield, 2019). The debrief should not be rushed, participants must be given time to raise any concerns. Contact details of the researcher or relevant person should be handed out in case they wish to get back on anything later (Morgan, 1997). Debrief is the responsibility of the moderator of the focus group.

7.4.2 Methods of Qualitative Data Analysis

There are various methods of qualitative data analysis, with the three most common ones used in healthcare being content analysis, thematic analysis and narrative analysis.

Content analysis is defined as "the process in which a researcher interprets the meaning or usage of written or visual data" (Hsieh & Shannon, 2005). Researchers use one of three methods of content analysis depending on the research question and the depth required: summative, directed, or conventional.

Thematic analysis has often been used interchangeably with content analysis due to a shared history. Some researchers believe that thematic analysis evolved from content analysis (Brewster et al., 2014). Thematic analysis is considered as the foundation method for qualitative data analysis (Braun & Clarke, 2006). Thematic analysis is an umbrella term aimed at identifying themes among qualitative datasets. Data is coded and categorised in the same way as content analysis, but the key difference is that in thematic analysis there is a lack of opportunity to quantify data, such as measuring frequency of words (Liamputtong, 2019). An exploratory thematic analysis identifies key words, themes or participant ideas that outline the analysis before the analysis is actually made (Guest et al., 2011).

Narrative analysis is a method "in which stories are used to describe human action" (Polkinghorne, 1995). In this method, data is generated and but analysed and represented in the form of stories (Schwandt, 2014). It is very useful in healthcare research when studying life experiences of patients or care providers over a long period of time.

7.4.3 Rigor and Trustworthiness in Qualitative Research

In qualitative research, the researcher collects their own data through conversation with the participant. There is therefore plenty of opportunity for the researcher to influence their findings. The qualitative researchers must therefore be concerned with rigor (Guba, 1981; Lincoln & Guba, 1985). Rigor is simply defined as the quality or state of being very exact, careful, or with strict precision, or the quality of being thorough and accurate (Cypress, 2017).

Rigor in qualitative research equates to the concepts reliability and validity used in quantitative research (Tappen, 2016). In Guba's framework relating to qualitative research, trustworthiness is used as the central concept to appraise the rigor of a qualitative study (Guba, 1981). It refers to the

quality, authenticity, and truthfulness of qualitative research which in turn affects the degree of trust, or confidence, readers have in results. (Schmidt & Brown, 2017). Lincoln and Guba proposed four criteria to attain trustworthiness (Lincoln and Guba 1985):

1. Credibility (addressing internal validity)
2. Transferability (addressing external validity)
3. Dependability (addressing reliability)
4. Confirmability (addressing objectivity)

The purpose and strategies to achieve them have been laid out in Table 2 below.

Table 2: Lincoln and Guba Criteria with Purpose and Strategies

Criteria	Purpose	Strategies
Credibility	To ensure the study tests what it is intended to test.	1. Adopt well established research methods like interviews and focus groups 2. Develop familiarity with participating organisations 3. Triangulation of data 4. Encourage honesty among the participants 5. Iterative questioning 6. Peer or Supervisor debriefing 7. Examination of previous research findings
Transferability	The extent to which the findings of one study can be applied to other situations.	1. Document the number of organisations taking part in the study and where they are based 2. Any restrictions in the type of people who contributed data 3. The number of participants involved 4. The data collection methods that were employed 5. The number and length of the data collection sessions

		6. The time period over which the data was collected Lincoln and Guba present an argument that it is the responsibility of the investigator to ensure that sufficient contextual information about the fieldwork is provided to enable the reader to make a transfer.
Dependability	To show the extent to which similar results would be obtained if the work were to be repeated in the same context with the same methods. However, the changing nature of the phenomena scrutinised by qualitative researchers renders such provisions problematic in their work. Lincoln and Guba stress the close ties between credibility and dependability, arguing that in practice, a demonstration of the former ensures the latter to some extent.	1. Document the research design and its implementations describing what was planned and executed on a strategic level 2. The operational detail of data gathering, addressing what was done in the field
Confirmability	To show the extent to which the research is objective. i.e., reflects the experiences and ideas of participants	1. Demonstrate reflexivity in your discussion of the results 2. Triangulation

	rather than the ideas of the researcher. Here steps must be taken to help ensure as far as possible that the findings are the result of the experiences and ideas of the informants, rather than the characteristics and preferences of the researcher.	

In Chapters 10 and 11, the methods and results of qualitative research have been presented. Within that, strategies implemented to achieve trustworthiness have been addressed.

7.5 MIXED METHODS

Mixed methods research brings together qualitative and quantitative approaches in the same research design. Mixed methods research is relatively new in the research lexicon and is also known as multimethod, multi-strategy or triangulation by method (Blumberg et al., 2008). It was developed in part in response to criticism that healthcare research ignores larger eco-social contexts (Krieger, 2001). If health problems are looked at as an individual responsibility, then solutions are sought via changing beliefs and behaviour. Larger structural inequalities like gender, race, and socio-economics escape notice as they lie outside existing frameworks (Padgett, 2011).

Caracelli and Greene (1997) state three reasons for carrying out mixed methods research: triangulation, complementarity and expansion. Triangulation refers to comparisons for the purpose of rationale, complementarity refers to clarification or enhancement, expansion refers to presenting findings to keep them intact.

Mixed methods research designs can be sequential or concurrent depending on the timing of the methods and can have one dominant method or equal weighting to both (Padgett, 2011). Bryman

(2006) states that concurrent mixing of standardised surveys and qualitative interviews is common where the latter is based on a sub-sample of a larger survey sample.

7.6 TRIANGULATION AND CRYSTALLISATION OF DATA

Triangulation is a process where multiple methods are used to enhance the relevance of the findings of a study (Bryman, 2004). It is one of the strongest reasons for multi-method study designs and is therefore a key method for mixed methods studies where data collected using one method is used to offset data collected using another method or to confirm the validity of the findings (Green & Thorogood, 2018). The logic behind triangulating data is to challenge bias arising from using one single method. The process of combining methods produces parallel data which is commonly used to corroborate findings, but should also be used to illuminate differences in findings from the various methods (Barbour, 2008).

There are four types of Triangulation categorised by Denzin (2017):

1. Data triangulation: Collecting data via multiple sampling strategies
2. Investigator triangulation: Multiple researchers collecting and interpreting data
3. Theoretical triangulation: Using multiple theoretical frameworks to interpret data
4. Methodological triangulation: Use more than one method for gathering data

Crystallisation emphasises the value of looking at the same concept from a variety of angles and may be preferred to triangulation in healthcare research (Richardson (2003), for example the variety of opinions and views of multiple people (patients, carers, professionals etc.) from their perspectives. The different players illuminate different aspects of the same problem. Here, the differences offer more insight than the similarities.

7.7 EVALUATING COMPLEX INTERVENTIONS

Interventions that contain several interacting components are described as complex interventions. Few dimensions of complexity as laid out by Craig et al., (2019) are:

1. Number of and interactions between components within the experimental and control interventions.
2. Number and difficulty of behaviours required by those delivering or receiving the intervention.
3. Number of groups or organisational levels targeted by the intervention.
4. Number and variability of outcomes.
5. Degree of flexibility or tailoring of the intervention permitted.

Complex interventions require special consideration as they pose a number of special problems for evaluators aside from the practical and methodological issues faced by any new intervention. The extra problems relate to the difficulty of standardising the design and delivery of the intervention, sensitivity to features within local context, and the organisational and logistical difficulty of applying new methods to service or policy change.

MRC has developed a framework for evaluating complex interventions. They provide guidance for development, evaluation and implementation of complex interventions to improve health (Craig et al., 2019) starting with a series of pilot studies targeted at multiple points of uncertainties in the design and moving onto exploratory and then a definitive evaluation. Lastly, the results are to be disseminated widely. Table 3 below summarises each specific phase of this process.

Table 3: Phases of the MRC Framework

Developing an intervention	1. Are you clear about what you are trying to do, what outcome you are aiming for and how will you bring about change? 2. Does the intervention have a theoretical basis? 3. Has theory been used in development of the intervention? 4. Can the intervention be described fully, so that it can be implemented properly for the purposes of evaluation and be replicated by others? 5. Does the existing evidence, ideally in a systematic review, suggest that it is likely to be effective or cost effective? 6. Can it be implemented in a research setting and is it likely to be widely implementable if the results are favourable? If the above is clear, you can go ahead to the next stage, else, further development work is necessary.
Piloting and Feasibility	1. Have you done enough piloting and feasibility to be confident that the intervention can be delivered as intended? 2. Can you make safe assumptions about effect sizes and variability, and rates of recruitment and retention in the main evaluation study?
Evaluating the intervention	1. What design are you going to use, and why? 2. Have you set up procedures for monitoring delivery of the intervention, and overseeing the conduct of the evaluation?
Reporting	1. Have you reported your evaluation appropriately?

	2. Has a systematic review been updated?
Implementation	1. Are your results accessible to decision makers, and have they been presented in a persuasive way? 2. Are your recommendations detailed and explicit?

The feasibility and piloting stage include testing procedures or acceptability, rates of recruitment and retention of subjects, and calculation of appropriate sample size. Pilot and feasibility study results are to be interpreted cautiously when making assumptions about the required sample size, likely response rates, etc. when it will be scaled up. Effects may be smaller or more variable when the same intervention is piloted in different settings. Here is where a mixture of qualitative and quantitative methods is likely to be needed to understand barriers to participation and in estimation of response rates.

The guidelines suggest that randomisation should always be considered, as it is the most robust method of preventing selection bias. However, if it is proven to not be appropriate, via a feasibility study or through evaluation, there are a number of other designs that can be considered such as cluster randomised trials, stepped wedge designs and preference trials.

7.8 RESEARCH METHODOLOGY USED IN THIS THESIS

As presented in 7.3.2, RCTs are expensive, time consuming and not always fit for complex interventions. They have arguably been difficult to conduct in public health promotion and hospitals alike. Lack of choice in terms of which group the participant wishes to be allocated to, has been discussed to have an effect on the outcomes of the study. However, RCTs are still regarded as the gold standard in clinical practice. In newer areas of research where evidence is lacking like my research topic, it is important to conduct an RCT. If positive, the results will help to convince clinicians about the benefits of Yoga on pregnant women who conceive through ART.

The first step towards that was a Systematic Review of Yoga and Pregnancy (Chapter 8) to review what is already known and develop a research design that would add to the existing knowledge on the subject. In the review, the narrative synthesis method was followed due to low numbers of RCTs and large diversity of outcome measures. As presented in the next chapter, RCTs of Yoga have been successfully completed and at the outset of this thesis, there was no trial conducted on Yoga in the post infertility treatment population.

A full RCT would not have fit into the scope of a PhD from a time and funding perspective, and as there was no RCT conducted in this topic, it was necessary to first conduct a feasibility study. Taking the pros and cons of RCTs into account, I adopted a pragmatic approach and used a mixed methods feasibility study design. A mixed methods approach was adopted as, along with the feasibility measures, it was important to assess the experiences of the participants involved which would affect the study design of the RCT in the future.

Although Yoga is not routinely offered to women in pregnancy by western trained obstetricians or midwives and might therefore be considered a new complex intervention, Yoga in pregnancy is actually a very well-developed intervention which has been practiced for several millennia. Appropriate protocols have been worked out for use in western health care settings (Field *et al.*, 2013b) and there is an accredited training programme for Yoga in pregnancy instructors (YAI, 2020). The recommendations for complex intervention development were therefore not appropriate for this research. The hospital in which the research was to be conducted had been offering Yoga to their patients for over three years with an accredited instructor. The planned intervention had been evaluated in multiple RCTs in India and elsewhere. What needed to be evaluated was the feasibility of offering Yoga in pregnancy to women who conceived with the help of infertility treatments, and the feasibility of doing this in the context of an RCT. On the basis of the information presented above and referring to Table 3 in this chapter, this thesis falls into the second phase of the framework- Piloting and Feasibility.

However, with every new RCT in any setting, it is possible that the trial will not succeed. We built in qualitative evaluation to address the barriers to conducting the trial. A pragmatic mixed methods waitlist-control feasibility study design was adopted with participant interviews as a qualitative arm of the study. In a waitlist-control design, the control group are given the intervention after a predetermined period of waiting. It allows for various comparisons between groups and the control group participants do not feel like they missed out on the chance to participate in the intervention. Padgett's (2011) reasons for qualitative research mentioned in Section 7.4 are pertinent to a study of Yoga in pregnancy after infertility: this is a nascent topic, it is very sensitive to the participants in question, the intervention needs to be assessed by going in-depth into the experience of the participants (through qualitative research), and process or program evaluation is required. The research methods followed in the feasibility study are presented in Chapter 9.

This thesis began with a concurrent design of quantitative and qualitative, with the quantitative part being the dominant method and the qualitative part being used on a sub sample of the quantitative participants to explore attitudes and opinions towards the intervention.

As the trial was completed, the quantitative part of the feasibility study raised many questions which could only be answered with qualitative methods (See Chapter 10). Hence it was decided to interview individuals who were directly linked to the trial and the participant's decision making. To understand if location and expert opinions could have affected the outcomes of the study, a focus group was conducted with doctors in the UK (See Chapter 11). In retrospect, it is possible to say that the extensions changed the study design from a concurrent to a sequential design.

Semi-structured interviews were chosen as the tool for qualitative data collection in India and Focus groups were chosen as the tool for qualitative data collection in the UK. Thematic analysis was conducted as it helps in capturing complexities of meaning within qualitative data. The step-by-step approach to thematic analysis has been described in Chapter 10 and 11 and has been shown in Appendix 15.1.

In this project, there is methodological triangulation of data via usage of the mixed methods research design and the qualitative arm of this project compares and contrasts opinions of various players in the same environment, achieving crystallisation of data.

7.9 CONCLUSION

This chapter discussed the overall flow of the research methodology for this project and the reasoning behind the choices made. In the next chapter, the Systematic Review conducted by the researcher is presented.

8 SYSTEMATIC REVIEW- PRENATAL YOGA AND PREGNANCY

8.1 INTRODUCTION

A Systematic Review was conducted to understand existing evidence on trials conducted worldwide as that foundation helps create an effective research design for the feasibility study.

This review aimed to search systematically for randomised controlled trials (RCTs) of prenatal Yoga published before the end of September 2018, to critically appraise included studies and provide an overview of the results. The decision to include all RCTs of prenatal Yoga was taken after a scoping study identified no RCTs in populations following assisted conception. This broader focus provided information on the outcomes which had been studied and the feasibility of such trials. The review question was "What are the benefits and harms of the practice of Yoga in pregnancy?

8.2 METHODS

A systematic search was conducted of 4 databases- AMED, EMBASE, MEDLINE and CINAHL, using the search terms 'Yoga' and 'Pregnancy' linked together by the Boolean operator AND, to identify studies using these words in the title or as keywords. The terms were intentionally kept broad to err on the side of inclusion. There was no start date to the search in order to gather as many papers as possible. The end date on the search was September 2019. The bibliographies of all papers were scanned for any studies missing from initial search results.

The inclusion criteria were:

- Study design: RCT
- Intervention: any form of prenatal Yoga
- Participants: women at any stage of pregnancy in either high or low risk groups
- Papers written in the English language

The exclusion criteria were:

- Interventions that did not include a Yoga practice
- Papers in other languages
- Non-RCT study designs

Prenatal Yoga was defined as the practice of traditional yoga postures with or without breathing exercises, meditation or mindfulness. Studies using an integrated Yoga approach, mindfulness-based Yoga, or generic Yoga were all included.

Data was extracted relating to country of study, participants age, gestational age, gravid status, complications of pregnancy, nature of the intervention and outcomes measured. Queries with regard to inclusion or exclusion were discussed by the research team. One researcher (AJ) extracted data and a second researcher (SSB) checked the data extraction.

The nine item Delphi check list (Verhagen et al., 1998) was used to assess study quality. A narrative synthesis was carried out due to heterogeneity of studies and the wide range of outcomes studied.

8.3 RESULTS

The search generated a total of 391 titles and abstracts. After removal of duplicates [n=71], irrelevant studies [n=230] (interventions investigating mindfulness/meditation alone, articles, interviews) were excluded and 90 full text papers were obtained. Though mindfulness is a separate practice entirely, it was observed that the word Yoga was often included in the text which was probably why those studies came up in the searches.

Studies were excluded if they were qualitative studies, reviews, case reports, surveys, pilot studies, pre/post-test experiments, quasi-experiments, or if the population included non-pregnant subjects leaving 15 RCT's reported in 16 papers (Babbar *et al.*, 2016b; Chen *et al.*, 2017; Chuntharapat *et al.*, 2008; Davis *et al.*, 2015; Deshpande *et al.*, 2013; Field *et al.*, 2013b; Field *et al.*, 2012; Jahdi *et al.*, 2017; Jayashree *et al.*, 2013; Martins & Pinto e Silva, 2014b; Newham *et al.*, 2014; Rakhshani *et al.*, 2010; Rakhshani *et al.*, 2012; Satyapriya *et al.*, 2013; Satyapriya *et al.*, 2009; Uebelacker *et al.*, 2016) [see Figure *1*: PRISMA Flow Chart]

These 15 RCTs are listed Table 4: Included Studies: Populations, Interventions, Outcomes and Results and in Table 5: Study Quality Scores using Delphi Checklist

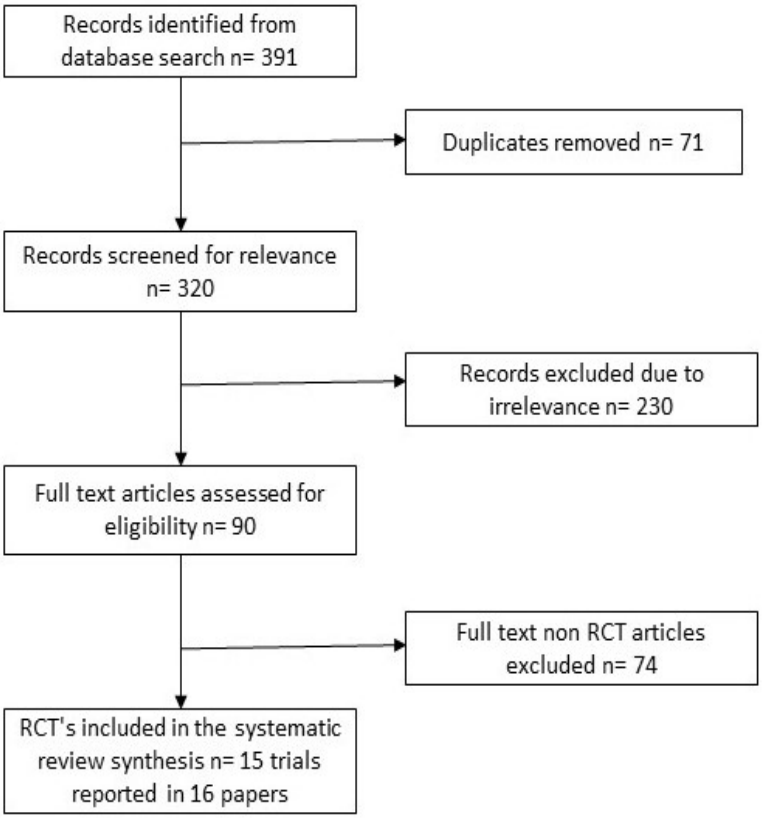


Figure 1: PRISMA Flow Chart

Table 4: Included Studies: Populations, Interventions, Outcomes and Results

Author	Population	Intervention/control	Outcome	Results
1. Babbar et al (2016) Kansas City, MO	Low risk women >17yrs 28 to 36 weeks pregnant with singleton No contraindications to exercise Exclusions: smokers, drug abuses, chronic illness, IUGR N=52	Intervention: Single I hr. session of yoga (23 postures, one breathing technique and final resting pose) delivered one to one. Colour pamphlet with yoga poses to be performed at home Qualification of Instructor: Certified Prenatal Yoga Instructor Control-PowerPoint presentation on exercise during pregnancy, obesity in pregnancy and nutrition in pregnancy)	Primary outcome Uterine artery systolic diastolic ratio, pulsatility index, resistance index measured before and immediately after intervention. Change in mean and % change from normal to >95% CIs Secondary outcome Maternal blood pressure, heart rate, uterine contraction, foetal heart rate, other umbilical Doppler studies	No significant group by time effects on uterine artery Doppler indices and systolic/diastolic ratio Foetal heart rate fell in both groups during the session (p=.01) but more in the control than intervention group (group by time interaction p=.09) No significant effects on maternal blood pressure, maternal heart rate fell in both groups (p=.01) with no group by time effects. Reviewer comment. This single session of yoga was well tolerated by the foetus as assessed by standard indices confirming that yoga is safe in normal pregnancies.

Author	Population	Intervention	Scales used	Outcome
2. Chen et al (2017) Taiwan	20-45 yrs. women; normal pregnancy; literate in Chinese; willing to attend sessions; willing to collect saliva samples Exclusions Oral steroids; severe illness; depression taking drugs; high risk pregnancy vaginal bleeding incompetent, cervix, IVF multiple gestations, IUGR or other abnormalities N= 101	Interventions: Yoga 2x70 min yoga sessions per week for 20 weeks with experienced yoga teacher Qualification of instructor: Midwife certified as a Yoga Instructor Control: Prenatal care	Saliva 10 mins before and immediately after yoga at 16, 20,24,28,32,26 weeks' gestation to measure cortisol and IgA levels Birthweight and gestational age	Significant reduction in salivary cortisol pre -post intervention in the yoga group but not in the control group this effect occurred at all gestations ($p<0.001$) Significant increase in salivary IgA levels pre-post intervention in the yoga group but not in the control group at all gestations tested ($p<0.001$) Yoga group had a higher Birth weight ($P<0.001$) and later gestational age ($P=0.014$) than the control groups Reviewer comment Yoga reduce salivary cortisol and increased IgA implying a reduction in stress and increase in immunity. There was a possible benefit in prolonging pregnancy and improving birth weight.

Author	Population	Intervention	Scales used	Outcome
3. Chuntharapat et al (2008) Thailand	Primiparous literate Women >17 yrs. without experience of Yoga practice before end second trimester. Exclusions serious illness or high-risk complications Thailand N=74	Intervention-Yoga programme (asanas chanting breath awareness relaxation and meditation) - six x 1 hr. sessions Qualification of Instructor: Not Specified Control – 20 min casual conversation during routine antenatal care	Visual Analogue Scale to assess Total Comfort- during labour (modified) (VASTC) Visual Analogue Sensation of Pain Scale (VASPS) Pain Behavioural Observation Scale (PBOS) Above 3 administered three times during the labour at 2 hourly intervals Maternal Comfort Questionnaire (MCQ)-completed 2 hours post delivery Birth outcomes Apgar length of labour birthweight	VASTC (mean/SD) Significant increase in maternal comfort at all-time points in the Yoga group compared to controls P<0.05 VASPS (mean/SD) Significant reduction in labour pain in the yoga compared to the control groups at all time points studied p<0.05 PBOS Significant reduction in observed labour pain in the yoga compared to the control groups at all time points studied p<0.05 1st stage and total length of labour significantly shorter in intervention group (P, <0.05) Birth weight, pethidine use, augmentation of labour and Apgar scores all similar in both groups Reviewer comment Significant effects favouring yoga group on labour comfort, labour pain, observed labour pain length of labour. STAI anxiety scores, age, education income and marital status stratified randomization.

Author	Population	Intervention	Scales used	Outcome
4. Davis et al (2015) USA	Women 18-45 yrs. <29 wks. Pregnant with depression (≥9 on EPDS) and/or anxiety (≥25 on subscale of the STAI-s or ≥35 on STAI-T) who were practicing yoga for less than 60mins week. Exclusions: Psychotic illness, suicidality, medically high risk N=46	Intervention 8 x 75 min weekly group classes' yoga intervention Video of practice for use at home plus the treatments as usual vs treatment as usual group. Average home practice 93.2 mins per week. Qualification of Instructor: Trained Antenatal Yoga Instructor (10 yrs. experience in antenatal Yoga) Yoga instructions were based on the traditional Ashtanga Vinyasa system of yoga and modified for the pregnancy Control : Treatment as usual	Edinburgh Postnatal Depression Scale (EPDS) State Trait Anxiety Inventory (STAI-S and STAI-T)) Positive and Negative Affect Scale (PANAS-N)	Significant (p=.011) group by time effect for PANAS-N (ES=.39) No significant group by time effect for EPDS (p=0.55) STAI-S (p=0.5) and STAI-T (p=0,1) Significant group effect (meaning both groups improved) for EPDS, and STAI-T Reviewer comment Small trial showing impact on mood but not on measures of depression and anxiety

Author	Population	Intervention	Scales used	Outcome
5.Deshpande et al (2013) Bangalore, India	High risk pregnancy (Hypertension, gestational diabetes History of pregnancy complications-pregnancy induced hypertension, gestational diabetes, pre-eclampsia, eclampsia, intrauterine growth retardation, placental abruption, foetal death, multiple pregnancies, age <20>35rys, BMI.30, family history of pregnancy complications Exclusions: Mental illness major medical disorders addictions or structural abnormality of reproductive tract N=68	Intervention-Yoga Qualification of Instructor: Not specified Control-prenatal stretching exercise	Perceived stress scale (PSS)-assessment done at baseline, 20 weeks and 28 weeks of pregnancy	Group by time effect favouring yoga group (F=4.29; P=0,02) Reduction in PSS score at first and second follow ups (P<0.001, p=0.02) Reviewer comment Yoga in pregnancy reduced stress

Author	Population	Intervention	Scales used	Outcome
6. Field et al (2013) USA	Women <40yrs and < 22 weeks' gestation meeting Structured Clinical Interview for Depression (SCID) criteria for depression at first trimester ultrasound clinics. Primarily low-income minority population Exclusion Other psychiatric disorders Multiple pregnancies Medial illness or pregnancy complications) N=92	Intervention-Tai Chi Yoga 20 minutes per week for 12 weeks delivered by trained yoga instructor Paid $20 for childcare expenses Qualification of Instructor: Trained Yoga Instructor Control-waiting list	Centre for Epidemiological Studies Depression Scale –CES-D Clinical depression classified ≥16 on the scale State Anxiety Inventory(STAI) Cut off for high anxiety was 48 at 34 weeks	Repeated measure ANOVA Group by time effect Depression p=0.001 Affect subscale p=0.001 Somatic/vegetative subscale p=0.01 Anxiety (STAI) p=0.01 Reviewer comment Benefit of Yoga on anxiety, depression and sleep

Author	Population	Intervention	Scales used	Outcome
7. Field et al (2012) USA	Women >18yrs, with uncomplicated, singleton pregnancy screening positive for depression on CES-D between 18 and 22 weeks Exclusion criteria: medical illness; 40+years; other psychiatric condition, or drug use; and SCID (Structured Clinical Interview for Depression) scores not confirming depression. N=84	Intervention 1 Yoga 20 min yoga routine twice weekly for 12 weeks. Qualification of Instructor: Trained Prenatal Yoga Instructor Intervention 2 20 min massage therapy twice weekly for 12 week) Control: Standard prenatal care	Centre for Epidemiological Studies Depression Scale (CES-D). A score of ≥16 considered as depression State Anxiety Inventory (STAI) State Anger Inventory (STAXI) Back pain and leg pain measures not reported Relationship questionnaire Gestational age at delivery Birth weight	Significant differences favouring yoga and massage group compared to control (group by time interaction repeated measure ANOVA) for CES-D scores p<0.001, STAI p<0.001, STAXI anger scores p<0.001 Back pain (p<.001) Leg pain p<0.001) Relationship scores p<0.001, Gestational age p<0.005, Birth weight p<0.001 Reviewer comment Large trial with important differences in mental health outcomes for both Yoga and massage Differences between yoga and massage group not tested statistically.

Author	Population	Intervention	Scales used	Outcome
8. Jahdi et al (2017) Iran	Primiparous with low-risk pregnancy, primigravida, BMI between 19.8-26, no previous experience of yoga, absence of any foetal abnormalities or IUGR, n= 60	Intervention: 60-minute taught Yoga sessions 3 times a week by yoga expert and recommendation for daily practice from 26-37 weeks with booklets and training DVDs Qualification of Instructor: Not clearly specified Control: Standard Care	VAS pain score, at 2 hourly intervals after 3 cm dilatation Mode of delivery C-Sec/Vaginal birth, Apgar scores, Birth weight	No statistical difference in Apgar scores & birth weight; duration of first stage of labour Mean duration of 2nd (p=0.04) and 3rd (p=0.01) stages were shorter in intervention group. VAS scores significantly lower in intervention group at all time points measured (p=0.01), Fewer C-Section in Intervention group- 13% compared to, Control group- 50%. (p=0.002) Planned induction: fewer in Intervention group- 29.3% than control group- 56.7% (=0.008) Reviewer comment Significant effects favouring yoga in terms or reduction of pain in labour, C-section rate and during of the second stage. Lower induction in Yoga group could be a confounder.

Author	Population	Intervention	Scales used	Outcome
9. Martins and Silva (2014) Sao Paulo, Brazil	Women with lumbopelvic pain between 12 to 32 weeks of gestation Exclusions twin pregnancy, receiving physical therapy or analgesics for pain and medical restrictions on exercise N=60	Intervention-Hatha yoga (asana and breathing exercise, meditation) for one hour a week for 10 weeks. Qualification of Instructor: Physiotherapist with license to teach Hatha yoga Control-Pamphlet on postural orientation and suggestions for daily activities.	Visual Analogue Scale (VAS) to measure the pain intensity Lumbar pain and posterior pelvic pain provocation tests	Pain intensity-VAS Anova (P=.006) Yoga group median scores reduced from 6 to 0; control group 7 to 4.5 Some analyses of physical examination tests scores suggested greater reduction in Yoga group Reviewer comment Statistical comparisons of change on physical examination scores not undertaken so difficult to interpret. Loss to follow up amounted to 25%. The results are suggestive of benefit

Author	Population	Intervention	Scales used	Outcome
10. Newham et al (2014) UK	Uncomplicated first singleton pregnancies in women >17years at 20-24 weeks gestation Exclusion: medical illness in mother or already practicing yoga. N=59	Intervention-I hr classes for 10-11 participants x8 weeks in Sure Start centres Accredited experienced prenatal yoga teacher offered mild hatha yoga a, postures, relaxation/breathing were included Qualification of Instructor: Trained Antenatal Yoga Instructor Control-treatment as usual (TAU)	Before and after first and last class Salivary Cortisol State Trait Anxiety Inventory (STAI-S) Edinburgh Postnatal Depression Scale (EPDS) A score of 14 or 15 indicative of probable antenatal depression Wijma Delivery Expectancy Questionnaire (WDEQ) modified version-indicator of pregnancy related anxiety	Before and after first and last yoga session Significant (P<.001) reduction in STAI-S at both sessions Significant reduction in maternal cortisol levels (P<.001 and P<.003) at both sessions Baseline to post intervention. No significant differences between Intervention and TAU groups on STAI –T, STAI-S or EPDS. Marginal difference (P<.06) on WDEQ) Per protocol analyses (in which 6 TAU group members who attended yoga classes were excluded) show significant differences between change scores favouring intervention group for EPDS (p=.04) and WDEQ (P=.005) Reviewer comment Study shows uncontrolled before and after positive physiological and psychological effects of single yoga session . No clear differences between control and intervention groups in main trial results may be due to contamination of control group due to availability of yoga classes outside the trial.

Author	Population	Intervention	Scales used	Outcome
11. Rakhshani et al (2010) Bangalore, India	Women aged 20-35 years between 18-20 weeks' gestation normal pregnancy Exclusions Medical conditions leading to pregnancy complications, multiple pregnancy, IVF, previous IUGR, preeclampsia or pregnancy complications, foetal or maternal abnormality, previous exposure to yoga. N=111	Intervention- Integrated approach to yoga designed for antenatal use including postures breathing and meditation Qualification of Instructor: Trained Prenatal Yoga Instructors Control- Simple stretching exercise Both practiced one hour three times per week from 20 to 36 weeks of gestation	World Health Organization Quality of Life -100 Questionnaire (WHOQOL) Fundamental Interpersonal Relations Orientation (FIRO-B) Assess three dimensions of interpersonal relationships	WHOQOL Out of the six domains four domains (physical p<0.001, ES 0.48; psychological p<0.001, ES 0.65; social p<0.003, ES 0.65; and General Health p<0.001, ES 0.65)) showed a significant improvement in the yoga group compared to the control group FIRO-B Yoga group showed a significant improvement in the expressed inclusion (p=0.02) and wanted control compared to the control group Reviewer Comment Large trial in low-risk populations with no experience of yoga showing important improvements in yoga group compared to control on 4 out of 6 quality of life dimensions and two out of six interpersonal relationship dimensions

Author	Population	Intervention	Scales used	Outcome
12. Rakhshani et al (2012) Jayashree et al (2013) Bangalore, India	Women aged under 20 or over 35 with twin pregnancy, maternal obesity, poor obstetric history or poor family history at 12 weeks' gestation, Exclusions Severe hepatic, heart or renal disease; STDs, maternal structural abnormalities, medical abnormalities precluding participation in yoga. N=93	Intervention- One hr weekly yoga sessions (breathing exercise, postures and meditation including visualizations guided imagery and sound resonance)-from 12 to 28 weeks of gestation offered by well-trained certified yoga therapist Qualification of Instructor: Certified Yoga Therapist Control-walking for half an hour morning and evening	Obstetric outcomes at any time during pregnancy or delivery Maternal BP, weight, uric acid, platelet count, blood glucose, urine albumin at weekly antenatal visits analysis conducted on data at 12 20 and 28 weeks	Significantly less in yoga group: pregnancy induced hypertension (intervention-10.3%, control-36.7%, p=0.02), preeclampsia (intervention-0%,control-13.3%,p=0.04), IUGR (p=0.05), preterm deliveries (p=0.04), GDM (p=0.05) small for gestational age deliveries (p=0.03) low Apgar at 1 min (p=.01) and 5 mins (P=.04) Incidence of large for gestational age babies, low birth weight babies eclampsia (intervention-two cases, control-no cases); PROM and LSCS was no different between the two groups Non-significant differences favouring yoga group in maternal Systolic BP and platelet count but not diastolic BP or uric acid levels, weight, blood glucose or urine albumin Systolic BP 12 -20- 28 weeks mean (SD) Yoga group

				108(13.25) - 107.91(12.57) - 109.65(9.15) P ns Control group 104.03(8.03) -104.63(11.87) 108.77(9.31) P=0.032 Between groups P =ns Platelet count Yoga group 12 – 20 – 28 weeks mean(SD) 280.67 (78.57) - 259.54(77.41) P=0.041 - 249.58(81.62) - P=0.006 Control group 12 – 20 - 28 weeks mean(SD) 246.43 (59.6)

				P ns Control group 104.03(8.03) -104.63(11.87) 108.77(9.31) P=0.032 Between groups P =ns Post hoc subgroup analyses of platelet and uric acid levels favouring yoga were significant. Reviewer comment Medium sized trial with (35% Int and 19% control drop out) and multiple analysis of physiological data Results are strongly suggestive of benefit on obstetric complications and suggestive of physiological effects, but a bigger trial is needed to confirm.

Author	Population	Intervention	Scales used	Outcome
13. Satyapriya et al (2009) Bangalore, India	Women 20-35 yrs. between 18- 20 weeks' gestation EXCLUSION- prior foetal or infant death multiple pregnancy, maternal physical abnormalities, psychiatric problems, pregnancy associated medical problems such as diabetes and hypertension, IVF pregnancy, previous IUGR, foetal abnormality during USG and previous exposure to yoga. N=122	Intervention: Yoga sessions Asana breathing techniques mediation and deep relaxation Qualification of Instructor: Trained Yoga Instructor Control: Standard prenatal exercises	Perceived Stress Scale (PSS), Heart Rate Variability (HRV) Both measures at 20 weeks and 36 weeks	Mean PSS was reduced by 31.6% in the yoga group and increased by 6.6% in the control group. Group by time effect significant p=0.001. HRV LF band and LF/HF ratio significantly reduced compared to start of session and compared to control at 36 weeks but not 20 weeks (P=.001). HF band significantly increased at 20- and 36-weeks P=0.001

Author	Population	Intervention	Scales used	Outcome
14. Satyapriya et al (2013) Bangalore, Indi	Normal pregnancy in women 20-35 years. 18-20 weeks of gestation Exclusions: previous foetal loss or infant death, IVF, multiple pregnancy IUGR, maternal physical abnormalities, foetal abnormality, previous exposure to Yoga N=105	Intervention: 2hrs a day x 3 days a week classes for one month. Home practice an hour a day until 36 weeks with pre-recorded cassette and refresher class at each antenatal visit. Integrated approach of yoga therapy (breathing exercises, Asana postures, Pranayama and meditation). Qualification of Instructor: Trained Yoga Instructors Control- 2hrs a day x 3 days a week classes for one month with home practice daily. .simple stretching exercise	Pregnancy experience questionnaire (PEQ) Assess the pregnancy related stresses and concerns State Trait Anxiety Inventory (STAI) Hospital Anxiety and Depression Scale (HADS) Measured at 20 and 36 weeks	State AnxietySignificant ($p<0.001$) group by time effect favouring Intervention group Trait anxiety Significant ($p<0.001$) group by time effect favouring Intervention group HADS Anxiety Significant ($p<0.001$) group by time effect favouring Intervention group HADS Depression Significant ($p<0.001$) group by time effect favouring Intervention group PEQ Significant ($p<0.001$) group by time effect favouring Intervention group Reviewer comment Large trial in low-risk women with no previous experience of yoga showing important improvements favouring yoga group on all measures of mental health

15. Uebelacker et al (2016) USA	Women 12 to 26 weeks of pregnancy ≥18 years of age with major or minor depression (QIDS ≥7-minor and ≥20 major depression) Exclusions: psychotic illness, severe PTSD or OCD, hazardous drug/alcohol misuse, suicidality N=20	Intervention-9 x weekly 75 min classes with registered experienced prenatal yoga teacher Perinatal yoga programme (breathing, meditation, gentle warmups, standing poses, floor poses and final resting poses). Participants encouraged practicing mindfulness with the emphasis on breath awareness. Home practice recommended and measured @45mins a week on average Qualification of Instructor: Trained Prenatal Yoga Instructor working to a manual with chapters on mental health problems and contraindications Control-9 x weekly 75 min classes on perinatal health: -Mom -baby wellness workshop –during the post-partum year Participants paid $10-20 for assessment and gift card of $10 for two consecutive sessions	1.Quick inventory of depression symptoms-clinical rating (QIDS) 2.Edingburgh postnatal depression scale(EPDS) At Baseline, randomization, and 3.6 and 9 weeks	Depression Non-significant differences favouring intervention group on both QIDS (ES= .48) and EPDS (ES=.4), maximal at 6 weeks. No significant differences on any scale at any time point Reviewer comment. Small underpowered trial suggesting need for larger trial

8.3.1 Study quality

As shown in Table *5*, Three studies (Field *et al.*, 2012; Martins & Pinto e Silva, 2014a; Uebelacker *et al.*, 2016) scored the lowest in the Delphi checklist with four points each. Four studies (Babbar *et al.*, 2016a; Jayashree *et al.*, 2013; Rakhshani *et al.*, 2010; Rakhshani *et al.*, 2012; Satyapriya *et al.*, 2009) scored the highest in the checklist with six points each. Seven is the maximum achievable in trials like these where blinding of the intervention is not possible for participants or the intervention provider. In six out of fifteen studies, the outcome assessors were blinded to the intervention group.

As presented in the following section, retention of participants varied from 8.1% to 61.8% which is a quality issue to be noted. Low powered studies were another quality issue identified among studies that reported insignificant results.

Table 5: Study Quality Scores using Delphi Checklist

Author (Year)	Randomization	Treatment allocation concealed	Similar baseline characteristics	Eligibility criteria specified	Outcome assessor blinded	Treatment provider blinded	Patient blinded	Point estimates/variability	Intention-to-treat analysis	Total
Babbar et al., (2016b)	1	1	1	1	1	0	0	1	0	6
Chen et al., (2017)	1	0	1	1	0	0	0	1	1	5
Chuntharapat et al., (2008)	1	0	1	1	0	0	0	1	1	5
Davis et al., (2015)	1	0	1	1	0	0	0	1	1	5
Deshpande et al., (2013)	1	0	1	1	1	0	0	1	0	5
Field et al., (2012)	1	0	1	1	0	0	0	1	0	4
Field et al., (2013b)	1	0	1	1	0	0	0	1	1	5
Jahdi et al., (2017)	1	0	1	1	0	0	0	1	1	5
Jayashree et al., (2013), Rakhshani et al., (2012)	1	0	1	1	1	0	0	1	1	6
Martins et al., (2014b)	1	0	1	1	0	0	0	1	0	4
Newham et al., (2014)	1	0	1	1	0	0	0	1	1*	5
Rakhshani et al., (2010)	1	0	1	1	1	0	0	1	1	6
Satyapriya et al., (2009)	1	1	1	1	1	0	0	1	0*	6
Satyapriya et al., (2013)	1	0	1	1	1	0	0	1	0*	5
Uebelacker et al., (2016)	1	0	0	1	0	0	0	1	1	4

*Newham et al., (2014) started with ITT and later added a per-protocol analysis.

*Satyapriya et al., (2009) and Satyapriya et al., (2013) followed per protocol analysis

8.3.1.1 Dropouts

The total number of dropouts from all the trials was 214. The dropout percentages of each study are shown in Table 6.

Table 6: Dropout %

Study	Dropout%
Rakhshani et al., (2010)	8.1
Jayashree et al., (2013), Rakhshani et al., (2012)	26.9
Deshpande et al., (2013)	61.8
Satyapriya et al., (2013)	8.6
Satyapriya et al., (2009)	27.9
Newham et al., (2014)	13.6
Chen et al., (2017)	6.9
Chuntharapat et al., (2008)	NA
Babbar et al., (2016b)	11.5
Jahdi et al., (2017)	8.3
Martins et al., (2014b)	25.0
Field et al., (2012)	25.0
Field et al., (2013b)	10.9
Davis et al., (2015)	13.0
Uebelacker et al., (2016)	10.0

The overall reasons for dropouts are shown in Table 7. The three most common reasons were relocation of the participant to another city [n=73]; no-show for measurement of outcomes [n=50]; and drop out from the intervention [n=24].

Table 7: Reason for Dropouts

Reason	n= 214
Changed location of residence	73
No show for measurements	50
No adherence	24
Unknown	22
Asked by clinician to quit trial	14
Work schedules	9
Lost interest in study	9
Not happy being in control group	7
Unwillingness to do Yoga	4
Abortion/Miscarriage	2

8.3.2 Country in which study was undertaken

Five of the trials (Deshpande et al., 2013; Jayashree et al., 2013; Rakhshani et al., 2010; Rakhshani et al., 2012; Satyapriya et al., 2013; Satyapriya et al., 2009) were conducted in India, all in the city of Bangalore and in collaboration with the Faculty of Division of Yoga and Life Sciences, Vivekananda Yoga Research Foundation. Three trials (Rakhshani et al., 2010; Satyapriya et al., 2013; Satyapriya et al., 2009) took place in Maiya Super specialty hospital, one (Deshpande et al., 2013) at St Johns Medical College and Hospital and one (Jayashree et al., 2013; Rakhshani et al., 2012) at both St Johns Medical College and Hospital and Gunasheela Hospital.

Five trials (Babbar *et al.*, 2016b; Davis *et al.*, 2015; Field *et al.*, 2013b; Field *et al.*, 2012; Uebelacker *et al.*, 2016) were conducted in the United States. One study each was conducted in Iran (Jahdi et al., 2017), Taiwan (Chen et al., 2017), the United Kingdom (Newham et al., 2014), Brazil (Martins & Pinto e Silva, 2014b) and Thailand (Chuntharapat et al., 2008).

8.3.3 Study participants

These trials included 1037 participants in total, ranging from low-risk singleton pregnancies to pregnancies at high risk due to a range of complications. Eight studies (Babbar *et al.*, 2016b; Chen *et al.*, 2017; Chuntharapat *et al.*, 2008; Jahdi *et al.*, 2017; Newham *et al.*, 2014; Rakhshani *et al.*, 2010; Satyapriya *et al.*, 2013; Satyapriya *et al.*, 2009) were undertaken on normal or low risk populations usually defined as uncomplicated singleton pregnancies, primigravida or multigravida with at least one living child [n=684). Four studies were conducted on participants with depression (Davis *et al.*, 2015; Field *et al.*, 2013b; Field *et al.*, 2012; Uebelacker *et al.*, 2016) [n=242]; two studies [n=161] on populations with or at risk of obstetric complications (Deshpande et al., 2013; Jayashree et al., 2013; Rakhshani et al., 2012), and one (Martins & Pinto e Silva, 2014b) on women at high risk of lumbopelvic pain [n=60].

8.3.4 Intervention and control conditions

Ten studies (Chen et al., 2017; Davis et al., 2015; Deshpande et al., 2013; Jayashree et al., 2013; Newham et al., 2014; Rakhshani et al., 2010; Rakhshani et al., 2012; Satyapriya et al., 2013; Satyapriya et al., 2009; Uebelacker et al., 2016) evaluated an integrated Yoga approach (postures, breathing, meditation and relaxation techniques). The rest of the studies used postures with components of breathing.

Eight studies (Chuntharapat *et al.*, 2008; Field *et al.*, 2012; Jayashree *et al.*, 2013; Martins & Pinto e Silva, 2014b; Rakhshani *et al.*, 2010; Rakhshani *et al.*, 2012; Satyapriya *et al.*, 2013; Satyapriya *et al.*, 2009) listed the names of the postures and breathing practices used in the intervention.

In nine studies the control arm received treatment as usual, or routine care, or standard care, or waiting list and in seven studies control participants were offered antenatal exercises either in classes or with instruction. Three studies offered one-to-one refresher sessions during antenatal check-ups after the initial intervention period.

In 12 studies, a qualified yoga instructor provided the intervention. In three studies (Chuntharapat et al., 2008; Deshpande et al., 2013; Jahdi et al., 2017) qualifications of the instructor were not mentioned.

8.3.5 Outcome measures

Maternal outcomes studied were depression [n=6] (Davis *et al.*, 2015; Field *et al.*, 2013b; Field *et al.*, 2012; Newham *et al.*, 2014; Satyapriya *et al.*, 2013), anxiety [n=5] (Davis *et al.*, 2015; Field *et al.*, 2013b; Field *et al.*, 2012; Newham *et al.*, 2014; Satyapriya *et al.*, 2013), stress [n=3] (Deshpande et al., 2013; Satyapriya et al., 2013; Satyapriya et al., 2009) pregnancy induced hypertension (PIH)

[n=2] (Babbar *et al.*, 2016b; Jayashree *et al.*, 2013; Rakhshani *et al.*, 2012), quality of life (Rakhshani et al., 2010), interpersonal relationships (Rakhshani et al., 2010), anger (Field et al., 2012), salivary cortisol (Chen et al., 2017; Newham et al., 2014), pain during labour (Chuntharapat et al., 2008; Jahdi et al., 2017), maternal comfort in labour (Chuntharapat et al., 2008), gestational diabetes mellitus [GDM](Jayashree et al., 2013; Rakhshani et al., 2012), preterm delivery (Jayashree et al., 2013; Rakhshani et al., 2012), platelet count (Jayashree et al., 2013; Rakhshani et al., 2012), uric acid (Jayashree et al., 2013; Rakhshani et al., 2012) and mode of delivery (Jahdi et al., 2017).

Foetal outcomes [n=5] studied were Intra Uterine Growth Retardation [IUGR](Jayashree et al., 2013; Rakhshani et al., 2012), birth weight (Chen et al., 2017; Chuntharapat et al., 2008; Jahdi et al., 2017), birth weight relative to gestational age (Jayashree et al., 2013; Rakhshani et al., 2012), APGAR (Chuntharapat et al., 2008; Jahdi et al., 2017; Jayashree et al., 2013; Rakhshani et al., 2012), uterine artery Doppler recordings (Babbar *et al.*, 2016b) and foetal heart rate (Babbar *et al.*, 2016b).

A variety of scales were used to measure depression; the Edinburgh Postnatal Depression Scale (EPDS) [n=2], the Centre for Epidemiological Studies Depression Scale CES-D [n=2], the Hospital Anxiety Depression Scale (HADS) [n=1], and the Quick Inventory of Depression Symptoms-clinical rating (QIDS) [n=1]. The scales used to measure anxiety were the State Trait Anxiety Inventory (STAI) [n=5], the Hospital Anxiety Depression Scale (HADS) [n=1] and the Wijma Delivery Expectancy Questionnaire (WDEQ) modified version-indicator of pregnancy related anxiety [n=1]. The Perceived Stress Score (PSS) was used to measure anxiety [n=3].

8.4 EFFECTS OF YOGA DURING PREGNANCY

The systematic review findings are presented in two categories – benefits to physical health including obstetric outcomes and benefits to emotional/social health.

8.4.1 Physical health and obstetric outcomes

8.4.1.1 Obstetric complications

Rakhshani (2012) and Jayashree (2013) in a trial with high risk pregnancies reported significantly fewer cases of GDM [p=0.049) and PIH or pre-eclampsia in the Yoga group as compared to controls [p=0.04].This trial also reported some evidence of a greater reduction in platelet count, within the normal range in the Yoga group at the 20th and 28th weeks of pregnancy (Jayashree et al., 2013).

8.4.1.2 Pain during pregnancy

Martins (2014b) reported benefits to the Yoga group compared to the control in pregnancy related lumbopelvic pain measured on a visual analogue scale (VAS) at the end of the program [p<0.0058]

and pre/post yoga sessions. The pain measures on the VAS progressively decreased through the sessions [p<0.024]. During post session discussions in this trial, Yoga group women reported a 100% reduction in pain after the session. Field (2012), reported reduced back pain [p<0.001] and leg pain [p>0.001] compared to no treatment control at the end of the Yoga intervention among prenatally depressed women.

8.4.1.3 Pain and comfort during labour and delivery

Chuntharapat (2008) reported that Yoga during the third trimester improved maternal comfort during [p<0.05] and after labour [p<0.05], shortened duration of 1st stage labour [p<0.05] and total time of labour [p<0.05]. Self-reported labour pain levels were also lower in the Yoga group [p<0.05]. In another trial Jahdi (2017) reported a significantly shorter duration of labour in second [p=0.04] and third stage [p=0.01], significantly lower VAS pain scores in the Yoga group at 3-4cm dilation [p=0.01] and 2 hours after 1st and 2nd investigation [p=0.000]. Out of 60 participants whose data was analysed, 29.3% of the Yoga group had a planned induction versus 56.7% in the control group and 13% [n=4] of the Yoga group had a caesarean section as compared to 50% [n=15] in the control group.

8.4.1.4 Foetal wellbeing

Babbar (2016b) reported no significant group by time effects on uterine artery Doppler indices and systolic/diastolic ratio during a Yoga session. Baseline foetal heart rate fell in both groups [p=.01], remaining within the normal range, but to a greater extent in the control group [group by time interaction p=.09]

8.4.1.5 Newborn Outcomes

Rakhshani (2012) reported significantly fewer small for gestational age (SGA) babies [p=0.03] and new-borns with low APGAR scores at 1 [p=0.01] and 5 mins [P=0.04] in the Yoga group compared to the control group in their high risk population. No significant difference was seen between Yoga and control groups in APGAR scores among babies of low-risk women in the Chuntharapat (2008) study. Chen (2017) reported a higher [p=0.001] birthweight and longer gestational age [p=0.014] in babies born to women in the Yoga group in a trial in a low risk population.

8.4.1.6 Harms

No studies reported any harms to physical health or obstetric outcomes. The studies that examined physiological markers of stress suggested benefit rather than harm. The one study (Babbar *et al.*, 2016b) examining foetal physiology during Yoga reported no evidence of stress to the foetus and some evidence of a relaxation response.

8.4.2 Emotional and social health

8.4.2.1 Anxiety

8.4.2.1.1 State Anxiety

Satyapriya (2013) reported reduced state anxiety levels compared to control between baseline and follow up in the Yoga group [p<0.001] in a low risk population. Field (2012) and Field (2013b) both reported significant group by time effects favouring the Yoga groups [p=0.001 and p=0.01 respectively] in depressed populations. Newham (2014) reported a significant reduction in state anxiety scores over the course of both Yoga sessions [p<0.001] in a low risk population, but no significant group by time effects between baseline and follow up. Davis (2015) reported no significant difference in state anxiety between Yoga groups and control groups [p=0.5] in a population with depression and anxiety at recruitment.

8.4.2.1.2 Trait Anxiety

Satyapriya (2013) reported a significant group by time effect favouring the Yoga group in trait anxiety [p<0.001] and on HADS anxiety scores (p=0.001) in a low risk population. Newham (2014) reported no significant differences in trait anxiety scores between intervention and control groups in another low risk population trial. Davis (2015) also reported no differences in a population with depression and anxiety.

8.4.2.2 Depression

Satyapriya (2013), Field (2013b) and Field (2012) reported significant [all p<0.001] group by time effects favouring Yoga groups, the first in a low risk population and the second two in populations with depression at recruitment. Davis (2015) reported no significant group by time effects on the EPDS but a significant effect [p=0.011; effect size 0.39] on the PANAS scale in a depressed and anxious population, but Uebelacker (2016) showed no significant effects on either QIDS or EPDS in a depressed population. Newham (2014) reported no significant differences between groups on the EPDS in an intention to treat analysis in a normal population; a per protocol analysis in which control group members who had attended a Yoga class were excluded showed significant benefit to the Yoga group [p=0.04]

8.4.2.3 Stress

Satyapriya (2009) reported a significant [p=0.001] group by time effect on PSS scores in a trial of low risk women favouring the Yoga group and Satyapriya (2013) showed a significant group by time benefit to the Yoga group on the Pregnancy Experiences Questionnaire in another low risk population

[p<0.001]. Deshpande (2013) showed a significant [p=0.02] group by time effect on PSS scores favouring the Yoga group among women at high risk for obstetric complications.

8.4.2.4 Relationships

In a low risk population, Rakhshani (2010) reported significant benefits compared to control in the Fundamental Interpersonal Relations Orientation (FIRO-B) in every domain of measurement in the Yoga group [p<0.001] and no significant improvements in the control group. In post intervention discussion, the words relaxing, favourable, tranquillity, decreased stress, easy mind, mental balance were used by the Yoga group women to describe their feelings. Field (2012) reported Improved relationship scores [p<0.001] in the Yoga group compared to control among prenatally depressed women.

8.4.2.5 Sleep

Field (2013b) reported a significant reduction in sleep disturbance scores in a population of depressed women compared to control[p=0.05].

8.4.2.6 Quality of Life

Rakhshani (2010) reported significant benefits compared to control in four out of six domains of the WHOQOL-100 including physical, psychological, social and general health for the Yoga group compared to control in a low risk population.

8.4.2.7 Stress Markers

Two studies measured physiological markers of stress before and after single Yoga sessions. Satyapriya (2009) assessed the high frequency band of the maternal heart rate variability spectrum and showed an increase of 64% and 150% in the 20th and 36th week respectively [P=0.001]. This study also reported a decrease in the low frequency band [p<0.001] and the low frequency/high frequency ratio after the deep relaxation sessions in the 36th week.

Chen (2017) reported significant pre-post Yoga session drop in salivary cortisol at 16 weeks gestational age [p<0.001], but no change in controls and this effect was maintained at 20, 24, 28, 32 and 36 weeks. Pre-test salivary cortisol was significantly higher in the control group at 36 weeks than at 16 weeks [p<0.001] but not in the intervention group. The study also reported a significant pre-post session difference in IgA levels favouring the Yoga group [p<0.001] and this effect was maintained at 20, 24, 28, 32 and 36 weeks.

8.5 ANALYSIS OF RESULTS BY STUDY POPULATION, SAMPLE SIZE, OUTCOME ASSESSORS AND INTERVENTION

The number of trials reporting psychological health outcomes was sufficient to undertake further analyses to investigate possible reasons why some showed positive effects and others showed none.

8.5.1 Study population

The differences in results were not explained by the population group. Of the three studies showing positive effects on anxiety, one (Satyapriya et al., 2013) was on low-risk women and two (Field *et al.*, 2013b; Field *et al.*, 2012) were on prenatally depressed women. Of those showing no effects, one was on prenatally depressed women (Davis et al., 2015) and one on low risk women (Newham et al., 2014). Results were similar for depression. Out of the three studies that reported positive outcomes, one was low risk and two were high risk. One low risk study (Uebelacker et al., 2016) reported no effects, one reported per protocol effects only (Newham et al., 2014) and one reported effects on a related measure but not the primary outcome (Davis et al., 2015).

8.5.2 Sample size

There was however a relationship between results and sample size suggesting that the variation in findings could be explained by statistical power. The one trial showing negative results on all psychological outcomes (Uebelacker et al., 2016) had a sample size of 20. The two studies with mainly negative results (Davis et al., 2015), (Newham et al., 2014)had sample sizes between 40 and 60. All other trials examining psychological effects [anxiety, depression, perceived stress, relationships] (Deshpande *et al.*, 2013; Field *et al.*, 2013b; Field *et al.*, 2012; Rakhshani *et al.*, 2010; Satyapriya *et al.*, 2013; Satyapriya *et al.*, 2009) had sample sizes over 60 and all showed significant effects favouring the Yoga group.

8.5.3 Outcome Assessors

As shown in Table 8, In six out of fifteen studies, the outcome assessors were blinded. Blinding of the outcome assessor does not seem to have an effect on the significance of the results. Out of all studies that reported significant results, there is an equal split of six studies each where assessors were blinded or not. The studies that have reported insignificant results did not have their outcome assessor blinded, but there are other characteristics like low sample size as mentioned in this section that could have potentially affected the results more than blinding of the assessor.

Table 8: Analysis by Blinding of Outcome Assessor

Trial	Outcome Assessor Blinding	Significant/ Insignificant Effect
(Babbar *et al.*, 2016b)	Blinded	Significant
(Chen et al., 2017)	Not Blinded	Significant
(Chuntharapat et al., 2008)	Not Blinded	Significant
(Davis et al., 2015)	Not Blinded	Insignificant
(Deshpande et al., 2013)	Blinded	Significant
(Field et al., 2012)	Not Blinded	Significant
(Field *et al.*, 2013b)	Not Blinded	Significant
(Jahdi et al., 2017)	Not Blinded	Significant
(Jayashree et al., 2013) (Rakhshani et al., 2012)	Blinded	Significant
(Martins & Pinto e Silva, 2014b)	Not Blinded	Significant
(Newham et al., 2014)	Not Blinded	Insignificant
(Rakhshani et al., 2010)	Blinded	Significant
(Satyapriya et al., 2009)	Blinded	Significant
(Satyapriya et al., 2013)	Blinded	Significant
(Uebelacker et al., 2016)	Not Blinded	Insignificant

8.5.4 Intervention

There was no difference in results by type of intervention as shown in Table 9. Most studies used an integrated approach to Yoga including postures, breathing and meditation. There was no difference in the three studies (Rakhshani et al., 2010; Satyapriya et al., 2013; Satyapriya et al., 2009) that offered personalised one-to-one refresher sessions whenever the participant came for an antenatal session. There was no indication that number and length of sessions made a difference to the results.

Table 9: Intervention Design vs Significance of Results

Trial	Type of Intervention	Significant/ Insignificant Effect
(Babbar *et al.*, 2016b)	IAYT- A single 60 min session followed by home practice	Significant
(Chen et al., 2017)	IAYT- 2 sessions (70min each) per week for 20 week	Significant
(Chuntharapat et al., 2008)	IAYT- 6 sessions of 60 min each at pre-determined weeks of gestation (26^{th}-28^{th}, 30^{th}, 32^{nd}, 34^{th}, 36^{th}, 37^{th} weeks), home practice three times a week for 10-12 weeks.	Significant
(Davis et al., 2015)	IAYT- 75 min, weekly session for 8 weeks followed by home practice	Insignificant
(Deshpande et al., 2013)	No data on intervention design	Significant
(Field et al., 2012)	Postures- 20 min session, 2 times a week, for 12 weeks	Significant
(Field *et al.*, 2013b)	Postures- 20 minutes session, weekly for 12 weeks	Significant
(Jahdi et al., 2017)	Postures- 1-hour sessions. 3 times a week for 11 weeks, home practice for other days	Significant
(Jayashree et al., 2013)	IAYT- 3 times a week for 3 months, followed by home practice	Significant
(Martins & Pinto e Silva, 2014b)	IAYT- 1-hour, weekly session for 10 weeks	Significant
(Newham et al., 2014)	IAYT- Weekly session for 8 weeks	Insignificant

(Rakhshani et al., 2010)	IAYT- 1-hour sessions, 3 times a week for 1 month followed by home practice until birth of baby. 1-hour refresher one-to-one session at every antenatal check-up	Significant
(Rakhshani et al., 2012)	IAYT- 1-hour session, 3 times a week for 28 weeks	Significant
(Satyapriya et al., 2009)	IAYT- 2-hour sessions, 3 times a week for 1 month followed by home practice of 1hr every day. 1-hour refresher sessions during antenatal check-ups- once in 4 weeks up to 28 weeks and once in 2 weeks up to 36 weeks	Significant
(Satyapriya et al., 2013)	IAYT- 2-hour sessions, 3 times a week for 1 month followed by home practice of 1hr every day. 2-hour refresher sessions during antenatal check-ups- once in 3 weeks up to 28 weeks and once in 2 weeks up to 36 weeks	Significant
(Uebelacker et al., 2016)	IAYT- 75min class, weekly for 9 weeks	Insignificant

8.5.5 Analysis of drop-out rates by country, population group and intervention design

When analysing the dropout rates by country, as shown in Table 10, it was seen that studies conducted in India appear at the bottom and top of the list. The studies with high dropouts are high-risk studies as explained further in this section. Studies in Taiwan, Iran, the USA (except one) and the UK have reported less than 15% dropouts.

It was also possible to undertake an analysis of all trials by population groups to examine possible reasons for variation in dropout rates. Dropout rates were noted to be higher in high-risk population trials as compared to low risk. The four studies (Chen et al., 2017; Jahdi et al., 2017; Rakhshani et al., 2010; Satyapriya et al., 2013) that reported a dropout of <10% were all in low-risk populations. The four studies (Field *et al.*, 2013b; Jayashree *et al.*, 2013; Martins & Pinto e Silva, 2014b; Rakhshani *et al.*, 2012; Satyapriya *et al.*, 2009) that reported a dropout >25% were all in high-risk populations. Two studies (Field *et al.*, 2013b; Field *et al.*, 2012) one with a high drop-out rate and

one with a moderate rate, provided monetary compensation for class attendance and/or assessments.

Results did not differ by dropout rates as shown in Table 11. There was no relationship between design and frequency of Yoga sessions, and dropout percentages.

Table 10: Dropouts by country of study

Country	Study	Dropout%
Taiwan	Chen et al., (2017)	6.9
India	Rakhshani et al., (2010)	8.1
Iran	Jahdi et al., (2017)	8.3
India	Satyapriya et al., (2013)	8.6
USA	Uebelacker et al., (2016)	10
USA	Field et al., (2013)	10.9
USA	Babbar et al., (2016a)	11.5
USA	Davis et al., (2015)	13
UK	Newham et al., (2014)	13.6
Brazil	Martins et al., (2014a)	25
USA	Field et al., (2012)	25
India	Jayashree et al., (2013), Rakhshani et al., (2012)	26.9
India	Satyapriya et al., (2009)	27.9
India	Deshpande et al., (2013)	61.8
Thailand	Chuntharapat et al., (2008)	NA

Table 11: Intervention Design vs Dropout Rate and Population group

Intervention Design	Dropout %	High Risk/Low Risk participant population
2 sessions (70min each) per week for 20 week (Chen et al., 2017)	6.9	low risk
1-hour sessions, 3 times a week for 1 month followed by home practice until birth of baby. 1 hour refresher one-to-one session at every antenatal check-up (Rakhshani et al., 2010)	8.1	low risk
1-hour sessions. 3 times a week for 11 weeks, home practice for other days (Jahdi et al., 2017)	8.3	low risk
2-hour sessions, 3 times a week for 1 month followed by home practice of 1hr every day. 2 hour refresher sessions during antenatal check-ups- once in 3 weeks up to 28 weeks and once in 2 weeks up to 36 weeks (Satyapriya et al., 2013)	8.6	low risk
75min class, weekly for 9 weeks. $10-$20 compensation for each assessment and $10 gift card for attending two consecutive classes (Uebelacker et al., 2016)	10.0	high risk
6 sessions of 60 min each at pre-determined weeks of gestation (26^{th}-28^{th}, 30^{th}, 32^{nd}, 34^{th}, 36^{th}, 37^{th} weeks), home practice three times a week for 10-12 weeks. (Chuntharapat et al., 2008)	10.8	low risk
20 min session, 2 times a week, for 12 weeks (Field et al., 2012)	10.9	high risk
A single 60 min session followed by home practice (Babbar *et al.*, 2016b)	11.5	low risk
75 min, weekly session for 8 weeks followed by home practice (Davis et al., 2015)	13.0	high risk
Weekly session for 8 weeks (Newham et al., 2014)	13.6	low risk

1 hour, weekly session for 10 weeks (Martins & Pinto e Silva, 2014b)	25.0	reported pain
20 minutes session, weekly for 12 weeks. $20 was paid for each session to compensate for transportation/childcare expenses (Field *et al.*, 2013b)	25.0	high risk
1 hour session, 3 times a week for 28 weeks (Rakhshani et al., 2012)	26.9	high risk
3 times a week for 3 months, followed by home practice (Jayashree et al., 2013)	26.9	high risk
2-hour sessions, 3 times a week for 1 month followed by home practice of 1hr every day. 1 hour refresher sessions during antenatal check-ups- once in 4 weeks up to 28 weeks and once in 2 weeks up to 36 weeks (Satyapriya et al., 2009)	27.9	low risk
No data (Deshpande et al., 2013)	No data	high risk

When looked at together, the factor that most influenced dropouts were high/low risk populations. However, even with over 25% dropouts, the majority of the studies conducted in India reported significant results.

8.6 DISCUSSION

A thorough search of databases and grey literature provided 15 trials for analysis. It is possible that some trials have been missed. In addition, it is possible that results have been influenced by publication bias. Included trials were heterogeneous.

Single trials are more prone to publication bias than multiple trials of the same intervention on the same outcomes. Whilst multiple trials of the impact of Yoga components of psychological health were identified, only small numbers of trials reported on obstetric complications and few trials on the impact on labour and pain reported on the same outcomes.

The quality of the studies varied from low to moderate and this adds to the risk of bias. Trials which fulfil all quality criteria are not possible for interventions involving active participation because participants cannot be blinded to the intervention. Dropouts from intervention are common in these trials and contamination is a risk where access to similar interventions cannot be controlled.

Most studies in this review did not declare specifically that their analyses were carried out on an intention to treat basis and only one study explicitly undertook both intention-to-treat and per protocol analyses. Trials meeting the criteria for high quality are well recognised to be difficult and sometimes impossible to achieve with health promoting interventions (Jadad & Enkin, 2008; Petticrew, 2013) but more attention to quality and an adequate sample size is possible and would enhance conclusions which can be drawn from reviews such as this.

Although all trials chose Hatha Yoga as the form of Yoga practice, some used an integrated approach where postures were integrated with breathing and meditation and some did not. Most common postures were repeated in all of the interventions, but seven trials did not give a clear description of the Yoga offered. Session length varied from 20 to 75 minutes. Studies also differed in the number of sessions offered and their frequency (from one single session to tri-weekly sessions for 28 weeks). This has an impact on the costs of the intervention for both health services and patients but did not seem to have an impact on effectiveness.

The majority of the studies included home based intervention. Participants attended sessions in the hospital/Yoga centre and later practiced at home with the help of pre-recorded audio materials and booklets. The extent of engagement with home practice is likely to influence the effects of the intervention and this was not objectively measured. Non-home-based interventions provide more opportunity to establish the dose of intervention needed to have an effect, but home-based practice is possibly easier for patients to implement.

It is important therefore that better quality trials are undertaken, and the results of this review are replicated in further reviews before precise estimates of benefit can be made. In particular, this review suggests that further studies should aim for a sample size of more than 60 participants since inadequate statistical power seemed to explain the negative results of studies of psychological health outcomes. As shown in 8.5.3, blinding of outcome assessors did not make a difference to the significance of the results in the studies included. However, blinding of outcome assessors is a possible step in this type of intervention and ideally should be adopted by researchers to improve study quality.

Within this context, these trials present a positive picture of the potential benefits of prenatal Yoga in both high risk and low risk populations and on both psychological and obstetric health outcomes. It is also notable that no studies reported any harms relating to Yoga and the one study, which specifically set out to investigate impact on blood flow to the foetus, found no evidence of any potential problems.

The question is whether this existing evidence base is sufficiently strong to incorporate prenatal Yoga into obstetric practice? The answer is likely to be that a more robust evidence base and more precise estimates of benefits and cost are needed before publicly funded health services routinely provide Yoga instruction to women in the antenatal period.

In the meanwhile, whilst trials that are more robust are undertaken, the results of this review provide sufficient evidence for obstetricians to be supportive to patients who inquire about the benefits of prenatal Yoga and possibly, to recommend prenatal Yoga practice in health promotion literature offered to antenatal women.

8.7 CONCLUSION

No trials were conducted amongst the infertility treatment population. Better quality trials with a consistent approach to Yoga intervention as well as an adequate sample size will be necessary to establish reliable estimates of the benefits of prenatal Yoga, but the existing evidence base shows no evidence of harm and provides strongly suggestive evidence of benefits to health particularly mental health.

The systematic review shows that moderate to low quality trials have been previously successful in India and there have been successful trials among the high-risk population. At the outset, there is no reason to suppose that conducting a trial in India would be a problem. With this systematic review as a foundation, as the next step, I designed and conducted a feasibility study which will be detailed in the next chapter.

9 FEASIBILITY TRIAL IN INDIA

9.1 FEASIBILITY STUDY DESIGN

I chose to undertake my feasibility study in India due to four reasons. Yoga is a practice that originated in India, and people are familiar with it. I completed my Yoga instructor qualification in India and have experience of teaching prenatal Yoga within a hospital setting. There is evidence that other trials have been successfully completed in India (See Chapter 8). Lastly, I had professional contacts at multiple hospitals, and I was connected with skilled Yoga practitioners I trusted, who would support in effectively running a trial.

Five hospitals were approached in two different cities in India- Bangalore and Hyderabad. These two cities were chosen as I had family in these cities which reduced my cost of living during the trial. Four of them did not work out as two of them asked me to pay them £800 to be allowed to run the trial and the doctors in two other hospitals were not interested. The feasibility study was conducted at Fernandez Foundation, Hyderabad, India. Fernandez is one of the oldest maternity hospitals in the city with five centres located across the city.

The study followed a randomised waitlist-control research design. This ensures that every participant gets an opportunity to experience the intervention at some point and might enhance recruitment as no-one "misses out" if randomised into the control group. A further benefit is that data could be collected at the start, after the first group finished and after the second group finishes giving the opportunity to test the intervention at different stages of pregnancy, and to undertake time series analysis.

The flowchart of the trial design is depicted in Figure 2. In this trial, the intervention group started the Yoga sessions immediately and finished at 10 weeks, while the control group waited for 10 weeks and then started Yoga for 10 weeks. The Yoga sessions were conducted at the hospital.

As part of the mixed methods approach interviews were conducted to collect qualitative data with a purposive sample of the participants to explore attitudes and opinions towards the trial and the intervention. The results of this part of the study are presented in Chapter 10.

In this chapter, the predominantly quantitative details relating to sampling, recruitment, retention, intervention, data collection and analysis are presented.

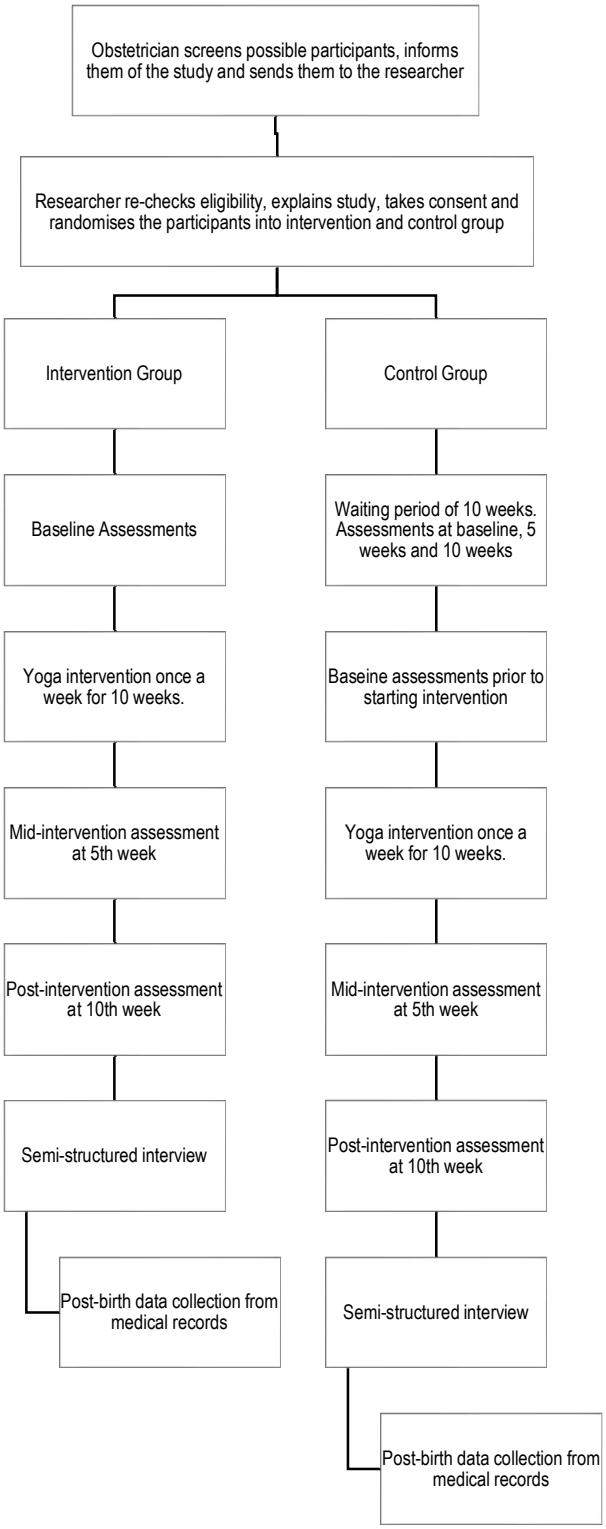


Figure 2: Waitlist Control Study Design

9.1.1 Ethical Approval

The feasibility study required a two-stage ethical approval process as it was conducted in India. Firstly, ethical approval was sought from the Biomedical and Scientific Research Committee (BSREC) at Warwick Medical School, Approval number REGO-2017-2108 . Post BSREC approval at the Medical School, I submitted the application to the BSREC committee at Fernandez Foundation for approval to start the study, Approval number ECF Ref# 31_2017. The ethical approval documentation can be referred to in Appendix 15.2 and 15.3.

It took 6 months for both the approvals to come through as concerns were raised by the obstetricians and the scientific committee of the hospital on the safety of the proposed Yoga intervention, which took further iterations of the protocol to resolve. The option of home practice of Yoga with a booklet provided after the Yoga class was removed in the second iteration due to concerns on safety. Final approvals were granted in January 2018.

9.1.1.1 Ethical Considerations

The submission for ethical approval addressed the following ethical issues.

a) Informed consent

Informed consent for the study was to be taken by me after a thorough discussion about the study. The discussion followed a systematic process (Appendix 15.4) and took place in a closed environment with no hospital staff in the room. As the study contains the topic of mental wellbeing, which is considered a sensitive topic to many, additional considerations were made regarding the process followed.

b) Right to withdrawal and Clinical Care

The participants were to be assured that their clinical care at the hospital would not be affected in any way by their decision as to whether to participate. Any differences in care reported by the participant were to be brought to the attention of the hospital administration. The Participation Information Leaflet (PIL) (Appendix 15.5) informs the participant that they can withdraw from the study at any point without fear of discrimination in the form of clinical care or otherwise.

c) Unexpected Emergencies

The Yoga classes were to be conducted on the hospital premises. In case of an unexpected event during the Yoga class, the participant would get immediate medical attention if appropriate. There was a provision for a critical incident report and an inquiry later in the presence of an obstetrician.

d) Privacy and confidentiality

The data security measures for this study were as follows:

I. Patient information: Every participant was assigned a unique code and data was identified by this code including in the Yoga session attendance register. The master file with the patient name and email address matched with the code was to be held in a password protected document only accessible to me. The master sheet will be deleted when the PhD is awarded.

II. Qualitative data: All audio files of interview recordings and transcripts are uploaded online to the University of Warwick server in a password-protected folder that cannot be accessed by anyone other than the me. All files are anonymised as per the participant codes. The audio files will be deleted when the PhD will be awarded, and the transcripts will be stored in the Warwick server for 10 years.

III. Data storage and security: All quantitative and qualitative data post digitalisation is currently stored in the University of Warwick server. The anonymised data will remain in the Warwick server for 10 years.

9.1.2 Inclusion and Exclusion Criteria

The four inclusion criteria were as follows:

1. Pregnancy post infertility treatment
2. Women at 12-16 weeks of gestation
3. Age $\geq$18
4. Can read, write and speak English

The four exclusion criteria were as follows:

1. Age < 18
2. ANY clinical contraindication to exercise in the mother as per the decision of the obstetric consultant. All clinical contraindications to be documented
3. Foetal abnormalities
4. Learning disabilities in the mother

In order to reassure the clinicians involved in the study who might have had continuing concerns about the safety of Yoga even after presentation of evidence to the contrary, the decision to exclude rested with the obstetric consultant. If they believed that there were clinical contraindications to Yoga, they were requested to document the case and the contraindication. If contraindications arose during the Yoga intervention (e.g., diagnosis of foetal abnormality) continuation with Yoga was at the discretion of the consultant.

9.1.3 Recruitment Process

A presentation was made to the obstetricians of the hospital regarding the study during their monthly academic session. This session is attended by most doctors in person or virtually (depending on which of the hospital branches they are working out of). Following that, emails were sent to all relevant doctors with details of the study seeking their support in recruitment. The obstetricians were requested to notify me if any new patient in their outpatient departments fulfils the criteria for research as many women get treated for infertility separately and come to this hospital for obstetric care once they have a viable pregnancy. The Head of the Infertility Department at the hospital identified a sample of 61 women and details were given to me.

Prior to consent, the obstetricians who had attended the information session about the trial and had demonstrated support, were requested to inform prospective participants about the study, provide the PIL and contact me if interested. Details of the prospective participants were also handed over to me by the Head of the Infertility Department.

9.1.4 Study Sample

As it was a feasibility study, power calculations were not carried out. There have been multiple recommendations with regards to sample sizes for pilot and feasibility studies (Lancaster *et al.*, 2004), Browne (1995) recommends a minimum of 30 participants, Sim and Lewis (2012) recommend at least 50 participants and Julious (2005) recommends 24. Hooper (2017) in the NIHR paper for sample sizes of feasibility studies, states that based on the estimates presented above, a researcher can reasonably justify a sample size between 24 and 50.

The aim was to recruit the maximum number of participants that could be recruited during the limited window of opportunity for recruitment. The total sample consisted of women who underwent Ovulation Induction/Intra Uterine Insemination treatment in the hospital between October 2017-February 2018 and had a viable pregnancy. This time period, October 2017-February 2018, was chosen to achieve a sample of women between 12-16 weeks' gestation at recruitment to the trial between February 2018-June 2018.

All 61 women were contacted by me over telephone. Each was re-assessed for eligibility for the study. An appointment was made over the phone for the potential participant to have a face-to-face meeting with me at the hospital where the contents of the PIL were explained, and consent was taken for the study.

As documented in the ethical considerations, I followed a systematic process of conversation during recruitment. The conversation covered the wellbeing of the mother and baby including the mother's mental health which is a sensitive topic. It adopted a positive approach focusing on wellbeing rather

than the perspective of stress, anxiety and depression. It also covered knowledge about prenatal Yoga and addressed any doubts they might have had. The flow of conversation is attached in Appendix 15.4.

After consent, as this was a feasibility study, the participants were randomised with the sealed envelope method. The intervention group started attending 10 weeks of Yoga sessions from a fixed date in the 1st week of March and the control group waited for 10 weeks before starting their 10-week Yoga intervention. A participant file was allocated to each participant. The file contained the participant code and the following documents (Appendix 15.6, 15.7, 15.8, 15.9, 15.10, 15.11):

1. Consent Form- 1 number
2. Demographic Questionnaire- 1 number
3. Questionnaires measuring outcome measures (See Section 9.6.1)
4. Yoga Class Card (which was handed over to the participant to record attendance)

9.1.5 Intervention

The intervention consisted of a 60-minute Yoga session in the hospital once a week for 10 weeks. The 60-minute sessions were split into 30 minutes of Yoga postures, 15 minutes of breathing exercises and 15 minutes of relaxation. Following the intervention, the Yoga instructor invited informal conversations so that participants could discuss their experiences and pose any questions. This lasted on average five to ten minutes. The Yoga postures used in the study are shown in Figure 3. Four sequences were followed in a rotational order throughout the 10 weeks. The sequences were developed by me as a Yoga Alliance International Certified Pregnancy Yoga Instructor. The postures were taken from the study by Polis et al., (2015b) where 26 Yoga postures were assessed for safety through markers like maternal heart rate, maternal temperature, foetal heart rate, uterine tocometry and post session 24 hour observation for problems.

Sequence 1	Sequence 2	Sequence 3	Sequence 4
• Tadasana • Urdhv Hastasana • Utittha Parshavakonasana • Utittha Trikonasana • Marjariasana • Bitlasana • Ado Mukha Svasana • Malasana • Sukhasana • Virasana • Ustrasana • Balasana • Paschimottasana • Ardha Matsyendrasana • Baddha Konasana • Viparita Karani • Ananda Balasana • Shavasana	• Tadasana • Uttanasana • Utkatasana • Garudasana • Marjariasana • Bitlasana • Ado Mukha Svasana • Malasana • Sukhasana • Virasana • Ustrasana • Balasana • Paschimottasana • Ardha Matsyendrasana • Baddha Konasana • Viparita Karani • Ananda Balasana • Shavasana	• Tadasana • Virabhadrasana I • Virabhadrasana II • Virabhadrasana III • Marjariasana • Bitlasana • Ado Mukha Svasana • Malasana • Sukhasana • Virasana • Ustrasana • Balasana • Paschimottasana • Ardha Matsyendrasana • Baddha Konasana • Viparita Karani • Ananda Balasana • Shavasana	• Tadasana • Urdhv Hastasana • Vrkshasana • Ardha Chandrasana • Marjariasana • Bitlasana • Ado Mukha Svasana • Malasana • Sukhasana • Virasana • Ustrasana • Balasana • Paschimottasana • Ardha Matsyendrasana • Baddha Konasana • Viparita Karani • Ananda Balasana • Shavasana

Figure 3: Yoga Postures

A local Yoga Alliance International Certified Prenatal Yoga instructor and doula who was already employed by Fernandes Hospital conducted the Yoga classes in the hospital. The sessions took place every Friday, 11:30pm-12:30pm, from March 2018- July 2018.

9.1.6 Data collection

9.1.6.1 Quantitative Measures

The primary outcome measures of this feasibility study were rates of recruitment and retention. The following quantitative outcome measures were tested for feasibility and acceptance by participants. Demographic details were collected at the start of the trial.

1) Warwick- Edinburgh Mental Well-being Scale (WEMWBS):
   WEMWBS is a 14 item self-completion Likert scale with scores from 1-5 for each item. The items all focus on positive aspects of mental health. The scores range from 14-70 with higher scores depicting higher levels of mental wellbeing. The test retest reliability of WEMWBS is 0.83 (Tennant et al., 2007). A change of more than 3 points has been proven to be a significant positive/negative effect and the Cronbach's alpha of WEMWBS in an adult population is >0.864 (Maheswaran et al., 2012).

2) Edinburgh Postnatal Depression Scale (EPDS):

   EPDS is a 10 item self-rating scale. Scores range from 0-30. Scores higher than 13 are considered as the cut point for probable post-natal depression and the need for referral to a clinical practitioner. EPDS has a split reliability of 0.88 and a Cronbach's alpha of 0.87. Sensitivity to change has been established making it a reliable outcome measure in intervention studies (Cox & Holden, 2003).

3) Perceived Stress Scale (PSS):

   PSS is one of the most common questionnaires used to assess perception of stress. It is a 10 item self-rating scale. Some items of this scale were designed to identify how uncontrollable, unpredictable and overloaded the participants find their lives to be. Scores range from 0-40. Cronbach's alpha score and test-retest reliability have both been reported as >0.70, Lee (2012).

The participants were followed up until birth of their baby when additional obstetric data was collected from medical records including gestational age at birth, birth weight, incidence of SGA babies and mode of delivery.

9.1.6.2 Qualitative Measures

The reasons for declining participation in the trial and reasons for dropout post consent were noted by me during phone conversations undertaken to elicit this information.

9.2 RESULTS OF THE FEASIBILITY TRIAL

9.2.1 Recruitment, Engagement and Retention

9.2.1.1 Recruitment

The names of 61 patients were given to me by the Head of the Infertility Department in February 2018. The document consisted of contact numbers, type of infertility treatment (IUI/OI) and gestational age. I contacted each patient by telephone and assessed eligibility. 14 women did not match the inclusion criteria for the study (they were residing in other cities (n=8) or were not English literate (n=5) or both (n=1)). Figure 4 shows the CONSORT flow diagram of this trial.

47 were given a detailed description of the trial and told they would be contacted again in two days to ask them about their decision to participate. This gave them time to think about it and talk to family members if required.

No patient referrals were received through individual doctors. It can be assumed that though the clinicians had agreed to support with recruitment into the study, the patients did not receive this

information from their doctors during consultations. The only patient referrals received were from the head of the department.

In order to increase recruitment, obstetricians were requested to look out for possible participants who had completed infertility treatments at facilities other than Fernandez Hospital but subsequently registered with Fernandez Hospital for obstetric care. They were sent regular emails throughout the recruitment period and visited by me in person to encourage them to identify further possible participants. No additional potential patient referrals were received from individual doctors.

Prospective participants who could not be reached on first call were contacted again two days after the first call and a further two calls were made in 2-day intervals. Women did not decline at the first instance, asking to be called back again and multiple calls needed to be made. Once they declined, there were not pursued. I think the recruitment was slow and the window for recruitment was restricted. The perceived pressure to recruit was high. To ensure that patients did not feel harassed, the outcome of every call was noted, and further calls were made only if requested or required. This process can be seen in Appendix 15.12. The reasons for non-participating in the study are shown in Figure 5.

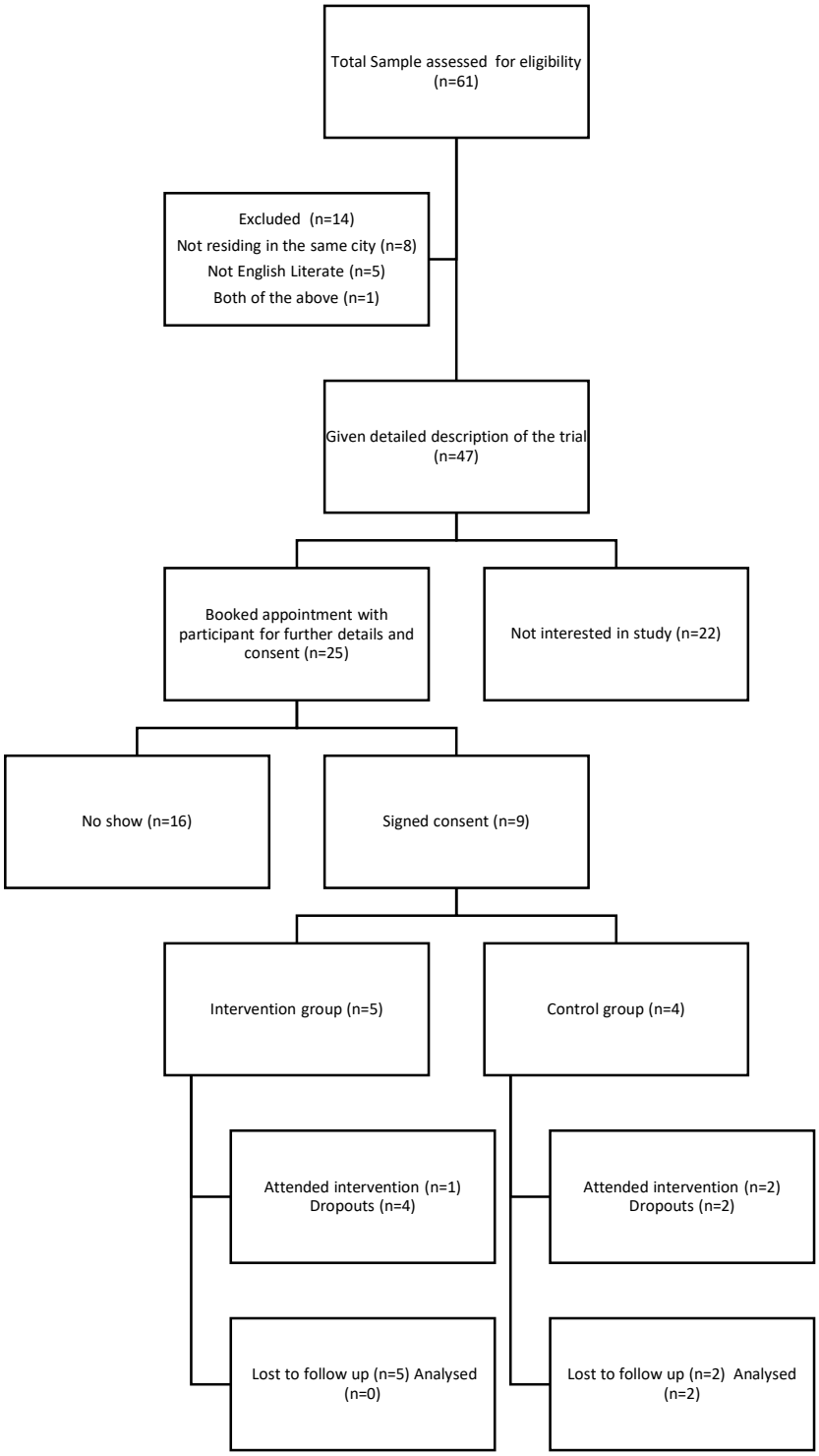


Figure 4: CONSORT Flow Diagram

Appointments were made with those who agreed to a face-to-face meeting with me at the hospital to complete consent. 16 women did not attend this appointment even after confirming appointment slots. By the end of the recruitment process, 38 participants declined to participate.

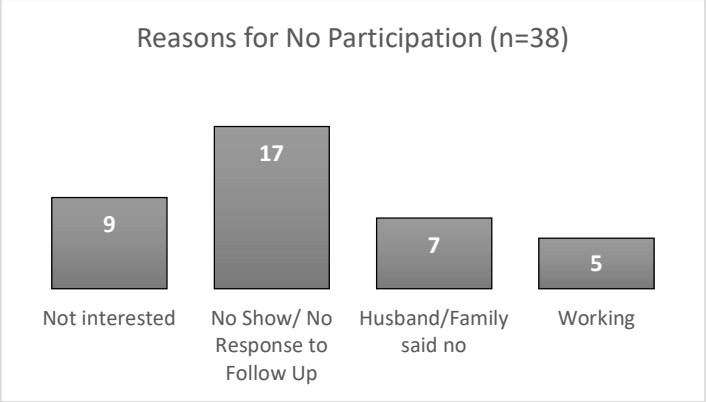


Figure 5: Reasons for No Participation

Nine women attended the face-to-face appointment with me. All consented to take part in the study and were randomised using the sealed envelope method. Five were randomised to the intervention group and four to the control group. Baseline demographics of the participants were similar as shown in Table 12. All nine participants completed baseline questionnaires.

Table 12: Baseline Demographic Characteristics

Age	Highest Educational Qualification	Marital Status	Employment	Past Experience with Yoga	Duration	Activity Levels	Diet	
Group 1								
21-25	Bachelors	Married	Employed	No		Very Active	No	
26-30	Masters	Married	Homemaker	No		Active	No	
26-30	Masters	Married	Homemaker	No		Very Active	No	
21-25	Masters	Married	Homemaker	No		Active	Yes	Self Prescribed
31-35	Bachelors	Married	Employed	Yes	2 years	Active	Yes	Nutritionist
Group 2								
21-25	Masters	Married	Homemaker	No		Active	Yes	Self Prescribed
26-30	Masters	Married	Homemaker	No		Active	No	
31-35	Masters	Married	Homemaker	Yes	6 months	Active	No	
26-30	Bachelors	Married	Homemaker	Yes	3-4 years	Active	Yes	Nutritionist

Qualitative observations made by me from conversations with recruited participants were that the majority raised the topic of stress themselves and were aware that stress has an impact on the baby. This was something that was 'just known'. None knew how stress impacts the baby. A majority knew about Yoga, but none had information about prenatal Yoga.

The conversation with one consenting participant revealed an issue that proved pertinent to the trial. Although repeatedly stating: “Everything is ok. We don’t need any help” this participant had a high baseline EPDS score of 18 at consent. During consent and baseline assessment she consistently looked at her husband’s reaction every time she spoke and eventually her husband had to be asked to leave the room as he was not letting his wife answer the questions herself. She said that the prospect of Yoga to relax and meet other pregnant women going through a similar journey would be something she would enjoy but did not attend any sessions. She did not respond to any follow up conversations. In the second follow up call, the husband picked up the call and spoke aggressively to me for calling his wife to “inquire about her mental health”.

Issues with mental health stigma seem to have affected three participants who did not turn up to the intervention following consent. Follow up telephone conversations reveal that family members were concerned about me identifying issues with mental health.

9.2.1.2 Dropouts

Four out of five intervention group participants dropped out of the study after consent and baseline assessment, before starting the intervention. Two of these moved to another city and two reported experiencing ‘family issues’ regarding participation in the study (see above). Two out of four control group participants dropped out of the study after consent and baseline assessment. One moved to another city and the family of the other participant refused to let her participate in a Yoga session (see above).

9.2.1.3 Retention

The single participant from the intervention group (UoWFH08) who attended the intervention dropped out after four sessions (beginning of 2nd trimester) and did not respond to two follow up calls. In the third call, she requested not to be contacted regarding the study again. She gave permission to use the existing data collected and any other information but did not want to continue with the intervention or the interview. Of the two participants from the control group, one attended seven and one attended eight out of ten intervention sessions.

9.2.1.4 Questionnaire Responses

No participants from the intervention group attended the intervention to complete the 5th or 10th week assessment. Two out of four control group participants completed the baseline and 10 weeks questionnaire during their control as well as intervention period, but not the 5-week assessment as both participants were not available during the 5th week. The results are shown in Table 13.

Average EPDS scores and PSS scores of the intervention group were higher than the control group at baseline. WEMWBS scores were higher suggesting better baseline mental wellbeing among the control group. No statistical test was done due to low numbers.

A meaningful change of more than 3 points in WEMWBS was recorded in the two participants of the control group who completed the intervention between the 10th week and 20th week assessments. EPDS and PSS scores improved over time, but the trend was similar over time and not clearly related to the intervention. The change in WEMWBS was great and clearly related to the intervention. As there were only two participants no statistical tests were carried out.

9.2.1.5 Birth Data

The medical record data of the nine participants have been summarised in Table 14.These cover mode of delivery, birth weight and gestational age at birth.

Table 13: Questionnaire Scores

	4 participants			**Intervention Group**	**5 participants**		
Baseline	**EPDS**	**WEMWBS**	**PSS**	**Baseline**	**EPDS**	**WEMWBS**	**PSS**
UoWFH01	8	46	16	UoWFH10	12	42	24
UoWFH03	18	44	17	UoWFH02	13	48	19
UoWFH05	9	64	19	UoWFH07	14	36	25
UoWFH09	3	56	12	UoWFH04	14	43	25
				UoWFH08	13	52	27
10 weeks	**2 participants**	**2 participants**	**2 participants**	**10 weeks**	**0 responses**	**0 responses**	**0 responses**
UoWFH05	11	59	11				
UoWFH09	5	58	14				
20 weeks	**2 participants**	**2 participants**	**2 participants**				
UoWFH05	4	65	3				
UoWFH09	10	70	9				

Table 14: Birth Data of Participants

ID	Gestational Age at Birth	Birth Weight	Mode of Delivery
Intervention Group			
UoWFH10	32+2 weeks of gestation with cerclage insitu, in preterm labour	1.86kgs	Emergency LSCS
UoWFH02	37 weeks	2.8 kgs	Vaginal
UoWFH07	40 + 3 weeks latent labour	2.84 kgs	Ventouse
UoWFH04	37 weeks	2.8 kgs	LSCS
UoWFH08	30 + 3 weeks monitoring for high BP	1.31 kgs	Emergency LSCS
Control Group			
ID	Gestational Age at Birth	Birth Weight	Mode of Delivery
UoWFH09	39+ 1-week gestation hypertension	2.84 kgs	Spontaneous Vaginal
UoWFH01	36 + 6 weeks latent labour	2.14 & 2.42	Emergency LSCS
UoWFH03	40 + 5 weeks latent labour	3.81 kgs	Spontaneous Vaginal
UoWFH05	39 + 4 weeks latent labour	3.52 kgs	Spontaneous Vaginal

*Orange- Participant who attended a few sessions and dropped out

*Green- Participants who completed the intervention

9.3 DISCUSSION

Although it took six months, it was feasible to get ethical approval for this study. There was support and engagement from the head of the infertility department and the intervention could be successfully conducted, which was a big positive. All three mental wellbeing measures seemed to work well. However, it appears as if WEMWBS is more sensitive to change in this Yoga intervention than either of the negative measures. It was feasible to gather birth data from medical records. However, the trial met several challenges which led to a conclusion that the trial was not feasible in its current form.

The ethics process took over six months which led to a very short recruitment window of five months. This had two implications. Firstly, the time window. Secondly and more importantly, a lower total sample to recruit from. Though the hospital had large numbers of women undergoing treatment, only successful and viable pregnancies from preceding months contributed to the total sample. There were variations in the number of successful pregnancies every month and a longer recruitment period might have balanced numbers which a short period could not.

The first major challenge was recruitment. Firstly, although there was agreement from the doctors in support of the trial, there is no evidence that any of the obstetricians aside from the head of the infertility department engaged in recruitment. Secondly, the hospital had 5 different units across the city and the potential sample was spread out. As a single researcher with no team, it was very difficult to co-ordinate and meet potential participants. It got increasingly tougher as patients would not keep to their timings or not show up which then delayed me from reaching the next meeting. Only a small proportion of those eligible consented and only a small proportion of those turned up for the Yoga sessions.

Reasons for declining to participate (Figure 5) very closely mimics the reasons for dropouts that were identified in the systematic review (SR) in Chapter 8. An issue that did not come up in the SR was a stigma towards mental wellbeing. It was observed that there were social and cultural factors that played a large part in women not wanting to be a part of this trial (further explored in Chapter 10).

The four key social and cultural reasons highlighted below played a role in the progress of this trial. Firstly, there is a lack of awareness in India about the importance of physical and mental health during pregnancy. Yoga, though originating in India, is not well accepted during pregnancy.

The couples who came for the recruitment session stated that they were not sure or in some cases had no knowledge at all about the importance of physical activity during pregnancy. Their discussion with me that lasted between 30-45 minutes was a step forward in their awareness towards the topic. The lack of awareness of the couples also highlights the gap in information dissemination from their

healthcare providers. Some couples seek out information on their own, but the majority rely on the information provided by their doctors. The women who opted out prior to the one-on-one discussion with me may not have been well informed about the topic and hence were not interested to know more. Starting with a one-to-one discussion rather than telephone, is a suggested change in recruitment design recommended for future studies.

Secondly, the behaviour of the patients of not showing up for appointments can be linked to a possible cultural issue of not saying "No" directly. They would respond with vague answers followed by no response to communication and no show at appointments. In addition, to have sufficient numbers to run a statistically significant trial, it is necessary to recruit four times over the required population to account for no shows and dropouts.

Thirdly, in India, there is a tradition of women moving to their maternal home during the 7th month of pregnancy. It is considered to be the responsibility of the maternal family to take care of the mother and bear the costs of birth and postpartum. The woman stays at her maternal home until the baby is born and for the first few months postpartum. In this study, there were participants who left for their maternal homes as early as at 4 months gestation. This led to low participation in the first place and then dropouts from the intervention post consent, as they could no longer attend the sessions. Some of the reasons given by the participants and documented by me (some are translated from Hindi to English) were: "There is no one here to take care of me. Hence, I came to my maternal house.", "My parents are worried that this pregnancy will not go well and want me to be at home and resting until the baby is born." and "My husband is too busy, and I need to be taken care of.". Home practice was initially part of the proposed research design, which was denied approval by the ethics committee due to safety concerns. A combined research design of few personal sessions and home practice could give better retention rates in this population.

Apart from that, this also highlights the fact that pregnant women are considered to be very delicate and someone who needs to be taken care of. Decisions are made for her and she is largely not under control of the situation. This links with the point above about awareness. In a society where decisions are being made for the mother, if the decision makers, in this case the husband and family, are not knowledgeable, it can directly affect the decisions made regarding the health of the mother and baby.

Lastly, the stigma about mental health amongst family members led to discontinuation post consent among 3 of the participants. Out of the three measures used, EPDS and PSS have negatively framed questions. In a situation where mental health is a sensitive topic, using only a positively framed questionnaire like WEMWBS might be a better option. From a patient perspective, it is important to

position the study as something that helps them and the baby and not as an investigation into their mental health. Framing the trial as an overall wellbeing intervention may work better.

There is a possibility that this trial might have had a different outcome if it was run by an obstetrician. The trials reviewed in the SR were conducted mainly by obstetricians and it is worth arguing whether recruitment is easier that way. Other options to consider are changing the recruitment design to add taster sessions and involving the family. Adding an additional inclusion criteria of recruiting participants who intended to stay in the city for the duration of the trial could possibly help in reducing dropouts. It is also worth exploring if the trial might have had different outcomes if it was run in the UK rather than in India.

Whilst a full trial requires a high level of funding and resources, it was reasonable to try and undertake a feasibility study. The study has provided valuable information about factors which need addressing before a full trial can be carried out in this population.

9.4 CONCLUSION

The feasibility study raised many questions, some of them being, why were the participants behaving this way? Why are some families supportive and some completely against? Are clinicians effectively advocating physical and emotional wellbeing during pregnancy? Is it a cultural problem? To answer these questions, I developed the qualitative arm of this project. It was important to uncover the various layers of perception and knowledge that affected decision making among these participants and their families.

10 QUALITATIVE INSIGHTS- THE INDIAN PERSPECTIVE

10.1 INTRODUCTION

A qualitative component was built into the feasibility trial from the start in order to explore issues that arose during the conduct of the trial and to gain ideas from participants about how the trial design might be improved. As it became clear that there were significant problems with this trial design especially relating to recruitment, this component of the study was extended to include interviews with doctors, yoga instructors and family members.

10.2 METHODS

In the initial protocol, this part of the study was limited to participants in the trial and their experiences and opinions about the research design and the intervention. It was amended to include a larger heterogenous population. The additional component of the qualitative study in India is illustrated in Figure 6 . Along with the participants, various individuals in the participant's ecosystem who have an effect on their decision making were added to the sample.

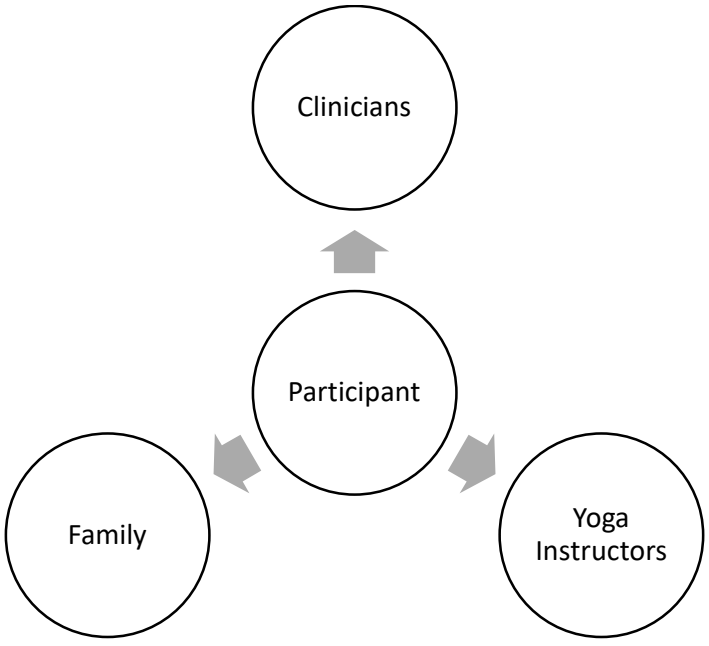


Figure 6:Qualitative Study Design

In this section, the methods followed have been presented.

10.2.1 Ethical Approval

The approval to interview participants of the feasibility study was included in the initial application (Refer to Chapter 9). An amendment application was made to add a new set of participants (families, doctors and yoga instructors) for the second phase of this project.

Firstly, an amendment approval was sought from the BSREC at Warwick Medical School (Approval number REGO-2017-2108). Post University approval, an amendment application was submitted to the BSREC committee at Fernandez Foundation for approval to start the second phase of the study (Approval number EC Ref# 31_2017). All BSREC approvals are attached in the Appendix 15.13 and 15.14.

10.2.1.1 Ethical considerations

The submission for ethical approval addressed the following ethical issues.

a) Informed Consent

   Informed consent for the interview was taken by me on the day of the interview, after giving the participants time to raise any queries they had from the Participant Information Leaflet (PIL). PIL's were emailed to the participants at least 3 days prior to the interview.

b) Right to Withdrawal

   Participants in the feasibility study were assured at recruitment that withdrawal from the study will not affect their clinical care and if they noticed a difference in care, it was to be brought to my attention which would then be further dealt by the hospital authorities. The doctors and the Yoga instructors were assured that their decision to participate was confidential and the data they provided was analysed and presented anonymously. The information leaflet (Appendix 15.15) informs the participant that they can withdraw from the study at any point without fear of discrimination in the form of clinical care or otherwise.

c) Privacy and confidentiality

   The data security measures for this study were as follows:

   I. <u>Participant information</u>: Every participant was assigned a unique code and data was identified by this code. The master file with the participant name and email address matched with the code was to be held in a password protected document only accessible to me. The master sheet will be deleted when the PhD is awarded.

II. Qualitative data: All audio files of interview recordings and transcripts are uploaded online to the University of Warwick server in a password-protected folder that cannot be accessed by anyone other than me. All files are anonymised as per the participant codes. The audio files will be deleted when the PhD is awarded, and the transcripts will be stored in the Warwick server for 10 years.

III. Data storage and security: All quantitative and qualitative data post digitalisation is currently stored in the University of Warwick server. The anonymised data will remain in the Warwick server for 10 years.

10.2.2 Recruitment

a) Feasibility Study Participants

While consenting for the feasibility study, participants were informed about the interview component of the study and additional consent was taken.

b) Family, Doctors, Yoga Instructors

Purposive sampling was the chosen method as the study design required the opinions and insights of the individuals in the environment where the feasibility study was conducted.

i. Family: Family of all participants who consented to the study were taken as the total possible sample. All the participants who consented for the feasibility study were called and informed about the family interviews. After the initial telephone conversation, a face-to-face meeting was scheduled with interested family members.
ii. Yoga Instructors: There were two Yoga instructors involved in the study. Both of them were informed about the interviews by telephone conversation and PIL's were sent by emails.
iii. Doctors: The recruitment for the doctors took place in two steps. Firstly, a presentation on the study was given to all the doctors (obstetricians and infertility specialists) in the monthly CPD and participation in this further component of the study was requested. After that, an email was sent by the Head of the Department as a follow up with the PIL attached. Three follow up emails were sent in total to maximise participation.

10.2.3 Data Collection

A semi-structured interview format was used as the data collection tool. An interview protocol (Attached in Appendix 15.16,15.17,15.18,15.19) was followed to ensure that there was in-depth discussion but within the scope of the topic. It was decided to go for a semi-structured format as it

gives flexibility to use probes to lead participants towards the research questions. It was necessary to probe participants to avoid rehearsed answers and extract their true opinions on the topic.

A one-to-one semi-structured interview was conducted with feasibility study participants from both intervention and control groups. The interviews were scheduled during the next antenatal visit to the hospital after the intervention finished. In the case of family and experts, a suitable time was arranged, and the interviews conducted in a private room in the hospital premises.

Interviews with participants aimed to help them reflect and talk about their experiences, emotions and feelings during the intervention period and what difference the Yoga intervention made or did not make to their life in that short time span. The interviews covered their experience of taking part in the trial, attitudes to early or late intervention, prior experience of Yoga, extent of personal Yoga practice, and experience of Yoga classes or supervision outside the trial.

Family and expert interviews aimed to help interviewees share their opinions about and experiences of Yoga, the trial, societal barriers, ideas to improve the study if replicated and the importance of this form of research.

The flow of the interview session is demonstrated in Figure 7.

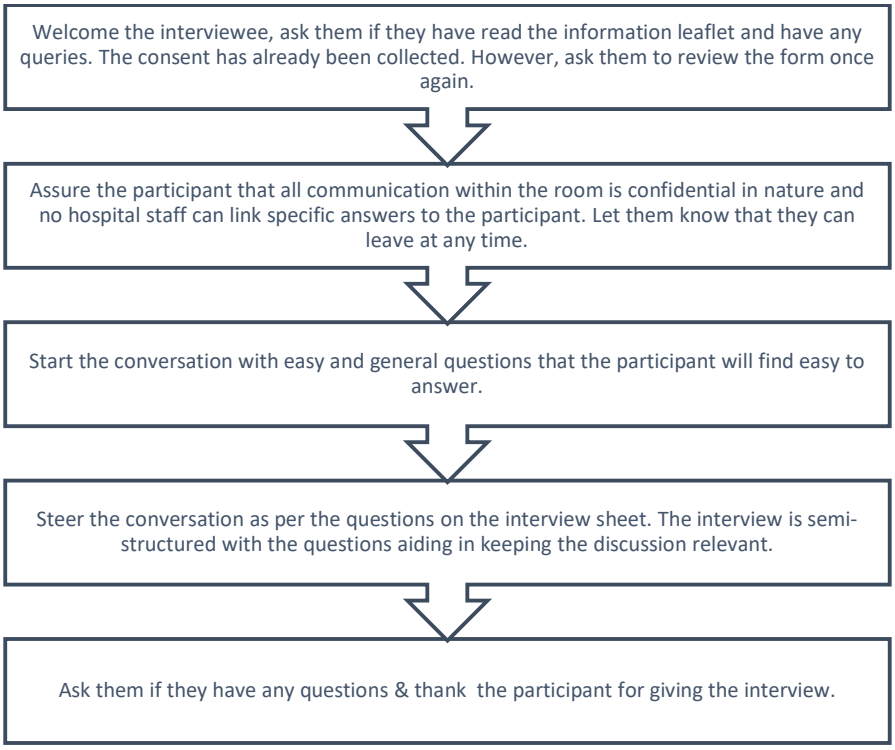


Figure 7: Interview Flow

10.2.4 Informed consent

The consent from participants of the feasibility study was taken in advance along with the feasibility study consent. For the family members, doctors and Yoga instructors, prior to consent, the PIL was provided via email. I obtained informed consent for the study prior to the interview (Refer to Appendix 15.20). The consent was taken after a thorough explanation of the complete study. The discussion took place in a closed environment with no hospital staff in the room (except the interviewee).

10.2.5 Data Analysis and Transcription

Thematic analysis was the technique used to analyse the data collected through interviews. In the first instance, it was intended to be a comparison between opinions of different participants and how to improve on the research design and intervention. When the study was extended to include doctors, Yoga instructors and family members, the aim of data analysis changed. It was now to analyse all interviews together to examine similarities and differences in perspectives of different groups of interviewees about Yoga, Yoga in pregnancy, participation in research and socio-cultural factors affecting decision making. There were some questions directed only towards the doctors and Yoga instructors, but the majority of the questions were on similar topics which allowed for comparison.

For thematic analysis, the audio recordings were transcribed verbatim and cross-checked by listening to the audio and matching to the written transcript. The transcripts were uploaded into NVivo for coding of data. Other potential mistakes in transcription were checked while coding the data. To ensure that no codes were missed, the process was repeated twice. The codes were combined into categories from which the themes arose.

10.3 RIGOR AND TRUSTWORTHINESS

The proposed methodology was considered against four criteria: credibility, transferability, dependability and confirmability as recommended by Lincoln and Guba (1985). Responses are set out in Table 15 below.

Table 15: Rigor and Trustworthiness- Interviews

Criteria	Purpose	Strategies	Steps taken in this thesis
Credibility	Does the study measure or test what it is intended to measure?	1. Adopt well established research methods like interviews and focus groups 2. Develop familiarity with participating organisations 3. Triangulation of data 4. Encourage honesty among the participants 5. Iterative questioning 6. Peer or Supervisor debriefing 7. Examination of previous research findings	1. Interviews was the data collection tool used. 2. I visited the hospital regularly, presented at monthly meetings and interacted with doctors online and offline. 3. In the overall thesis, there is triangulation of data through multiple methods. 4. Probes were used to encourage participants to speak in depth about the topic. 5. There were monthly meetings with my supervisors where we would discuss the progress of the project and I would receive feedback on my work. 6. In the discussion chapter, the findings of this thesis have been examined in relation to literature.

Transferability	The extent to which the findings of one study can be applied to other situations. Lincoln and Guba present an argument that it is the responsibility of the investigator to ensure that sufficient contextual information about the fieldwork is provided to enable the reader to make a transfer.	1. Number of organisations taking part in the study and where they are based 2. Any restrictions in the type of people who contributed data 3. The number of participants involved 4. The data collection methods that were employed 5. The number and length of the data collection sessions 6. The time period over which the data was collected	1. All the related data have been described in detail in Section 10.2 of this chapter under Methods.
Dependability	If the work were repeated, in the same context, with the same methods and with the same participants, similar results would be obtained. However, the changing nature of the	1. The research design and its implementations describing what was	1. Detailed drafts of interview protocol were created and checked by the supervisors. 2. The entire process has been documented.

	phenomena scrutinised by qualitative researchers renders such provisions problematic in their work. Lincoln and Guba stress the close ties between credibility and dependability, arguing that in practice, a demonstration of the former ensures the latter to some extent.	planned and executed on a strategic level 2. The operational detail of data gathering, addressing what was done in the field	
Confirmability	Is the research objective? Here steps must be taken to help ensure as far as possible that the work findings are the result of the experiences and ideas of the informants, rather than the characteristics and preferences of the researcher.	1. Reflexivity 2. Triangulation	1. Triangulation by methods have been implemented in this thesis as a whole. 2. As a single investigator with no team, data collection was done only by me. 3. The objectiveness of the research has been maintained through a process-based approach to data collection, regular debriefings and support from the supervisors.

10.4 RESULTS

10.4.1 Recruitment and Dropouts

a) Participants: Out of seven participants who initially consented for the interviews during consent process for the feasibility study, four participants withdrew when contacted to set a date. Two participants had relocated to another city and two participants changed their mind about giving the interview and decided to withdraw.

   Two of the three participants who gave the interview were from the waitlist-control group (UoWFH05 and UoWFH09) and one was from the intervention group (UoWFH04). The intervention group participant did not attend any session or complete any assessment except the baseline whereas the control group participants had attended almost all the sessions and completed assessments.

b) Family: All nine participants who consented for the feasibility study were contacted to request an interview with one family member. Seven participants refused the request. Husbands of two participants from the control group (UoWFH05 and UoWFH09) were keen to do the interviews. A point to be noted is that they were the same as the regular attendees of the study. However, one of the two husbands withdrew due to work and travel commitments and only one interview was conducted.

c) Yoga Instructors: The two Yoga instructors involved with the study were approached and both consented to, and were subsequently interviewed.

d) Doctors: Twenty-five infertility specialists and obstetricians of the hospital were approached via the formal presentation and email from the Head of Department. Eight doctors consented to being interviewed. Among them the Head of Department and the founder managing director of the hospital were included.

10.4.2 Coding Process

The fourteen interviews were uploaded onto NVivo 10 software and line by line coded. As new codes were generated, previous transcripts were scanned again for missed coding opportunities. The codes had varying levels of abstraction from “emotional health” to exact words or phrases like “fear” or “financial challenge”.

This process generated 55 codes. The codes were assessed to see if they can be merged. However, there was a sufficient degree of difference to keep them separate. The 55 codes were clustered into eight categories as shown in Table 17.

After the codes were divided into eight categories, each category was analysed on its own. All the identified topics were put together and were analysed for similarities and differences of views between the interviewees and how they fitted into the larger scope of the problem being addressed by this project.

Interviews aimed to provide context for the results of the feasibility study. The semi-structured interview protocol aimed to gather views on infertility, appropriate care in pregnancy, stress in pregnancy and its importance, on Yoga and on participation in trials.

With a focus on the scope of the project the data selected for inclusion in each category was further scrutinised to identify overarching themes. As shown in Figure 8 the eight categories combined to form four main themes- Infertility as a social disability, Doctors' and Yoga Instructors' views on Stress in Pregnancy, Yoga, and the Trial.

The following key identifies quotations by group of participants: FH/H: Participants and Husband, OB: Obstetrician, IF: Infertility Specialist, Y: Yoga Instructor.

Demographic data was collected for interviewees who were also trial participants but apart from gender, relationship to participant and occupation, no demographic data was collected for other participants of this interview- clinicians, family and yoga instructors. Available details are provided in Table 16.

Table 16: Demographic Data

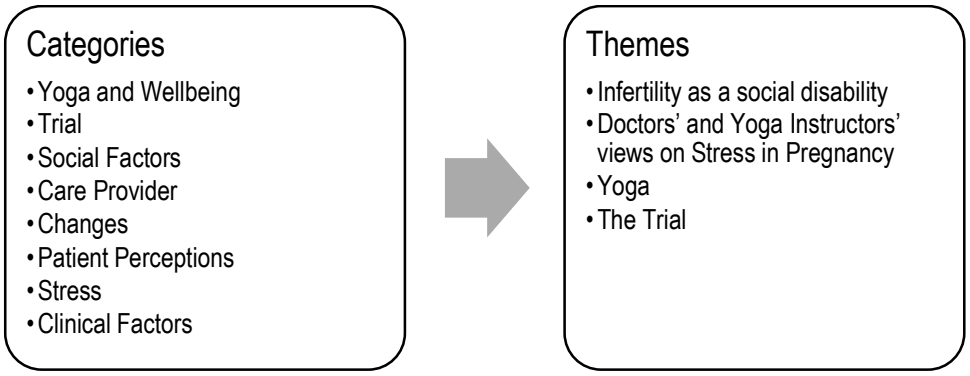
Participant	Gender	Role	Occupation
UoWFH05	Female	Participant	Housewife
UoWFH09	Female	Participant	Housewife
UoWFH04	Female	Participant	Housewife
H	Male	Husband	Medical Sales Representative
IF1	Female	Part of care team	Infertility specialist
IF2	Female	Part of care team	Infertility specialist
IF3	Female	Part of care team	Infertility specialist
OB1	Female	Part of care team	Obstetrician
OB2	Female	Part of care team	Obstetrician
OB3	Female	Part of care team	Obstetrician
OB4	Female	Part of care team	Obstetrician
OB5	Female	Part of care team	Obstetrician
Y1	Female	Conducted Yoga sessions for the trial	Yoga Instructor
Y2	Female	Substitute Instructor for the trial	Yoga Instructor

Table 17 below sets out the eight categories and the codes that contributed to them followed by Figure 8 which sets out the four themes derived from the categories.

Table 17: Fifty-Five Codes Under Eight Categories

Yoga and Wellbeing	**Trial**	**Social Factors**	**Care Provider**
Benefit of activity	Doctors and recruitment	Family support	Assurance
Experience of yoga	Intervention Design	Fear	Hospital processes
Knowledge of Yoga	Participation and adherence	Financial challenge	Multiple care providers
Lifestyle	Patient behaviour	Socio-economic status	Patients doing yoga
Lifestyle change	Randomisation	Last resort situation	Doctor guidance
Patients doing yoga	Recruitment Design	Working mom	Screening
Safety of Yoga	Trial	Relationship issues	Change in perceptions
Why wellness/wellbeing	Usefulness	Religion	Challenges
	Location	Peer or Social Pressure	Emotional health support
	Motivation	Change in perceptions	Emotional state
	Challenges	Challenges	Labour and birth
	Comments	Emotional health	Miscellaneous
	Labour and birth		
Changes	**Patient Perceptions**	**Stress**	**Clinical Factors**
Home visit	Change in perceptions	Effect of stress on outcomes	ART vs normal
Idea	Challenges	Effect on Baby	Physical Problems
Improvements	Emotional health	Current evidence	Type of ART
Comments	Self esteem	Emotional state	Duration
	Peer advocacy	Cause for stress	
		Stress	
		Stress relief	

Figure 8: Categories and Themes



10.5 THEME 1: INFERTILITY AS A SOCIAL DISABILITY

Interviews set out to investigate participants' understanding of the attitude of family, peers, and the wider community, towards infertility. The impact of these attitudes was then explored under four sub themes: family and peers, religion and community, and deteriorating self-esteem.

10.5.1 Family & Peers

In India, conceiving a child soon after marriage is often required for the woman to be respected in the society. All interviewees reported intense pressure from family and peers to conceive within a short period of marriage. Pregnancy is a family affair that exposes the couple to comparison with other family members or peers, intimate questions about their relationship decisions and when a child could be expected. This interviewee was typical of most highlighting a competitive aspect to fertility.

> "if her sister conceives in the family, or sister-in-law, or relatives, friends, they keep comparing themselves with others […], why not I [why I have not conceived]?[…]they keep comparing with others[…] Second thing is family, mothers-in-law … are very particular that they should conceive as early as possible."-IF3

The pressure is high, especially if the process of conception takes longer than two years.

> "In this social culture, they expect a woman to get pregnant within 2 years and have a baby and [when] that is not happened [happening], and they're going in for a treatment, that puts lot of stress on the mother."-Y2

The above-mentioned family pressure and scrutiny have a detrimental effect on the mother. Mothers are prone to social seclusion which helps her and her husband avoid being on constant scrutiny.

> "most often what happens is, as the years pass by, and women are all having children, they tend to isolate themselves socially. They stop going to the family do's, they stop going to the social functions, because everybody laughs - oh, how many years now married, no children. [No children after so many years of marriage?]. Then it just starts all over again, so they don't tend to mix much."-OB2

> "Family occasions very stress [stressful]. Everyone asks questions. I feel bad. Husband [also] feel bad. I don't go anywhere. [I} Stay home only."-FH04

Pregnancy post infertility treatment is often termed as a 'precious pregnancy'. It lays emphasis on the importance of the pregnancy to the couple and their family. It was found during the interviews that the fear of losing the baby is an underlying factor in the actions of the couple and the family. The mother is not "allowed" to do anything that in the family's view might damage the chances of a healthy baby .

> "So, when it comes to somebody who did a treatment to conceive, that pressure is much more […] some of them are literally not allowed to do anything. They may want to be a part of study, they may want to exercise and all, but they are told that they should not. I think that is a major issue"-Y1

Participants have highlighted that the pressure from the family unit and relatives on them to get pregnant, to maintain the pregnancy and have a healthy baby has led to relationship struggles and issues between the couple as well.

> "Because of that only, wife and husbands stress and pressure and quarrels, all will come by that only"-FH09

A pattern identified by the doctors is that the immediate family have a strong influence on the actions and decisions of the couple. There is a visible dependency of the woman on her husband and her in-laws and the woman tends to be the target of various types of advice which are not always optimal.

> "[pregnant women] are very very vulnerable, they listen to all advice from anyone, especially they are influenced by their family a lot. Sometimes, the do's and don'ts that they get from their family have no scientific basis […] Despite our reassurances, they tend not to listen. So as long as there's no harm we also let it go."-IF2

> "Especially pregnant women, they are totally dependent, they don't want to come out of the house alone - they wouldn't do that. Family doesn't allow them. They have mothers and their aunts telling them that, oh, we all have delivered [we know what's best]..."-OB1

Women who suffer from infertility have a constant and crippling fear which arises from the duration it took for them to conceive and the range of treatments they might have undergone. The fear continues post conception up until childbirth and there is often influence of family members.

> "See, in our culture, pregnancy is kind of a big thing for women. So now since they've already gone through infertility, they don't want to lose the baby. Let's be very clear [….] we still have women consider that they need to be very careful during pregnancy."-Y2

> "Some of them are even scared of going out; they are scared of telling people they are pregnant because they are scared, they will lose the child."-Y1

> "Lot of stress. I don't know if success or not. Very scared."-FH04

Infertility led pregnancy is a tough journey for these couples and it is established that the presence or absence of support plays a role during conception and pregnancy. Support from parents, in-laws and workplaces can make a difference in a couple's experience of pregnancy.

> "Society, family plays a big role. For example, my mother, my father I asked them, parents, that only, there is so and so programme - so she [the husband's mother] blindly told that you go ahead, you go and join the classes, because she knows the actual value of our labour […] family plays a very big role. Support is very important."-H1

> "And the other thing is working women. They are against rest - how many days leave can we get, or 6 months is not enough, most of the organisations may not be giving them 6 months

private companies and all. What do I do next, how do I deal with the breastfeeding, what do I do? So, from day one they are stressed about it. - "OB1

10.5.2 Religion & Community

Religion and community are the next circle in society after the immediate family and peers. In some communities and religions, childbirth and the continuation of the family line is seen as a key part of marriage. The presence of an urgency for conception soon after marriage could be prevalent in all religions and cultures but is reported to be higher in the Muslim community. The doctors I interviewed identified that men belonging to the Muslim community were resistant towards taking part in infertility diagnosis and treatment as women are considered as the source of the problem.

> "So, most of the Indian men, I mean I am not against it, religions and all - but in Muslim culture, the last thing they ask is husband. In Hindu culture, even we ask for husband semen analysis they'll accept it. But Muslims they will not, so they will ask us, without his semen analysis, can you give treatment. We straight away refuse"—OB4

> "Clearly in the Muslim communities it is very important for they to have a baby and have one fast. So, they are very stressed, we have many women coming to the OPs within 3 months, 6 months of marriage, for treatment, asking for treatment."-IF1

10.5.3 Deteriorating Self Esteem

The result of failing to spontaneously conceive along with the immense pressure from the society impacts the self-confidence and self-esteem of the couple. They feel that they failed as a couple and as individuals as well. When the treatment is not successful, they take it as a personal failure. This feeling of incapacity increases mental health problems.

> "we couldn't, we failed"-H1

> "Why I am not having child [children?]."-FH04

10.5.4 Theme 1 Conclusion

In India, there is an expectation of early pregnancy post marriage. Infertility is a social disability in this society and has lasting repercussions on the couple, especially on the woman. Family and society are a source of stress for the couple who may come for treatment of infertility long before they would meet the accepted criteria for infertility.

In the next theme, the opinions of the doctors and Yoga instructors about stress and its solutions are explored.

10.6 THEME 2: DOCTORS' AND YOGA INSTRUCTORS' VIEWS ON STRESS IN PREGNANCY

Theme 1 shows that couples start infertility treatment in a state of stress which then continues into pregnancy. Family members exert pressure on women to conform to certain behaviours whilst pregnant and the key expectation is to rest. In this theme the interviews set out to explore the understanding of doctors and Yoga instructors on stress during pregnancy.

The four sub themes are: prevalence of stress, effect of stress, current solutions offered and awareness and advocacy of wellbeing practices.

10.6.1 Prevalence of Stress

The interviews with the clinicians confirm that the women in this patient group are anxious and stressed during infertility treatment and during pregnancy. The one anomaly was clinician OB4, who highlights that stress and anxiety are prevalent during treatments and not so much once a couple conceives.

> "What I feel is that all infertility patients will be stressed definitely. But if they conceive, most of them will not have any problem. Conception is the main thing […] Stress, I don't think so much-"-OB4

The number of years the couple have been trying to conceive is suggested to be proportional to levels of stress and anxiety. The time, physical impact of the treatments and the financial burden add to the deteriorating mental health. Intra Uterine Insemination treatment patients are perceived to handle themselves better than In-Vitro Fertilization patients. This could be attributed to IVF being an invasive and painful method. One clinician (IF2) highlighted that these patients require continuous reassurance as the smallest things like vomiting (something common in pregnancy) worries them.

> "First they worry about whether they would conceive or not. Once they conceive, they are looking at the final outcome […] So simple [things like] vomiting, they worry so much. And mostly they say I have aches here and pains here - they are part and parcel [of pregnancy], but they worry too much."-IF2

It can be inferred that there is a recognition of the mental state of this patient group. The following sub-theme probes into the effects of this stress on pregnancy.

10.6.2 Effect of Stress

Amongst the majority of the clinicians (five out of eight), there is a lack of recognition on the effects of mental health on pregnancy. The responses varied from not knowing enough to comment, to a

belief that there is no effect at all. One doctor (IF3) has vague knowledge about the hormonal implications and attempted to connect the dots. Lack of knowledge about this topic needs to be addressed as there is large amount of research literature available. In Chapter 3, the evidence on the effects of stress on pregnancy was presented. The implications of a clinician's lack of knowledge on this topic can be long lasting.

> "What's been done already if I can ask you? Because I haven't read of anything on all of this." – IF1

> "I don't think medically it is proven […] I personally don't feel that stress itself is directly causative."- OB1

> "But some people will do feel stress [will feel stressed], but that doesn't affect anything else physically."- OB3

> "I don't know much about [it] [...] So they are doing research, whatever the woman thinks, the mother thinks, is affecting the baby. Mother is angry, the baby is also reacting to this type of- it is because of the hormones which are integrated into the body circulation, like most of them are cortisol, adrenaline or cortisol - these are the things which are, few things which I know. "- IF3

Three of the eight doctors (IF2, OB2 and OB5) had strong opinions on the causative effects of stress on pregnancy outcomes. It can be suggested that the patients being cared for by these doctors have different pregnancy experiences and advice.

> "For a long time [its known that] if you have stress it can lead to medical problems like blood pressure, even heart disease, sugars can go up with stress, vomiting's. And they can end up with premature labour and low birth weight babies. So, they can cause medical problems, persistent stress"- IF2

> "Stress affects a human life with everything - physically, mentally, emotionally. And it has its own bearing, there is enough evidence to now support saying that physically also it can be quite disabling if you are extraordinarily stressed"- OB2

> "Sleep disturbances, High blood pressure, Increasing weight"- OB5

The knowledge of the possible impact of stress on maternal and foetal outcomes, and the degree of it, is critical as it will influence the behaviour of both the clinician and the patient. As shown earlier, doctors do recognise that stress and anxiety are prevalent in this population, but it is clear that the

impact of stress is not well understood. Lack of recognition of the impact leads to a lack of importance given to the problem. The current thinking appears to be 'If it's not a problem, why look for a solution?'.

10.6.3 Current Solutions

As there was recognition of the prevalence of stress amongst this patient group, the current solutions offered to patients as stress relievers were looked at and counselling by the doctors themselves was the most common answer.

> "If woman comes to me, if I counsel them, things will be little better - I can give a scientific background and I can counsel them, give the positive thoughts to her, and ask her to remove the negative thoughts from her, be positive. That itself made my patients conceive, actually most of the time without treatment […] So directly the primary doctor who should be responsible."-IF3

Though counselling is the most common response, there is discrepancy in who should offer it and how. Doctors prefer themselves to be the first point of counselling for their patients but also do not have the time to offer help and support. Other resource constraints mean that there is minimal support from qualified psychologists. Clinicians are always going to be busy and if counselling is the solution they wish to offer their patients, new resources (psychologists) would need to be added into the team.

> "Partially we are doing here, because we don't have a support, the support of psychologists."-OB4

> "Actually, we should have a psychologist […], for counselling. Each infertility unit should have. We thought of getting one, but it is very difficult for us to get them daily, because we have daily OPs."-OB4

> "Group therapy - group counselling. Other complementary therapies which are, which don't involve too much of posture changes- […] equally there is another way to look at it. If you do with friends, with colleagues, with a group, as a class, then you have the feeling you're not alone."-IF2

Apart from counselling, other alternative solutions suggested were listening to music, hypnobirthing, acupuncture, physical activity like walking and taking up hobbies. OB3 mentions that interventions combined with lifestyle patterns may work better.

> "If they have some interests, they can explore those […] Some people like dance or something, some people like sitting and stitching, or but those, yes, they are good stress-relievers, but it's not clubbed with an activity for lifestyle pattern."-OB3

New and uncommon therapies are not easily adopted amongst this patient group. There is a need for patient education on stress relieving solutions, its safety, benefits and credibility.

> "I believe acupuncture. Yeah. I had done myself during pregnancy and but the same thing - here it's not so popular […] because the new thing, people are not willing to go for it - they are scared."- Y1

A minority of clinicians (IF3 and OB1) emphasised the importance of patient education. Educating the patient group about the nuances of their treatment, what to expect and how to cope can be beneficial. Post conception, childbirth education helps couples navigate the nine months.

> "Infertility is education is main […] I think they should have a simultaneous clinician who can talk - clinician come counsellor - so it is more of teaching than the medical aspect."-IF3

However, there is a misinterpretation of information by OB1. When patients ask about exercise, OB1 refers to childbirth classes. Childbirth classes teach breathing exercises but nothing else. Increased acceptance of childbirth education classes does not necessarily mean higher levels of physical activity or exercise among the pregnant women. This also highlights that for accurate signposting, the clinicians need to be made aware of the details of the sessions conducted for the patients.

> "we encourage them to attend these childbirth classes, where so much of knowledge is being given about all these exercises […] to attend those classes where practically things will be told to you. Like yoga and other things. Yeah, we don't use the word yoga, we just tell them childbirth classes, and there I think yes, definitely the acceptance is there - it has increased."-OB1

Yoga instructors have a very holistic view, suggesting solutions that have an emotional benefit and a physical benefit. There is importance given to how a woman perceives herself and her inner strength. This correlates to qualitative literature in Chapter 5 where women experienced a greater sense of confidence and strength after a few sessions of prenatal Yoga.

> "I advise them to start at least walking […] So start going out, start moving around, do some form of exercise, because the moment they realise they are capable of exercise and do something, they start believing in themselves. Again, having some more confidence about their

bodies, and for some of them, some kind of meditation may help. Yeah, and talk to people."-Y1

10.6.4 Awareness and Advocacy of Wellbeing Practices

10.6.4.1 Wellness/Wellbeing

The interviewees tend to use the term wellness in the place of wellbeing and there is a basic understanding of the meaning of wellness and the various aspects that contribute to it. Yoga instructors are of the opinion that tackling wellbeing of the patients can influence their resilience to stress. However, the clinicians rarely spend time enquiring about it while talking to their patients.

> "Physical, emotional, mental, spiritual. Everything put together is wellness […] Again I have to be honest; we have not spent that much time enquiring about the wellness."-IF1

> "Oh, I would say that is the most important thing once you get pregnant because if you're physically and mentally well, I would say well, you can handle any stress. That helps you to take out the anxiety, manage your stress, also the fear in your mind. You're able to handle people well, you're able to understand the situation well, so it's very important you stay physically and mentally healthy during your pregnancy"-Y2

Though there is an understanding of the concept of wellness, when it comes to advocating activity advice to their patients, most clinicians see this as important only for people with high BMI.

10.6.4.2 Emphasis on body weight and BMI for Activity advice

Polycystic Ovarian Disorder (PCOD) and high Body Mass Index (BMI) are particularly common in this patient population. High BMI has been attributed to lack of activity, diet and sedentary lifestyle. One doctor (IF3) highlighted that PCOD was common amongst the low BMI/ normal weight population as well.

> "I didn't come across so many of hypothyroidism, diabetes, hypertension, but most of them are overweight and they have irregular cycles, anovulation and PCOD. I feel that their lack of exercise is making them to increasing their BMI, which is responsible for increasing androgens in the body, and that is making them have anovulatory cycles and infertility."-IF3

> "Almost all of them. Good 70-80% of them have got a BMI which is above average."-OB2

There is a pattern that's linking BMI and activity suggestions by doctors. Activity advice is being linked to higher BMI. Though we can recognise that this patient population is being reported to have higher numbers of overweight or obese patients, as per the American College of Obstetricians and

Gynaecologists (ACOG) and the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines that are followed worldwide including India, regular activity 3-5 times a week or 150 minutes of moderate activity, is advised to all pregnant women for physical and mental health. Though not conclusive, there is a small possibility that women with normal BMI are being left out of activity advice in this case. One doctor (IF2) mentions that the patients do not take heed of their advice and they let it go if there is no harm.

> "we look at the - I mean if the BMI is normal, usually we don't stress much because everybody is busy nowadays."-OB4

> "It does release endorphins, gives a feeling of wellbeing. I encourage all these women, because most of these women who are having problems with conception are overweight". -OB2

> "Despite our reassurances, they tend not to listen. So as long as there's no harm we also let it go."-IF2

A possibility is that women with low BMI do not get the required activity advice and in turn the benefits from physical activity.

10.6.4.3 Working Women

Long working days have led women towards neglecting their wellbeing. Doctors highlight that this has also played a role in low activity/exercise levels in this population. There can be an argument made that if they are motivated, they will find 30 minutes a day for some form of activity.

> "Even if the patients are thin also, they are sitting long hours in the office by 4, this is something in working women - they don't have any choice, they have to work for 12 hours, 8-8, 9-9. When they come home, they are tired, they take dinner and go to bed - so there is no time for them to spend in active. That's what I feel, they are forced to do this work, they have no other choice to exercise"-IF3

> "So already if they're stressed that they don't have time, it is very difficult for them to take time for it, but most of the time, what I see is, the moment I say take your time for this - they say where? It's difficult."-OB3

10.6.5 Theme 2 Conclusion

An analysis of views expressed about stress in pregnancy shows that doctors recognised the issue

of stress but not its effects on obstetric outcomes and physical health. In terms of solutions, doctors think first of counselling their patients themselves with possible referral to psychologists who are in short supply. A small number of doctors recognised other options of stress relief but did little to communicate this to their patients. Yoga instructors see the importance of physical activity to combat stress. The next section discusses views on Yoga in more depth.

10.7 THEME 3: YOGA

Interviewees were all asked about Yoga to understand the context for the trial and some differing views emerged. Perhaps the most important finding, in the context of the trial, is that the results of this small sample we interviewed would suggest that maybe that the general public may not be well informed.

The five sub themes in this section are Experience of Yoga, Benefits of Yoga, Doctors Advocacy of Yoga, Safety of Yoga and Alternative Solutions.

10.7.1 Experience of Yoga

Out of the three participants, two (FH04 and FH09) had never practised Yoga prior to this study. One participant (FH05) had prior experience of Yoga practice but wasn't sure about pregnancy Yoga. Only one clinician (OB2) had extensive experience of Yoga practice. Irrespective of prior experience of Yoga, assurance and guidance is required during the prenatal period on how to go about safe Yoga practice.

> "Actually, I generally do it at home. During pregnancy, I was thinking whether I should do or not. After meeting you, I started again […] I knew it will definitely help. Like when we do pranayama and all, stress levels automatically go down. So, I was having doubt that can we do [Yoga] at this time or not. So now I feel like we should do it"-FH05

Participants had been exposed to prenatal Yoga on television, but as they weren't given any guidance or information about it from their care providers, there was a disconnect in whether they could attempt it. The husband of one of the participants had experience with Yoga but, like FH05, wasn't aware of pregnancy Yoga. As the influence of family on this patient population has been reported as being very high, this reiterates the need for education and awareness building amongst the general population.

> "See I was knowing about Yoga, I have been into Yoga classes also, because I am having a breathing problem. So, I used to do pranayama, but I was not having the idea that Yoga can help with a pregnant woman in such a way"-H1

Regular Yoga practice amongst this patient population is limited. The few who have reported to be attending Yoga sessions have found it beneficial.

> "Very few, very few and motivated persons. Very educated people and I can count on my numbers actually."-IF2

> "a few of the women […] who I have actually encountered, they find it very very helpful. They definitely find it very helpful, but the percentage of women actually doing it is less. Very, very less. So somewhere we need to introduce."-OB1

10.7.2 Benefits of Yoga

When the medical interviewees were asked about the benefits of Yoga, the majority did not have a comment. Two of eight doctors highlighted the physical benefits of Yoga in relation to aches and pains, weight management and oxygenation. Lack of comments by six of the doctors emphasise the need for doctors to be educated about the practice and its benefits. Unless the doctors are aware, they will not be able to effectively communicate with their patients on this topic.

> "Yoga should be advised because it keeps them active, blood circulation will increase, and then there is enough oxygenation […] I think the body pains and all these things will be better with yoga. And weight reduction, weight will not increase, they can maintain their weight."-IF3

The Yoga instructors detailed the benefits of Yoga for this population in terms of physical benefits along with emotional benefits. They referred to lesser aches and pains as mentioned above by IF3, easier labour and birth, improved self-confidence, positive birth affirmations, lower stress levels and higher mental wellbeing.

> "So, it depends. If you attend a class that only focuses on asanas or exercise, then mostly they get the physical benefit, but even then, because of their hormones and all, they get the benefit. But I try to incorporate pranayama [breathing] […] it really helps them to relax and get rid of anxiety. -Y1

> "first things is about back pain and pelvic pain […] lot of relief physically."-Y1

> "lot of breathing exercises helps the woman to calm down and handle the stress."-Y2

Another aspect highlighted by a Yoga instructor was the impact of the Yoga sessions on self-esteem. Self-esteem and confidence are a recurring concept in literature and here, when addressing benefits of Yoga.

> "we had one in this group who had some issue with her leg, and the moment they start doing yoga, they understand that oh wow, I can do this."-Y1

The husband believed that the Yoga classes, which were a part of the feasibility study, helped his wife with labour and birth.

> "because of these yoga classes and all things, it was very easy for my wife to get through the labour time. Almost within 3 hours, we could be able to give birth a birth to a baby."-H1

10.7.3 Doctors Advocacy for Yoga

When the clinicians were asked about advocacy of Yoga, they are happy to encourage if the patient proactively asks for permission to start Yoga practice. However, they are not comfortable addressing the topic if it wasn't asked. Two of the eight doctors are keen on proactively suggesting Yoga as they believe it can impact the mothers experience of pregnancy and birth.

> "I feel that is going to be good because at least encouraging everyone to be flexible and active. So that will definitely help for throughout pregnancy and also later."-OB3

> "A must for every pregnant woman […] Yoga compels women into a discipline and that itself reduces stress […] I have no scientific explanation. I only know Yoga benefits people who practice it."-OB5

Although the hospital has regular prenatal Yoga sessions, there is an evident lack of knowledge within the staff on the facilities offered by the hospital. This has previously occurred in Theme 2 as well with respect to childbirth classes.

> "If women want to, they can, we don't actually offer it per se."-IF1

In line with global trends, during the interview, doctors identified Yoga to be increasingly popular in the higher classes of society i.e. higher incomes, better education. However, another doctor (OB4) points out that education on its own does not determine interest towards Yoga. Fear towards

research or anything unknown is present in all patients irrespective of their education level.

> "Again, it depends on see, yoga and things like that is in a little higher, what do you call, socio-economic status. Those kinds of women will actually go for it."-OB1

> "Most of the patients are educated. They should understand, but educated patients, I don't know - they may get scared, what are they going to do, are they going to do extra tests or anything"-OB4

10.7.4 Safety of Yoga

None of the interviewees were of the opinion that the practice of Yoga is unsafe. Concerns were raised by doctors and Yoga instructors about the need for this patient population to be educated about the boundaries of prenatal Yoga, and for classes to be led by a certified Yoga instructor with specialist knowledge or certification in Pregnancy Yoga. One clinician who had extensive practice of Yoga (OB2) was of the opinion that if someone has attempted Yoga prior to pregnancy, there is no harm in continuing, but they also felt that it's not something to be started during pregnancy.

> "There is lot of evidence for yoga. I agree there is some controversy about its safety, but maybe women need more reassurance, and we should supplement them with that safety data."-IF2

> "Interesting, great, it should be done [...] if they've already been practising, but I wouldn't say that it's something… they can learn during the pregnancy."-OB2

> "I would say it is very safe to do yoga during pregnancy as long as you understand what and how much to do. So, if you make it very clear as to what extent you can do, what are the right postures you should be doing during pregnancy"- Y2

10.7.5 Alternative Solutions

When women taking part in the trial were asked about alternative solutions to stress in pregnancy, two of three participants were not currently practising anything as a stress reliever. One participant practiced meditation. Two participants were not sure of options they could take up. Neither of these had been offered any options and counselling did not come up as an option offered to them their doctors.

> "Actually, I used to do meditation, so that helped me a lot to relieve stress"-FH05

10.7.6 Theme 3 Conclusion

This theme highlighted that whilst some doctors thought Yoga was likely to be of benefit to pregnant

women most did not actively promote the practice. A clinician's personal experience of Yoga influenced the extent to which they were likely to advocate it to patients. All interviewees thought Yoga was safe in pregnancy but with the proviso that it is practiced with a qualified prenatal Yoga instructor. Yoga is considered a higher socio-economic class practice. All around education of doctors and patients will be necessary if Yoga is to be recognised as an option to improve mental wellbeing of women in the population.

10.8 THEME 4: THE TRIAL

Lastly, the interviewees were asked about participating in clinical trials. The biggest revelation was the widespread view among professionals that research was regarded with suspicion by patients and that signing consent forms raised anxiety.

The four sub-themes that emerged here were reasons for the results of the trial, research design ideas and improvements, comments on the study and future options.

10.8.1 Reasons behind the results of the trial

10.8.1.1 Fear of research

There appears to be much fear of the word "research" amongst this patient group in India. The fear stems in part from not being previously exposed to medical research as a safe practice. The fear relates to the possibility of extra tests related to research and being experimented on. Filling and signing consent forms seems also to instil fear in the couple.

> "Yes, yes. Research is very focused in some centres, not routinely done so they think out of the box. They are doing something, and I don't want to risk my baby. These kinds of attitudes."-IF2

> "Yeah, so probably the people here are still not used to that, yes. So, I think that's a big hindrance."-IF1

If the couple is in agreement and ready to participate, participation may be vetoed by the family. The deep influence of society and family has been addressed in Theme 1. In terms of research, there is fear that family matters would be exposed to the researcher. This reason was also quoted by a dropout from the feasibility trial.

> "Because in India, I think in India that is, we are a society we are conservative […] they are dependent on family members for everything. A study means they get worried - their identity will be known, husband will also not consent, mother will also not consent. So, they have a taboo like thing, study means something they are exposed to, I think."-IF3

> "Even if the lady is willing, the mother-in-law will not be willing or something like that. They all feel it's some experiment being carried out, so just say no, they don't even want to listen to what you want to explain."-IF1

10.8.1.2 Fear of Exercise/Movement/Activity

Although doctors advocate physical activity, the patients and/or their families have a strong belief that exercise is harmful to the baby. The wide range of benefits of activity, for both mother and baby are not well known or accepted, the concept of rest during pregnancy is highly prevalent as pregnant women are considered delicate, frail and possibly weak. This consistent fear of movement/activity/exercise deeply impacted this research study.

> "Yeah, I think fear, fear. And that too, not based on good reasoning. It's just that they have this myth they shouldn't move too much; they shouldn't do this and that."-IF2

> "A lack of awareness, again. I think they have lot of fears. For example, we all say breathing helps; but they have a myth that fast breathing might hinder blood supply to the pregnancy. So, we need to dispel their myths, get them out first and dispel them in a scientific way."-IF2

> "Many of the people here actually think they have to be on bed-rest. It's a very common question. Especially after conceiving, with treatment, they think they must just be confined to the bed. They are afraid of antenatal exercises."-IF1

One of the Yoga instructors recollects that a family member accompanied a participant to the intervention sessions to check what was happening during the sessions. A lack of trust is widespread.

> "even in this batch, I had a mother, the lady came, she was quite regular, but the mother used to come and sit there […] They don't think they can just leave that person to just go to the class and enjoy. So that trust factor is missing."-Y1

From the data presented above, it is clear that fear of research is likely to act as a barrier to recruitment to the trial and fear of physical activity acts as an additional barrier to recruitment to a trial of Yoga. This section also highlights the lack of autonomy experienced by this population. Women need to do what their families say.

10.8.1.3 Practical Problems Faced by Participants

Travelling to the facility for Yoga sessions was quoted as an inconvenience by the participants and as a possible demotivating factor in terms of recruitment and dropouts. Travelling within large Indian cities is an issue due to heavy traffic. Weekends are preferred for any sessions as pregnant women are often not allowed to travel alone and require husbands to accompany them to the hospital.

> "Weekends. Because most of the time I hear them, no I don't have my husband, husband is busy… they are totally dependent, they don't want to come out of the house alone - they wouldn't do that. Family doesn't allow them."-OB1

The dependence on family members for travel is highlighted by the quote below from the husband of a participant who was brought to the sessions by her husband.

> "Travel was only the big problem because otherwise I was okay […] And after that, why we stopped in the middle - because going on bike from here to there was absolutely for 3 or 4 times it was okay, but after that- "H1

10.8.1.4 Motivation

When asked about their motivation to take part in the study, all participants had two things in common; they were all internally motivated to attend the session and had support from the family.

> "I didn't ask anyone. Just I directly came to the class. Motivation was there […] And every time my husband motivates me continuously."-FH09

> "Actually, I was waiting for something like this […] can I do it or not? I needed some guidance. So, I got that from you. Then I planned to take it."-FH05

> "My family was very happy that something I am doing at least [...] being active […] so they gave support by taking me to the classes and bringing me back [...] they took care of me"-FH05

In terms of participants who did not consent or attend the sessions, the Yoga instructor and a minority of the doctors recognise a pattern of "convenience over effort" in this group. Unfortunately, there is a cultural acceptance of lack of activity, which is worrying.

> "So, it's never perceived as because I'm not active, because I'm not exercising, because I'm overweight, I have these problems - it's not perceived. In the families also and acceptance rates for diabetes and weights are very, very easy in the family. So, it is fine to have diabetes, it is fine to have overweight. So, I think that culture also needs to change"—OB3

10.8.1.5 No-shows and Missed Appointments

A major issue faced during recruitment for the trial was no shows and delays. When the doctors were asked about this attitude, they reported a general lack of respect for time and appointments. It is apparently common for patients to miss appointments.

> "They don't respect the time and they don't understand they are blocking the slot for other patients. They don't make an effort to cancel […] But yes, in general the default rate is quite high here."-IF2

The hospital consistently struggles with getting patients to attend the free childbirth education classes that run in the facility.

> "We are literally pushing them; I don't know here, maybe it's only about 10 or 20%, it's very low…so they give their appointments, they go to the reception, they give their names, and they say okay, we'll come, but they don't turn up."-OB1

This shows a pattern of patient behaviour as no-shows and missed appointments. Lack of attendance after consent was a problem faced during the feasibility study.

10.8.1.6 Change in Care Providers

In India, there is a cultural norm of women moving to their maternal homes by the 7th month of pregnancy. Aside from that, the infertility population change doctors after the viability scan. Some remain with the same hospital until the birth of the baby but not all. As many patients come for specialist consultations and treatments from surrounding areas, the doctors do their best to reduce the number of visits required. These factors drastically reduce the total sample available to recruit from for a study that spans throughout the pregnancy.

Secondly, multiple care providers mean a possibility of various types of advice depending on the protocols followed by them or their personal opinions. This adds to the existing confusion from peer and family advice.

> "We are basically only dealing with them until after the point of conception. Once they conceive, we actually transfer them to our obstetric colleagues."-IF1

> "They come from surrounding areas, surrounding villages, and we do help them, we ask them to get scans done there and send, text us the report, and we advise them accordingly. We try to cut short the visits here, for them, to help them."-OB4

10.8.2 Research Design Suggestions

As the feasibility trial faced multiple challenges, all interviewees were asked for suggestions to improve the research design for future trials. Their suggestions have been presented below.

10.8.2.1 Involvement of Doctors and Family

Involvement of doctors and of family members is going to be critical for future success. This study design did involve doctors in the recruitment process but except for the head of the infertility department, no patient referrals were received from the individual doctors.

> "If doctor tells, it will be good. Also, if husband and wife are ok with it, then it should be fine."-FH05

A key pattern throughout this study has been the importance of family and their influence on the pregnant woman. Involving the family in the research study has been suggested as important to the success of any study.

> "See first of all we should talk to their husbands, we should convince their husbands, because once if husband is convinced, then he will convince his parents."-H1

> "I think the researcher have to take two three people together and work towards this. First is the doctor, the patient and somewhere if you can include the family as well."-Y2

10.8.2.2 Education and Awareness Building

Lack of awareness and need for education in areas of long-term effects of stress on outcomes, benefits of yoga, advocacy of wellbeing etc, have been a common thread throughout this chapter. Options for patient education are posters, videos, classes and free sessions. Doctors are keen on helping patients make an informed choice through advocacy.

> "I think spreading the benefits of yoga. Initially, make it free so money wouldn't be a hindrance. And then gradually we can build the numbers."-IF2

> "We should put posters, we should give more health education, it takes a long way. But persistence might pay off […] We need to make pros and cons data and put it in a public place, especially in our clinics where they can read it while waiting in the waiting hall and then make an informed choice."-IF2

> "Awareness, awareness. So, we need to constantly tell them, and I think we as obstetricians, we are the people who have to tell. Because they listen to us"-OB1

Increasing awareness about Yoga through word of mouth and patient suggestions, building community through free classes and involving social media channels have been suggested to increase acceptance.

> "But the moment they start coming, then they will speak to others in the other groups, of their own pregnancy groups will be there. Then, people will come. "-OB3

> "if that also [details about the study] coming in the social media, Facebook thing, they are more ready to accept. And if they see people are actually going in for their, and they are recruiting themselves, that maybe encourage others to also go"-OB3

Although various ideas have been given on how patient awareness can be increased, the doctors did not address their lack of knowledge on the topic and ways to be up to date with latest research.

10.8.2.3 Incentives and Time

Free Yoga classes, other incentives, making Yoga and psychological help part of regular care were suggested to improve rates of recruitment in future studies. Time factor in reading forms and signing consent were suggested as possible issues. The process of signing up for research studies needs to be simple and quick.

> "Part of care and we should make all psychologist and yoga trainers available. That is something I feel yeah. That helps us, that helps the doctors have a good success, I feel."-OB4

> "Experts with the counselling skills […] Incentives. A freebie of some sort like two free Yoga sessions"-OB5

10.8.2.4 Intervention Ideas

The intervention was positively received by the participants. Bi-weekly classes or more, in a larger group with an instructor, longer meditation and positive affirmations were suggested. Low numbers of participants were linked to lower motivation during the class.

> "It was ok. If only it was a little closer, I mean not once in a week but maybe twice in a week, it would be much more better." -FH05

> "You can include a longer duration of meditation. At the end of the class, they were giving some instructions and making us to feel the baby and all. So that part can be a little bit more extended"-FH05

Conducting classes and collecting information without any consent forms or paperwork was suggested by a doctor. However, that would be unethical medical research practice.

> "if it's a free class, they would have walked and maybe you could have given a questionnaire after the class. If you had a choice to do it again, just advertise as a free class, safe yoga for pregnant women. Do it, and then give a questionnaire post class […] official study, everything they'll back off."-IF2

10.8.2.5 Home Visits

There are mixed reviews on home visits/ sessions at home. Seven of the interviewees are of the opinion that sessions at home will increase participation in the studies as it tackles challenges like travel issues and family being able to witness what is happening. As per IF2, the participants will have a sense of safety in their own home. However, the participants in the study had the opposite view as they prefer the session in the hospital with the instructor present.

OB3, Y2 and OB2 raise a valid point of ensuring direct supervision even if it's a home session. Yoga is safe but requires instruction especially during pregnancy as there are limitations and guidelines on what can be practiced.

> "So, if you offer, we will come to your home and teach. Maybe the acceptance could improve, in their own environment. Maybe they feel safer"-IF2

> "I think that especially some religions, they, are very conservative. So, if you advise them to do at home, they will do. The acceptance is more if it is at home."-IF3

> "few will need a little training. So probably 2,3 classes here, then they can do yoga at home."-OB4

> "I don't think you can do it over Skype […] I'm not sure at this point of time I would be comfortable with a pregnant woman in her house, and you here, she is on her own and you tell her to do something - she does something else and then she has a fall, or she has something"-OB2

10.8.2.6 Type of Research

When asked if women would be more or less likely to come to a class which was not part of a controlled trial, OB5 believed it does not make a difference. However, IF1 raised concerns whether the patients actually understand the process of randomisation. If the patients believe they will be withheld from any service or care, it can lead to low acceptance rates. Two participants preferred not being part of a randomised trial. However, the husband believed that his wife was given special care because she was part of a trial and that was important to him.

> "Both are good but when we come to trial, we will have great, how you say, support will be there, we will have extra care will be there because you are doing a trial and you want the proper results […] So, I thought this will be the best one other than going to the regular"—H1

> "Yes. When forms not there and freedom is there, less scary"-FH04

10.8.2.7 Screening to identify mental wellbeing issues

Out of eight doctors, one emphasised on the importance of screening for mental health issues. The doctor recognised that though it is necessary to give equal importance to emotional health, it is not being practiced currently due to lack of time during consultations. Success rates of pregnancy are given priority and other considerations are ignored.

> "I think first of all we have to screen for the mental health, which we're not doing at all. Among all the pregnant women […] we're not actually looking at the mental health […] Once we identify the problem, then probably we'll know how to deal with it."-IF1

> "Yeah. We are hard-pressed for time - I shouldn't put that as an excuse, but most of the time we are looking at that aspect only"-IF1

10.8.3 Comments on the study

The participants in the feasibility trial and the family interviewed had positive comments on the study as a whole. Yoga was believed to have helped them with their pregnancy, labour and birth both physically and emotionally. The participants felt supported and cared for during the class by their instructor and myths about Yoga and exercise were cleared.

> "today, I am talking after seeing the miracles of yoga […] at this juncture I know what effective yoga is and how effectively it has helped my wife. I have seen the situation so I would absolutely support yoga in pregnancy women, especially the women who have conceived through IVF or IUI."-H1

> "It was nice and comfortable as well. And the exercises were really helpful for me…what I felt was completely good. The trainer was very interactive, and she was asking every time "how are you feeling, did you eat anything", she would tell us what to expect and very clearly talking so it was comfortable for me"-FH05

The doctors and Yoga instructors commented on the importance of identifying the challenges that were faced during this study. The focus on culture and society is high. Increasing patient awareness and education have been mentioned to be the first course of action for improved recruitment in future studies.

> "I just think it's sad that people didn't come though it was free and all. But whoever came, I think they got some benefit and one of them, she, it was a challenge for her to come. (name of participant omitted) But I know the other one, she came very regularly and even the day she got admitted she actually, it was the class, and she didn't feel well, so she decided to go and get admitted. She was really enjoying coming here and her mother was really happy to be with her."-Y1

> "I feel extraordinarily sad that you weren't able to complete this study, it would've given us a good data and I mean certainly there would've been a lot of positives that would've come out of it […] Perhaps, whoever is planning to do it in the future really should endeavour to tackle the challenges you faced."-OB2

10.8.4 Future Options

In terms of future options for research in this subject doctors emphasised the importance of RCT's. There is an understanding of the barriers to conducting an RCT, but these are still the only form of research these doctors felt could prove the benefits of Yoga in this patient population.

> "See, obviously, RCTs comparing yoga with other exercises might show you benefit of yoga over that, that's one. And yoga versus no yoga. That data is very valid and more acceptable, but directly to do an RCT might be very difficult. So, feasibility first, what are the factors that are hindering these women from participating in these research studies. We need to explore that and try to cut those barriers. Then you will have more numbers to do RCTs."-IF2

10.9 Discussion

These interviews showed how infertility is a source of stress in Indian society, how this leads to a demand for infertility treatments, and the perception from family towards the need for extra care in

pregnancy which was translated as a need for the pregnant woman to do nothing. The patients and husband believed that stress was a problem in pregnancy but not specifically why.

Although not universal, the belief that pregnancy was more stressful for these couples was widespread among doctors. Very few doctors knew that stress was a cause of problems in pregnancy or understood the outcomes influenced.

Doctors felt the first line for stress if it was present in pregnancy, was counselling from themselves. Doctors were more concerned about obesity and physical inactivity than they were about mental health, and some felt Yoga was a good idea to improve physical activity.

Doctors were not familiar with the literature about the benefits of Yoga in pregnancy. A minority of doctors were in favour of suggesting Yoga for this population especially those who had personal experience. Some doctors felt it was safe for pregnant women of this population to do Yoga if they have previous experience of Yoga practice. All thought the practice was safe with a qualified instructor and if asked by their patients would encourage use.

Two issues were identified in these interviews that were a major problem for recruitment to this trial and raise the question as to whether it was a good idea to run the trial in India. The first was a general fear of research and the second was a widespread public belief that physical activity was dangerous in pregnancy. Against this is the findings from the systematic review that it has been possible to run trials of Yoga in pregnancy successfully in other parts of the country.

Dissemination of information about the benefits of Yoga in pregnancy to doctors and greater clinical involvement in recruitment might have improved uptake rates. Consideration of some class-based sessions with home practice might have got over some of the practical issues, but the principal issues would have remained.

There were two main limitations while conducting interviews- no shows and lack of time from doctors. The project would have greatly benefitted from more involvement of family members. It would have made the data richer and potentially more variant. However, no amount of reassurance from my side convinced more family members to participate. Some who initially consented, dropped out when contacted for a convenient date.

Doctors are busy and find it very hard to take out time to talk to researchers. The interviews with doctors varied between 10 minutes to 20 minutes depending on the time of the day, how busy their schedule was and if they had a patient in labour. Longer interviews would have given more space to talk in detail and cross question each other. Unfortunately, this is going to be a common issue with healthcare professionals everywhere.

10.10 CONCLUSION

At present a trial of this design is not feasible in India and for any future trials, a change in attitude amongst the general population about exercise and Yoga in pregnancy is required. Whilst there is arguably enough information to promote Yoga in pregnancy, the results of this study make it questionable whether conducting a further trial in this topic within this patient population in India, in the current situation, is warranted.

Prior to a future trial, there is groundwork to be done by means of educating both the medical professionals and the families that they care for about the impact of stress in pregnancy and the value of Yoga as an intervention. There is also groundwork to be done to reassure pregnant women and their families that research is now safe and can bring benefits. Once the groundwork is done, awareness is raised and there are doctors willing to take an active part in the trial, a redesigned trial can be proposed.

In the next chapter, the methods and results of the focus group of obstetricians conducted in the UK is presented.

11 VIEWS OF THE UK OBSTETRICIANS ON YOGA IN PREGNANCY AND RESEARCH EVIDENCE

11.1 INTRODUCTION

The feasibility study in India demonstrated that an RCT of Yoga in Pregnancy post infertility treatment is unlikely to succeed at present unless existing cultural barriers are addressed, and the study is redesigned. A question that arose was whether it would be feasible to run a similar trial in the UK. The decision was taken to explore this possibility via a focus group with UK obstetricians at University Hospital Coventry and Warwickshire (UHCW). This part of the thesis also provided an opportunity to make a cross-cultural comparison of doctors' views on the topic of Yoga in pregnancy.

11.2 METHODS

11.2.1 Ethical Approval

Ethical approval was sought from BSREC at Warwick Medical School for this additional component of the study. Approval number REGO-2018-2338. The BSREC approval is attached in the Appendix 15.21.

11.2.1.1 Ethical Considerations

a) Informed consent

Participation Information Leaflets (PIL) (Attached in Appendix 15.22) were provided via email and participants were given a further copy on arrival at the focus group venue. The consent forms (Attached in Appendix 15.23) were signed by all participants after an additional verbal explanation of the study. The focus group took place in a closed room at the Clinical Sciences Research Laboratory building in University Hospital Coventry and Warwickshire.

b) Privacy and confidentiality

The data security measures for this study are as follows:

1. Participant information: Every participant had an assigned code. The focus group transcripts and audio files were identified by the code and not their name. The master sheet with the participant name and email address matched with the code was a password protected document only accessible to me. The master sheet will be deleted after the corrections are completed.

2. Qualitative data: Audio files of the focus group recordings and transcripts are uploaded online to the University of Warwick server into a password-protected folder that cannot be accessed by anyone other than me. All files are anonymised as per the participant ID's given. The audio file will be deleted after the PhD has been awarded; the transcripts will be stored in the Warwick server for 10 years.
3. Data storage and security: All demographic questionnaire data post digitalisation have been stored in the University of Warwick server. The anonymised data will remain in the Warwick server for 10 years.

c) Right to withdrawal

The PIL informs the participant that they can withdraw from the study at any point without fear of discrimination.

11.2.2 Recruitment

Convenience sampling was the method used for recruitment into this focus group discussion. An email was sent by the Head of the Department with the PIL attached to all doctors (consultants and trainees working in the department) requesting their participation in the focus group discussion. This was to be run as an accredited Continuing Professional Development meeting. Eight doctors agreed to take part.

11.2.3 Data Collection

A focus group in a semi-structured format with a defined topic guide was the chosen tool for data collection (Attached in Appendix 15.24). A debrief was conducted at the end to summarise the discussion and clear any questions regarding what happens next from the participants. The discussion was moderated by an experienced clinician, the head of the department, who is also the second supervisor of this thesis. During the discussion, I made observational notes and recorded the discussion on audio.

To investigate whether the focus group discussion itself changed opinions, participants were asked to complete a questionnaire before the presentation and at the end of the focus group.

A presentation was made, covering existing evidence, both quantitative, i.e., the systematic review (Chapter 8), and qualitative literature on Yoga and pregnancy. The results of the feasibility study conducted in India was then given as a foundation for the discussion. A semi-structured approach led the participants to take charge of the discussion with the moderator intervening only to keep the conversation on track. The flow of the session is shown in Figure 9.

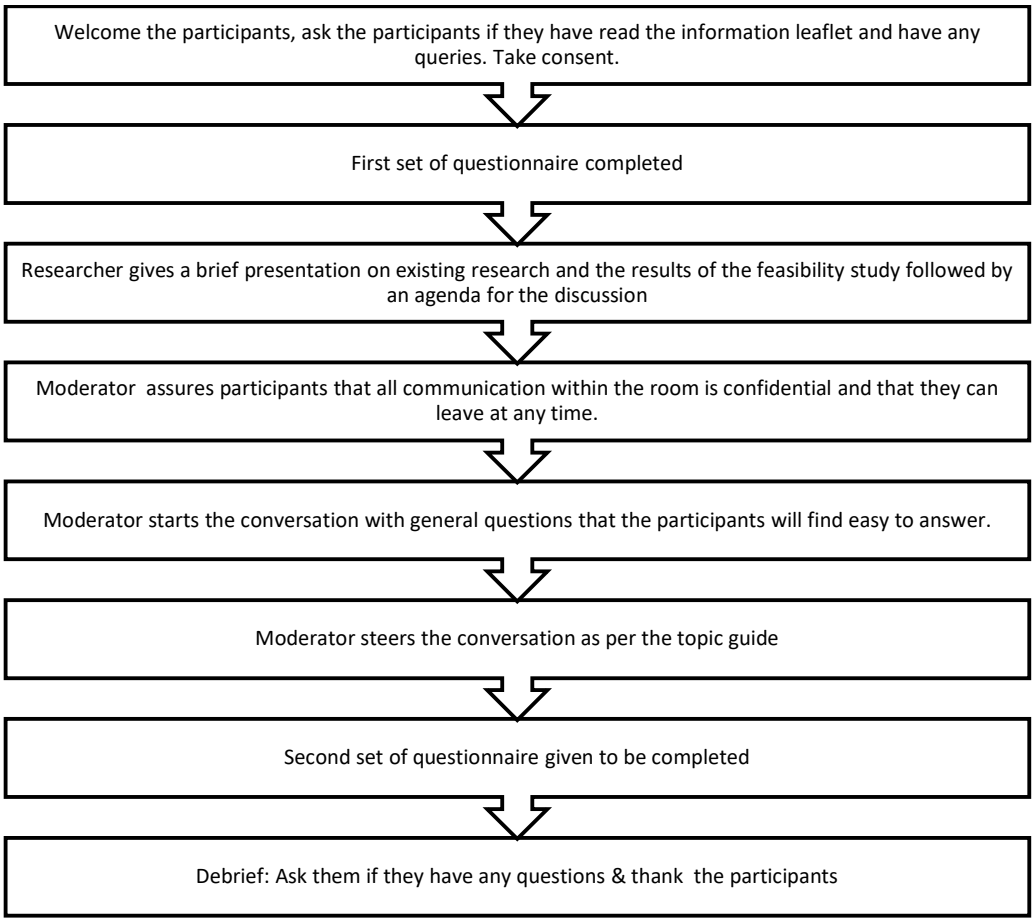


Figure 9: Focus Group Flow

11.2.3.1 Pre and Post Focus Group Questionnaire

Prior to the start of the presentation and the focus group discussion, a questionnaire was completed by participants addressing two scenarios. It was repeated at the end to identify possible changes in opinions after discussion.

Scenario 1

"You have a patient who is 8 weeks pregnant with a viable pregnancy. It was a natural conception with no previous clinical issues or treatments that could have affected the pregnancy."

Scenario 2

"You have a patient who is 8 weeks pregnant with a viable pregnancy. She has conceived post infertility treatments and is very worried and stressed. She has been asked to relax but is looking for ways to do so."

Both scenarios were followed by three questions:

1. She says she wants to continue her Yoga classes. Would you say- YES/NO
2. She says she heard about Yoga and wants to start. Would you say- YES/NO
3. She doesn't mention Yoga. Will you proactively suggest Yoga for mental and physical health?- YES/NO

11.2.4 Data Analysis and Transcription

Thematic analysis was used to analyse the data collected through the focus group discussion. The audio recording was transcribed verbatim and checked by listening to the audio and matching to the written transcript. Other potential mistakes were checked by listening to the tape multiple times while coding the data. The transcript was uploaded into NVivo for coding the data. The codes were combined into categories from which the themes arose.

11.3 RIGOR AND TRUSTWORTHINESS

The focus group method achieves trustworthiness through the strategies described in the table below. This table also identifies the steps taken to address these strategies in my PhD research.

Table 18: Rigor and Trustworthiness in the Focus Group Session

Criteria	Purpose	Strategies	Steps taken in this thesis
Credibility	Does the study measure or test what it is intended to measure?	1. Adopt well established research methods like interviews and focus groups 2. Develop familiarity with participating organisations 3. Triangulation of data 4. Encourage honesty among the participants 5. Iterative questioning 6. Peer or Supervisor debriefing 7. Examination of previous research findings	1. Focus group was chosen as the method of data collection. 2. Triangulation of data was achieved in the thesis through multiple methods of data collection. 3. The moderator of the focus group was familiar with the participants. 4. The moderator probed the participants when required to gather opinions and perspectives. 5. Peer and supervisor debriefing were conducted throughout this process.
Transferability	The extent to which the findings of one study can be applied to other situations. Lincoln and Guba present an argument that it is the	1. Number of organisations taking part in the study and where they are based	1. All the related data have been described in this chapter under Methods.

	responsibility of the investigator to ensure that sufficient contextual information about the fieldwork is provided to enable the reader to make a transfer.	2. Any restrictions in the type of people who contributed data 3. The number of participants involved 4. The data collection methods that were employed 5. The number and length of the data collection sessions 6. The time period over which the data was collected	
Dependability	If the work were repeated, in the same context, with the same methods and with the same participants, similar results would be obtained. However, the changing nature of the phenomena scrutinised by qualitative researchers renders such provisions problematic in their work. Lincoln and Guba stress the close ties between credibility and dependability, arguing that in practice, a	1. The research design and its implementations describing what was planned and executed on a strategic level 2. The operational detail of data gathering, addressing what was done in the field	1. Detailed drafts of focus group protocol were created and checked by the supervisors. 2. The entire process has been documented.

	demonstration of the former ensures the latter to some extent.		
Confirmability	Is the research objective? Here steps must be taken to help ensure as far as possible that the works findings are the result of the experiences and ideas of the informants, rather than the characteristics and preferences of the researcher.	1. Reflexivity 2. Triangulation	1. Triangulation by methods have been implemented in this thesis as a whole. 2. The focus group was moderated by my second supervisor and I observed the session. 3. The objectiveness of the research has been maintained through a process-based approach to data collection, and regular debriefings and support from the supervisors.

11.4 RESULTS

11.4.1 Coding Process

The transcript of the focus group was uploaded onto NVivo 10 software and coded. As new codes were generated, the transcript was scanned again for missed coding opportunities. To ensure that no codes were missed, the process was repeated twice.

The codes had varying levels of abstraction from "knowledge of Yoga" to exact words or phrases like "credibility as a doctor".

This process generated 25 codes. The codes were assessed to see if they could be merged. However, there was a relevant degree of difference to keep them separate. The 25 codes were clustered into 4 categories as shown in Table 19.

Table 19: Categories and Codes

Yoga	Cultural Contrasts	Advocacy by clinicians	Research
Difference in Prenatal Yoga	Community support	Advocacy to special populations	Future research interest
Experience of Yoga	Cultural assumptions	Advocacy of Yoga	Requirement for advocacy
Family influence on Yoga	Private healthcare	Credibility as a doctor	Types of research
Misunderstandings of the practice	Socio-economic strata	Exercise	
Need for more knowledge		Infertility	
Weight loss		Infertility and Yoga	
		Mental health and Yoga	
		Patient perception	
		Patients asking about Yoga	
		Risks	
		Yoga and obesity	
		Yoga as part of treatment plan	

Each category was analysed to identify possible themes. The themes that arose were compared with each other to identify possible similarities and combine them if needed. The themes were analysed for similarities and differences of views between the participants and how they fell into the larger scope of the problem being addressed by this project.

The focus group was undertaken to investigate participants' opinions and understanding of Yoga, its relevance to obstetric practice and research. Three themes emerged from this analysis: Yoga, Yoga for special groups and further research.

11.5 THEME 1: YOGA

This theme is further explained within three sub themes: experience of Yoga, obstetric practice and Yoga, and Yoga as exercise.

11.5.1 Experience of Yoga

The discussion opened with questions about personal experience of, and exposure to the practice of Yoga. Both of these were associated with more accurate knowledge and a more positive attitude to Yoga. Four of the eight participants (n=3 women, n=1 man) had previous experience with Yoga.

One participant who had some exposure to Yoga also had experience of a very specific effect. She had lost weight during a summer camp which she attributed to Yoga.

> "I have to say an interesting thing is that a few years ago I went to a summer camp for like a couple of weeks where we were made to wake up at 6 o'clock in the morning and do yoga in the morning and I did not really change what I was eating and I wasn't doing any exercise where I was sweating [….], but [….] I am absolutely convinced that it was those two weeks of yoga I came back, and all my clothes were looser […]. You know you watch videos of yoga and you think you can't lose weight doing yoga"- P6

This same participant made an observation that the practice of Yoga was more difficult than exercising as Yoga requires greater mental focus. She commented that the emotional investment required by Yoga can be a barrier towards getting people to start and continue the practice when there are easier options available where a physical presence is enough.

> "I think it is something that is really difficult to get into because it requires so much more focus than, it is actually much easier to go to the gym and get on the cross trainer, than to focus yourself on yoga"-P6

Regular exposure to Yoga practice within the family while growing up plays a role in the attitude towards the practice. When it is something that is normalised, like walking or running, the understanding of the practice will be higher and the fear lower.

> "My mum is, does a lot of yoga and from when I was little, she would always do yoga, so my personal view is completely different. She would wake up at 6 and do it and then take me and make me do it"-P9

One participant had had negative experience of the practice personally. Whether this would have influenced her attitude to recommending Yoga to patients is not clear.

> "I am not a fan of yoga, sorry, I have tried to get into it because a few of my friends like it and I just find it breathe in and breathe out and I can't really, I don't get it"-P3 a doctor who had experience of Yoga.

Availability of Yoga classes influences experience of Yoga in this community.

> "I have done yoga….I do it intermittently, like if there's a class, there is a lot less availability here than where I used to live, urm I enjoy it I am not very good"-P8

Misconceptions about Yoga practice was common across the group, even amongst participants who had some experience of Yoga in the UK. Safe practice was the common concern.

> "I think the people in India that are really into yoga […] take it to [..] quite an extreme level where, they do things and you watch and think how are people doing these positions and I can imagine why doctors will say don't do yoga because they will be worried about these women [……..] doing positions where they are actually lying flat on their tummy and they doing all these kind of … you would not want to be doing that really when you are pregnant anyway"-P6

In contrast, participants of the interview study in India (See Chapter 10) did not share these beliefs. Instead, they highlighted a lack of interest in the practice in the general population.

11.5.2 Obstetric Practice and Yoga

As the discussion progressed to Yoga in clinical practice in the UK, the group was asked about their encounters with patients who proactively ask about Yoga. Only one out of the eight had a patient who explicitly inquired about Yoga. As none of the others were exposed to patients asking about Yoga, they had no incentive to inquire or research more about the practice.

> "I have had 1 person ask me once"-P9

11.5.3 Yoga as Exercise

As exercise is recommended during pregnancy, the discussion progressed towards their opinion of Yoga as an exercise.

The majority of the participants believed that recommending exercise to pregnant women is good practice irrespective of prior experience.

> "
>
> P3 – I think it is a good idea to recommend exercise to pregnant women
>
> P2- providing they have done it already [exercise]
>
> P3 – even if they haven't
>
> P1 – low intensity
>
> P8 – they would only do what they could tolerate anyway
>
> P1 – especially if they are in a group that are at risk
>
> "

As there are established guidelines and research on benefits of exercise on pregnancy outcomes, the participants were of the view that continuing exercise during pregnancy is acceptable. However, the group were unsure about women continuing Yoga. In comparison to Yoga, there is an evident difference in how other forms of exercise like running is perceived.

> "I would recommend that (park runs) only if they were running already but not yoga…just some exercise, making you generally healthier, having better pregnancy outcomes"-P

> "I think it's highly unlikely that you are going to get somebody to start yoga in pregnancy"-P6

This hesitancy about Yoga can be attributed to misconceptions about the practice due to lack of experience or knowledge. Reluctance to talk to patients about Yoga was in part due to erroneous beliefs as to what the practice entailed. Extreme temperatures, extreme postures and high intensity sessions were some of the worries that came up.

> "if you go to a proper yoga class and not to just these classes where they sit you cross legged for half an hour just breathing, if you go to a proper yoga class, they are really hard, like I have been to a hot yoga class before like they sit you in a room that's 38 degrees and I actually left after 20 minutes it was so humiliating because I could not do half the things, they were asking us to do."-P6

> "the other thing is as number 7 was saying I think there is such a huge spectrum, for me I would want to know what yoga are you doing because I have watched some yoga videos where you see these people and you think how are you even doing that with your body and it's amazing and how, you would want to know exactly which sort of yoga they are doing, you know if they want to go and do yoga classes at David Lloyd then I would be happy for them to do that in pregnancy because they can be a bit pathetic … a yoga class in like a proper yoga school then I would want to know which one they are picking to do-"-P6

Participants thought that risk assessments might be done at the Yoga centres but also that they are not based on criteria specific to pregnant women.

> "I know that we obviously live in a society which is very health and safety dominated and I'm guessing that many of these companies that are organising yoga classes will have risk assessments-P7

> I think what you said is right, they probably don't let people do it, but it's not really based on anything is it?-P2"

A participant with personal experience countered the discussion with details of how the good/credible classes are tailored to the levels of the participants attending. This is another example of how personal experience of the practice can influence the attitude of an individual towards Yoga.

> "like when I went to a yoga class, I wasn't expected to do all those kind of poses and stuff I was like having fun and doing the chill ones, I suspect they would be like oh ok don't do this one, do this one and you have to also like have a brain, if you are pregnant you are not going to be jumping on your fingers"-P9

11.6 THEME 2: YOGA FOR SPECIAL GROUPS

As this thesis was focused on women who conceived with the help of infertility treatments, the discussion progressed into Yoga for special groups of patients. This theme is presented in five sub themes: medical risks, obesity, mental health, infertility and professional credibility.

11.6.1 Medical Risks

There was a range of opinions towards recommending Yoga to women with specific prenatal disorders or complications. A specific argument was that the patients would not find a suggestion to participate in Yoga for a prenatal disorder or complication credible. A minority considered the possibility of recommending Yoga as an adjunct to clinical care for special groups. Participants expressed the need for more evidence of benefit for particular disorders or complications for doctors to be able to confidently recommend Yoga to special groups.

> " P9 – I don't know you talked about stress and things, some people I guess would be too anxious, I wouldn't recommend again say, that this is safe, this and that, I wouldn't
>
> Chair – 'for that group of patients?'
>
> P6 – because it's really difficult to say because if someone [with] […….]pre-eclampsia [is told] oh why don't you try and do Yoga; she might sort of look at you and be like well umm what difference is that going to make
>
> P9 – as an adjunct though … and Yoga, you can have both
>
> P6 – I think if she was already doing yoga before pregnancy then I would say carry on but if it was something that they would want to recommend as a treatment for a medical condition of pregnancy then I would say I would need to see the evidence before I would recommend it
>
> "

11.6.2 Obesity

There was some discussion about Yoga in the context of obesity. There is hesitation to recommend Yoga to obese women due to two reasons. Firstly, a perception that Yoga requires a certain form of attire that obese women would not want to wear. Secondly, a fear that obese women would be disheartened due to their lack of ability to manage Yoga postures. For obese women, the doctors preferred advocating walking or swimming.

"

P2 – as long as I see what they are doing, I think actually yoga is not so low intensity if you are like morbidly obese and then actually maybe they just need to like walk a bit more

P1 – in that circumstance you do [would] not even [finish] a whole session would you

P3 – they just wouldn't be able to like to get up

P2 – aren't you just on the floor for most of yoga anyway

O – prenatal yoga for most of it yes

P – I think they would just get really disheartened actually, be like sweating, if they are morbidly obese

P1 – maybe swimming would be nicer

Chair – morbidly obese you wouldn't recommend, what about moderate obese

P3 – I don't think most people like going swimming when they are heavily overweight though

P1 – you just said that the yoga would make them feel bad about themselves because they can't do it, swimming will be the same

O – it will be worse

P1 – yeah it will be worse

P2 – you have to wear less yes

P – I have not been to prenatal yoga so

P1 – it is body image isn't it, for them it's the body image that will be the problem

P – but yoga in leotards

"

11.6.3 Mental Health

With regard to mental health issues, none of the participants said they would recommend Yoga. Cognitive Behavioural Therapy (CBT) was the preferred option as recommended in the protocol they follow.

> "for anxious patients:
>
> P3 – CBT is the first line
>
> P 1– yes CBT…I think I would go CBT over yoga
>
> "

11.6.4 Infertility

When the conversation turned towards women suffering from infertility, the participants recognised that currently there are posters in infertility clinics about complementary therapies like Acupuncture, Yoga and Reflexology. If women have started these therapies during their treatment, there is a possibility that they might want to continue if during pregnancy. With specific focus on Yoga, the participants report the need for more evidence of no harm from the practice, before they would be comfortable recommending women to continue or start Yoga during pregnancy after infertility treatments. A consistent message throughout this discussion was that the participants would like patients rather than themselves to raise the topic of complementary therapy.

> "
>
> P3 – they might have been doing yoga to get their BMI into the range
>
> P6 –I don't think if I saw someone in the clinic who was pregnant who had conceived through infertility treatment [….], I would think oh, let me think about offering Yoga to her because she is really anxious but at the same time I have been to clinics in the infertility setting where preconception these patients are sort of not offered but it is mentioned about acupuncture and reflexology and Yoga, all those three things are mentioned to them preconception and […] one person might actually really like acupuncture and ask is it ok for me to continue that in pregnancy, and one person might take on Yoga during infertility treatment and say is it ok for me to continue and again I would want the evidence of no harm to say carry on […..] but I don't think I would see a patient in clinic and say oh have you thought about Yoga to help your anxiety it is almost like it would have to come from the patient
>
> "

It was highlighted that although infertility treatment led pregnancies are considered as high risk, doctors try to treat these patients as normally as possible so that they don't worry too much. Additional care is taken in the way the participants talk to this population.

"

P1 – ante-natal, slight difference in the way you manage and deal with them though isn't there, you are aware this is a bit more of a precious pregnancy, so you treat them, even though your clinical treatment and clinical management is no different the way you speak to them etc I think is different

P6 – they do go into a high-risk clinic, like they will be seen and managed by a consultant through pregnancy rather than being managed by a midwife as normal pregnancies are and as you were saying they might be looked at being precious pregnancies they might be induced a little earlier but other than that consider whether to do serious scans

P6 – in fact you would actually go the opposite and say we will try and treat, now that you have got to this point in the pregnancy, we will treat you as normal as possible

"

11.6.5 Professional credibility, patient choice and blame

In an attempt to understand why the participants are not proactive in advocating complementary therapies like Yoga, a unanimous belief emerged from participants that advocating Yoga or other complementary therapies would affect their credibility as a medically trained doctor.

"

Chair – so the next question was do you think that advocating Yoga, especially number 2, or other complementary therapies are credibility issues for your status as a doctor

P2 – yes

P5 – they must be as an exercise

P9 – as number 5 said I wouldn't label it as Yoga I would probably say the same things that they do but if I have to say something then I would be like have a little exercise that doesn't stress you out too much but that you breathe

P2 – but we are not going to recommend it as a treatment are, we, we are not going to be saying this is your management

Chair – so this is interesting so as doctors are, we saying it is ok to recommend exercise to maintain our credibility as a western trained doctor, but saying Yoga sounds a bit

P1 – I think so

Chair – it sounds like you are a bit, ohhh, and the patient will not take you seriously

“

What is interesting is that all participants felt that talking about the value of exercise was important and that most felt that Yoga was exercise. It might be easier to ‘sell’ Yoga to doctors as a valuable option for physical activity than as a way of addressing mental health issues.

“

P5 – I would recommend exercise to a patient

P2 – yeah

P5 – but it is an exercise

P1 – it is an easier exercise to get into

P – are you saying that Yoga is not an exercise

P9 – stretching, bending, making your core

“

Some participants objected to promoting Yoga on the grounds of patient choice. They felt that patients should be allowed to choose whatever form of exercise they would like to do and hence advocating Yoga specifically was inappropriate.

“

P1 – I think part of it is not necessarily the fact that it is Yoga I think that when you recommend exercise you are recommending generic exercise aren’t you, it’s like saying to somebody I recommend you go and play football; I feel like it takes away the same level of respect

P5 – because it’s like different people like different sorts of exercise don’t, they

P1 – it’s that fact that you are saying this is what I think you should do; rather than I think you should do exercise go out and find the one that suits you

Chair – and even like saying go and do a park run that doesn’t sound as good as saying exercise

P5 – people would never do it if you said that

“

On the theme of credibility and risk, a strong concern emerged amongst a minority that there is potential for patient blame if something goes wrong because of the practice. Though the majority believe that there is no evidence of fault by the doctor, it is perceived as common patient behaviour to believe so. Hence, the participants do not want to take the risk of advocating Yoga or other complementary therapies.

“

P5 – I think people make all kinds of spurious bizarre wacky associations based on their bizarre health beliefs and if you have got super super anxious infertility patients who might, and if anything goes wrong, they’ll be like it’s Yoga, that doctor told me to do Yoga and it must have been when I pulled that muscle in my thigh and it all started there, then you could just imagine it, when you look

P1 – I kind of agree with that

P3 – but there is no justification for them to think like that, as in they might think that, but they can’t say it is your fault as there is no evidence that it is your fault

P5 – people will say, do you think it is because I ate curry

P3 – so you have to say no it was definitely not

“

11.7 THEME 3: FURTHER RESEARCH

In the final theme attitudes and beliefs about the need for and approaches to further research in this subject were explored. It emerged that some participants might gain enough confidence to recommend Yoga without further research and in this context three things could help: more information about the practice; evidence that patients value the practice and more requests from patients about Yoga classes. This conversation came towards the end of the focus group discussion and might have been influenced by the knowledge participants acquired during the session – for example that there are various types of Yoga, that there is no evidence of harm and that there is some evidence of benefit in many physiological and psychological aspects.

“I think understanding that there is a spectrum to Yoga recognising there is as we said the higher intense positional Yoga versus the simpler meditative breathing version of Yoga then recognising that in pregnancy one may advocate one form over another rather than this overall sort of stereotypes”-P7

> "although equally if they are asking then they are not necessarily going to be going to do high intensity stuff are they, if someone asks me oh can, I start running when I am pregnant, I will usually say yes just don't go crazy when you start"-P1

> "I think personal experience, if I see that Yoga that you are recommending being done safely and how the patient felt so I guess personal experience. If there is no RCT and a patient comes to me and says that last pregnancy I did this, and it was very good can I continue in this pregnancy then I would be like ok and then if 10 people say that then I would be like oh there is some trend happening about Yoga and everybody is happy about it"-P9

But that view regarding confidently recommending Yoga was not universal and some participants were clear that RCT evidence was essential. Others were able to discuss the types of study that might convince them and also the types of outcomes that could be valuable.

> "I don't think any of us is ever going to recommend it as a treatment plan, or you have had a previous SGA [Small for Gestational Age], I'll not say, for your pregnancy I will prescribe you some aspirin and a healthy dose of Yoga every day… you are not going to ever recommend, sorry"-P2

A clear distinction was made between the need for evidence of no harm and evidence of benefit.

> "umm probably that it doesn't harm if people, well for me to actively suggest it then evidence of benefit but then for me to not discourage if someone already does it or wants advice about it then"-P8

> "so I think if you have got somebody who was going to ask you about Yoga in pregnancy it's going to be somebody who is fond of Yoga already or is interested in Yoga or has tried it previously so I think for me what would sell it is as number 8 said evidence that it doesn't do any harm because if this person feels that it is beneficial to them and they are asking can I continue it in pregnancy you want to know that it is not harmful because as number 1 was saying if she feels that it has got mental or emotional benefits to her then you want to be able to say yes you can carry on-"P6

There was an argument towards social benefits being equally important as clinical benefits and that these might be sufficient to recommend Yoga.

> "[I] would on the basis of the social benefit, if you could show me that there's social benefits to a pregnant lady doing this then I think there is additional benefits there, it doesn't necessarily have to be clinical outcomes but if there's social benefits because we are supposed to be more holistic aren't, we, mental health is the biggest component now that we are supposed to be pushing, if you can show me socially that it's better then yes."-P1

In view of the fact that RCTs can be difficult to apply to interventions like Yoga, participants were asked what sort of evidence would be sufficient to convince them of the benefits of this practice. They were given a list of eight study designs in the post discussion questionnaire and asked to rank them: cohort studies, systematic reviews, pre-test-post-test, experimental, observational, cross-sectional, qualitative and surveys. Not surprisingly, systematic reviews and cohort studies were ranked highest, and in fact both may include RCTs. Interestingly pre-test-post-test studies were considered to provide reasonable evidence. Qualitative studies were either considered very valuable or not valuable at all.

Only one participant was clear s/he would never recommend Yoga unless high quality RCT's had established benefit.

> "an RCT please, and a meta-analysis… (if it's not there) I'm never going to recommend it… for evidence of benefit you have got to show it as a treatment and to show an effective treatment you have got to have an RCT"- P2

But other participants countered this extreme view with latest research on limitations of trials.

> "Number 2 I refer you to last week's edition of nature which is speaking about the limitations of P values and clinical trials and how actually there's various clinical trials that show no effect that if in the long run you look at the true epidemiological data, they have massive impacts"- P1

11.7.1 Research options considered

A positive note towards future research in this topic is that there was interest and curiosity amongst participants towards investigating the effect of Yoga in pregnancy and there was an active discussion on what might be feasible. An example given by one participant was recording blood pressure of women during antenatal check-ups, offering Yoga sessions during waiting time and comparing results over time of women who did Yoga versus who did not. Though the discussions did circle back to trials and evidence from trials, there was a lot of interest in this approach.

> "
>
> P1 – so it is very simple, preeclampsia, all preeclamptic or sort of last trimester whenever they come in for a blood pressure check or something, they get a half hour Yoga class or something at the same time then you see what happens
>
> Chair – so you would want a randomised control trial
>
> P1 – I don't think you could random, well what it would be is a cohort study, you would have a cohort of patients, I guess you could randomise them but because you
>
> P5 – you could do block randomisation

Chair – if you do a block randomised trial and then of preeclampsia see who had the best obstetric outcomes then you would recommend it in preeclampsia and would number 2 recommend it

P2 – … I would happily do the trial

P5 – I think just a cheap photocopy, NHS badge on, a few black and white hand drawn poses on it, I would hand it out to anyone with a BMI, no seriously, if it was just like a generic, it's a good time to modify peoples risk factors for life and get them to do a bit of exercise.

"

It is clear from this discussion that there is potential and indeed interest in research and advocacy of Yoga during pregnancy in the UK. One key finding that distinguished this discussion from the findings of the interviews with doctors in India was recognition of the effects of wellbeing on the mother and baby (addressed in Chapter 10, Theme 2). Unlike majority of the doctors interviewed in India, the doctors in the UK all accepted that maternal mental wellbeing mattered for infant health. That is one step ahead towards a conducive environment for research in this topic. Research designed in collaboration with doctors could help create the necessary enthusiasm to run the study in the UK.

After the discussion, the participants were asked to fill up a second copy of the same questionnaire given before the discussion to check if any views had changed.

11.8 Pre and Post-Focus Group Questionnaire Results

The results of the questionnaire responses collected before and after the focus group and presentation can be seen in Table 20. One participant came late to the discussion and was not part of the pre-discussion questionnaire filling.

Scenario 1: Normal Pregnancy

Before the focus group, all participants (n=7) stated that they would encourage women to continue Yoga if they were already practising. Four participants stated that they would encourage women to start Yoga during pregnancy if they were specifically asked about this by the patients, but none would proactively bring up the topic of Yoga.

After the focus group, all participants but one (n=7) agreed that they would encourage women to continue Yoga if they were already practising. The one exception changed her position from Yes to Maybe depending on the type of Yoga the patient was doing. The discussion that had taken place led this participant to a position where she could make a more informed recommendation to her patients.

Regarding starting Yoga during pregnancy, two participants changed their answers from No to Yes which was an increase in comparison to the pre-focus group numbers (six in total). No participants changed their minds about proactively suggesting Yoga.

Table 20: Pre and Post Focus Group Questionnaire Results

	Pre Discussion (n=7)			Post Discussion (n=8)		
Scenario 1- Normal Pregnancy	**Yes**	**Maybe**	**No**	**Yes**	**Maybe**	**No**
She says she wants to continue her Yoga classes. Would you say	7	0	0	7	1	0
She says she heard about Yoga and wants to start. Would you say	4	0	3	6	0	2
She doesn't bring this topic out. Will you proactively suggest Yoga for mental and physical health?	0	0	7	0	0	8
	Pre Discussion			**Post Discussion**		
Scenario 2- Infertility Treatment Led Pregnancy	**Yes**	**Maybe**	**No**	**Yes**	**Maybe**	**No**
She says she wants to continue her Yoga classes. Would you say	6	0	1	7	1	0
She says she heard about Yoga and wants to start. Would you say	5	0	2	6	0	2
She doesn't bring this topic out. Will you proactively suggest Yoga for mental and physical health?	1	0	6	2	0	6

*There is 7 in the first set and 8 in the second as one doctor arrived late to the discussion and missed the first round of questions.

Scenario 2: Pregnancy following infertility treatment

Before the focus group all but one participant (n=6) agreed they would encourage women to continue Yoga classes if already practicing. Five participants agreed they would respond positively if asked by a patient whether it would be a good idea to start Yoga during pregnancy and one agreed that they would proactively suggest to this group of women that they should take up Yoga during pregnancy.

After the focus group discussion, all but one participant (n=8) agreed they would encourage women to continue Yoga classes if already started before pregnancy. The one participant who had responded negatively before the group chose the response 'Maybe' depending on the type of Yoga. This participant moved from the "No" group into the "Maybe" group which can be seen as a step in the positive direction.

One additional participant (six in total) agreed that if asked they would encourage women to start Yoga during pregnancy and one additional doctor (two in total) would proactively recommend Yoga during pregnancy to this group of women.

In this scenario, one participant said No and Maybe to all three options due to worry about fall risk and guilt if a miscarriage occurs. One participant who had said that they would respond negatively to women inquiring about starting Yoga during a normal pregnancy (scenario 1), would however respond positively in the post infertility scenario 2.

Comments by doctors:

A few participants proactively made notes next to the questions on the questionnaire sheets given to them. Those have been discussed here. A comment made on lack of bringing up the topic of Yoga in either scenario was that it is not part of routine antenatal care, there is a lack of information on the safety and benefits of Yoga and that it depends on the culture of the locality where they are practising.

The participant who changed from No to Yes regarding starting Yoga in pregnancy in both scenarios after the discussion, commented on the need for advice and guidance. Another participant raised similar concerns regarding proactively advocating Yoga, they mentioned the need for evidence and direction for pregnancy related classes to direct patients towards it.

A comment worth mentioning from a participant who previously would not encourage women to start Yoga in pregnancy was that post discussion s/he see no evidence of harm, so could encourage within sensible limits. One of the two participants who mentioned they would proactively encourage Yoga in Scenario 2 commented that Yoga was worth considering if really struggling with other options of stress relief like CBT.

In all scenarios either one or two participants changed their views in a way which was more positive towards Yoga. The participants seemed more in favour of Yoga for infertility treated patients than normal patients. It could be because they had seen patients being offered Yoga during infertility treatments (addressed in Theme 2). Lastly, it is worth noting that none of the participants views became more negative as a result of the discussion.

11.9 LIMITATIONS

The key limitation of this section of the thesis is that only one focus group was conducted. If there were no time constraints, two or three focus groups with mixed groups of obstetricians and midwives would have been better. To be able to compare the views of doctors in India and the UK, only doctors were invited to the focus group in the UK. However, as midwives are the primary care providers for

pregnant women in the UK, for establishing future research designs and feasibility, midwives would be a critical part of the discussion.

11.10 CONCLUSION

The understanding among UK doctors that maternal wellbeing affected the foetus and infant was positive; recognising maternal wellbeing as a problem meant that they were more open to looking for interventions that might help. However, it was also true that these doctors could relate more easily to Yoga as way of providing exercise than as a way of improving mental health.

Personal experience of Yoga does play a role in a doctor's advocacy of the practice. A key point is that the fear of losing credibility as a medically trained doctor plays an important role in the advocacy of complementary therapies. It is clear that changing clinical practice to the extent that doctors promote Yoga in pregnancy will require more research, but this may not need to be limited to RCTs.

A positive outcome that arose from this session was that a 45min focus group session could change the opinions and beliefs of some doctors in a way that is favourable towards Yoga. Another finding was that most participants would not discourage women from practising Yoga if they are already doing so, if they had better knowledge of the practises and if there was evidence that Yoga did no harm.

It is possible that the focus group design in the UK influenced the results. Learnings from the group and the confidence that participants derived from talking with their colleagues may have made it a more positive experience. This is a learning for future research.

To make a trial feasible in the UK, it would be important to enhance the level of knowledge about Yoga in pregnancy amongst the clinicians. This can be done via Continuing Professional Development (CPD) sessions where mental health effects could be discussed. Providing Yoga classes in the hospital as a method of promoting doctor wellbeing would also be valuable. Future research needs to be designed in collaboration with doctors.

The next chapter discusses the entire thesis, the learnings and limitations.

12 DISCUSSION

The aim of this thesis was to undertake research to investigate the effects of Yoga on the wellbeing of women pregnant post infertility treatments. A feasibility trial was planned and undertaken in India.

There were five research objectives laid out in the beginning of this thesis.

1. Review evidence on infertility and its impact on the wellbeing of women, and the effect of maternal wellbeing on the pregnancy, the labour, the infant and the postpartum period.
2. Search and appraise existing literature on pregnancy & Yoga.
3. Evaluate the feasibility of conducting a randomised controlled trial on Yoga and pregnancy post infertility treatments.
4. Explore the perspectives of trial participants and family members on infertility, Yoga intervention, and participation in the trial.
5. Explore expert opinion on perceived benefits and disbenefits of Yoga among the target patient group, and the need for randomised controlled trials.

Objectives 1 and 2 have been achieved in the literature review (Chapters 1-6) and a systematic review (chapter 8). Objectives 3 and 4 were achieved through the feasibility study conducted in India (chapter 9) . Objective 5 was achieved through interviews reported in Chapter 10 and 11. This aspect of the study was strengthened part way through my thesis as the problems with the feasibility study emerged. Additional interviews were undertaken in India and a focus group was held with obstetricians in the UK.

The results of the feasibility study show that a number of problems would need to be overcome before a trial could be run successfully on this topic in India. The qualitative component of this mixed methods study investigated the reasons why the proposed protocol did not work and what steps could be taken to make the study feasible.

This chapter discusses the following: the key findings from this thesis, including the positives and negatives of the feasibility trial, a discussion on RCTs, the role of patient preferences in research, and future research recommendations.

12.1 KEY FINDINGS AND THEIR IMPLICATIONS

12.1.1 Infertility, Pregnancy and Mental Wellbeing

The literature reviewed in chapters two to six confirmed that Infertility is a stressful condition for women as it challenges their womanhood, their status in their family and cultural expectations. Moreover, the treatment for infertility is stressful and often invasive.

It showed that Infertility is prevalent across the world with infertility rates in different countries varying between 5%-30%. In India, the rate of infertility is close to 15% which makes infertility a public health concern as per the World Health Organisation (Nations, 2017). The population of women undergoing pregnancy post infertility treatments is therefore large. Women in this population are most often older and have multiple pregnancies which are often associated with risk factors like hypertension, haemorrhage and preterm labour (Adashi et al., 2003; Dhont et al., 1999).

The fear and anxiety after every treatment session regarding the viability of the pregnancy is high and it gets more severe with every attempt (Bhat & Byatt, 2016; Domar *et al.*, 1993). This was reiterated by the doctors I Interviewed in India as they mentioned that the anxiety and stress were higher among couples who have had multiple rounds of treatments.

Prolonged exposure to stressors increases the potential for an individual to have anxiety. Anxiety and depression are established to be co-morbidities and as presented previously; one increases the risk of the other (Belzer & Schneier, 2004; Garber & Weersing, 2010).

Women who conceive with the help of infertility treatments are therefore highly susceptible to stress, depression and anxiety in pregnancy. All three are detrimental to the health of mothers and their infants. Mothers experience increased pregnancy discomforts like nausea and low blood pressure (Volgsten *et al.*, 2008). There is equivocal evidence on risk of preeclampsia, preterm birth and growth retardation.

The literature therefore also shows that stress continues after successful infertility treatment and that this stress is linked to pregnancy complications such as, surgical births due to elective caesarean sections, prolonged labour, requests for epidurals, and physical and emotional distress (Alhusen & Alvarez, 2016; Andersson et al., 2003; Andersson et al., 2004; Bayrampour et al., 2015; Kelly et al., 2001; Martini et al., 2010; Rauh et al., 2012; Rejnö et al., 2019; Rhudy & Meagher, 2000; Simkin & Ancheta, 2011; Smorti et al., 2019; Wiklund et al., 2007). Mental health problems lead to an increase in hospital admissions, a disproportionate use of the health care services, and a higher cost to the public health system or the individual (if private healthcare).

Risks to the infants include compromised foetal development, shorter gestation period, and a lower birth weight. Foetuses are also at risk of a lower resilience to stress in-utero and after birth and of developing into babies with difficult temperaments (Diego et al., 2005; Van den Bergh, 1990). Stress, anxiety and depression in the mother is further reported to lead to longer term mental health problems and behavioural disorders like ADHD and OCD in the child (Talge *et al.*, 2007).

A report by Bauer et al., (2014) looked at the financial implication of perinatal mental health problems in the UK. When averaged over all births, the combined costs of perinatal depression, anxiety and psychosis amount to £9,929 for every woman giving birth, including costs of £2,137 falling on the public sector. Nearly three-quarters (72%) of the total cost relates to adverse impacts on the child rather than the mother. Along with better outcomes for mother and baby, mental health interventions can save millions every year.

Although maternal mental health is only one factor contributing to these problems it is one that is potentially responsive to interventions which can in turn influence maternal and infant health outcomes.

12.1.2 Yoga

Yoga is an ancient practice that originated in India and over the last few decades it has been found to have beneficial effects in a wide range of clinical conditions including in pregnancy (Shearer, 2010; Taylor, 2003). There are multiple forms of Yoga, but Hatha Yoga is the most commonly used form in medical research.

As discussed in Chapter 4, Yoga has been reported to be beneficial to individuals across age groups, suffering from anxiety, depression, stress, eating disorders, sleep disorders, asthma, non-specific lower back pain and emotional trauma (Balasubramaniam *et al.*, 2013; Neumark-Sztainer, 2014; Wieland *et al.*, 2017; Yang *et al.*, 2016).

Prenatal Yoga is an adaptation of the original practice. Modifications include removal of postures that involve forward bending, twisting and lying on the stomach. There were no reports of adverse outcomes or harm to pregnant women or foetuses post Yoga in the literature reviewed in Chapter 5 and 6.

Research on the benefits of Yoga during pregnancy is predominantly from the last two decades, with the majority in the last ten years. Interest in this area is growing and researchers are studying it across various countries. In Chapter 5, non RCT literature on Yoga and pregnancy was reviewed and studies show evidence of benefit on stress (Beddoe *et al.*, 2009; Bershadsky *et al.*, 2014; Kusaka *et al.*, 2016; West *et al.*, 2004; Yadav *et al.*, 2012), anxiety and depression (Beddoe *et al.*, 2009;

Vieten & Astin, 2008), pregnancy discomforts (Beddoe et al., 2009), back pain (Holden et al., 2019; Pont et al., 2019b), gestational diabetes (Youngwanichsetha et al., 2014), preeclampsia, labour pain and duration, and use of pain medication in labour (Bolanthakodi *et al.*, 2018; Muzik *et al.*, 2012; Pont *et al.*, 2019a; Sun *et al.*, 2010; Westbury, 2019), growth of baby, and preterm birth (Narendran et al., 2005).

As discussed in Chapter 5, women who practice Yoga in pregnancy report that it helps them with stress relief and becomes part of a self-care routine (Kinser & Masho, 2015b). Yoga was reported to improve existing relationships, and self-confidence (Doran & Hornibrook, 2013), and instil a sense of strength (Kinser *et al.*, 2019; Kinser & Masho, 2015b); fear and low self-confidence increase requests for analgesia, elective c-sections and other interventions in labour. Yoga groups provided an outlet where women could talk openly with others in similar circumstances and create an additional support system.

In Chapter 8, the systematic review reported a wide range of outcomes precluding a meta-analysis. Although the quality of RCTs varied from moderate to low the results suggested multiple potential benefits in line with evidence from non-randomised and qualitative studies.

On the basis that there is no evidence that reports a problem with safety in practising Yoga during pregnancy under a qualified instructor, and that there appear to be multiple benefits, it could be argued that pregnant women should be given information about prenatal Yoga and encouraged to try the practice.

The literature review chapters confirmed that whilst there is research to suggest that Yoga is likely to be helpful in post infertility treatment related pregnancies, and trials of Yoga in other pregnant populations have shown benefits, at the outset of this thesis there were no trials in this population. That led me to choosing this population for my thesis.

12.1.3 Randomised Controlled Trials

In the field of medicine, RCT's are the gold standard of research. This is the method most trusted by the clinicians as it is the only approach that accounts for bias and confounders, gives results of net harm or net benefit and proves efficacy of intervention/treatment (Machin & Fayers, 2010; Matthews, 2006; Threlfall et al., 2014). Randomising participants assures internal validity by limiting selection bias and with the optimum power calculation provides the most reliable results most efficiently (Petticrew, 2013).

However, RCTs can be expensive and difficult to carry out (see later). As there was no previous trial of Yoga conducted in this population, it was important to conduct a feasibility study to identify if an RCT was practical and possible.

Prior to embarking on any trial, it is important to conduct a systematic search and critical appraisal of the trial literature in order to ensure that there are no existing relevant trials. The systematic review in Chapter 8 searched for any trial of Yoga in pregnancy in order to make sure there were no existing trials in post infertility treatment population and understand the various RCT designs and the outcome measure which had been studied.

The systematic review identified fifteen trials of varying quality looking at a range of different outcomes (Babbar *et al.*, 2016b; Chen *et al.*, 2017; Chuntharapat *et al.*, 2008; Davis *et al.*, 2015; Deshpande *et al.*, 2013; Field *et al.*, 2013b; Field *et al.*, 2012; Jahdi *et al.*, 2017; Jayashree *et al.*, 2013; Martins & Pinto e Silva, 2014b; Newham *et al.*, 2014; Rakhshani *et al.*, 2010; Rakhshani *et al.*, 2012; Satyapriya *et al.*, 2013; Satyapriya *et al.*, 2009; Uebelacker *et al.*, 2016). India and the USA were the most common locations with five trials each, followed by one each in Iran, Taiwan, the UK, Brazil and Thailand. There was a wide range of participants from low-risk singleton women to high-risk mothers with pregnancy complications. No studies reported any harm to the mother or the foetus.

Yoga was reported to be significantly helpful in physiological outcomes like obstetric complications (GDM and Preeclampsia), back pain, labour and birth (shortened duration of labour, labour pains and vaginal births) and birth outcomes (APGAR scores, gestational age and birthweight), and psychological outcomes like anxiety, depression, stress, interpersonal relationships, sleep disturbances, quality of life and biological stress markers. Across various markers in adequately sized trials, Yoga was shown to be a useful intervention for anxiety and depression among low risk and psychiatrically at-risk mothers. A higher dropout rate was noted in high-risk populations as compared to the low-risk populations.

A range of different intervention designs was used, but home-based practice was a key component in most studies. The engagement of the participants with home practice was not measured and the extent of adherence to home practice could have had an influence on their results. Precise estimates of benefit cannot currently be made. Based on this review, trials should aim for sample sizes over 60 especially while measuring psychological health outcomes; trials focusing on high-risk populations should recruit higher numbers to account for higher dropout rates in that group.

Overall, the review presents a positive picture of potential benefits to the mother and the foetus with no harms being reported in both low-risk and high-risk populations. The lack of unequivocal high quality RCT results remains a barrier for doctors to be convinced of benefits and there is possibly a

need for better high-quality research evidence before doctors can be convinced to incorporate promotion of Yoga into their obstetric practice. But arguably there is enough evidence for doctors to be supportive of patients who want to try prenatal Yoga and for researchers who wish to conduct research in this subject. I chose India as my location for field work as I had experience in the healthcare sector in India and was aware of the increasing numbers of women having infertility treatment, so I wanted to investigate solutions for the increased risks in that population. Additionally. India is the birthplace of Yoga.

The Systematic Review informed the view that it was feasible to undertake a trial in India and the feasibility trial was designed with the systematic review as a foundation. Although the infertility patients could be seen as a high-risk population, the Systematic Review suggests no reason why this should be a problem.

12.1.4 Feasibility Trial

The feasibility trial in India suggested that a larger trial of the same design was unlikely to be successful for a number of reasons. A literature search on the frequency of feasibility trials showing no feasibility resulted in no relevant evidence. That statistic would be helpful for researchers embarking on feasibility trials to put their results in context.

In this event, the only obstetrician who gave me names of potential participants was the head of department. None of the other obstetricians supported recruitment. Out of the 61 potential participants identified by the head of department, only 25 showed interest in the study, only 9 consented and only 3 took part in the trial. The recruitment rate was therefore 15% (9/61) which compares reasonably with other studies reviewed in the Systematic Review in Chapter 8, but the dropout rate post consenting to participate was very high at 66% (6/9). The reasons for non-participation were no response/no show, not interested, husband/family saying no and not being able to attend as they were working. The reasons for dropout were relocation and family issues.

The reasons for non-participation in the study closely mimic the reasons for dropout stated by the authors of the papers reviewed in the Systematic Review. The three most common reasons were, relocation of the participant to another city [n=73], no-show for measurement of outcomes [n=50] and drop out from the intervention [n=24]. However, it may be of interest that the lead authors of the successful trials were all obstetricians, who may have had personal contact with the participants and encouraged them to attend. I am not a health care professional and so do not have the same credibility and professional authority and it does not seem that the head of department spoke personally to the women on the list. It may be that it is just more difficult for an outsider such as myself to get a trial like this off the ground. There is no published evidence of this, however,

anecdotally, within the medical research environment, it is believed that trials are more likely to succeed if run by Clinical Trial Units or practising clinicians.

As mentioned in Chapter 9, a change of more than 3 points is considered a meaningful change in WEBWBS. Among those who participated in the intervention, meaningful change was observed in the mental wellbeing measure scores (WEMWBS) of two of the participants from the control group who contributed post intervention data in their third trimester. There were changes in all the three questionnaires but WEMWBS was the most sensitive to change in this scenario. It was possible to gather outcome data on this population relating to mode of delivery, complications of pregnancy, birthweight, and gestational age. The two participants who completed the trial had spontaneous vaginal births. A future RCT should be powered to pick up differences in these outcomes as they are potentially influenced by Yoga.

12.1.5 Qualitative Research

12.1.5.1 Family Influences

The key finding from the qualitative interviews in India is the crucial role that society, family and peers play in the healthcare related decision making of pregnant women in the Indian context. In situations like infertility, family are also one of the causes of mental health problems. Lack of sensitivity and disrespect to women suffering from infertility, cultural requirement of pregnancy to affirm a marriage and comparison between family members are all aspects of family pressure highlighted during the entirety of this thesis.

A key example from this study is the very widely held belief that pregnant women need rest. Hence family members discourage women from any kind of physical activity. As the participants in this study were infertility patients, fear of complications from any form of movement/exercise was very high. The need for all family members to approve of the mother's decisions and actions affected this study.

The fear of movement during pregnancy has been reported in a cross sectional survey study (Sujindra *et al.*, 2015) conducted in South India (n=200) where 67.3% women were afraid of exercising and the level of practise of prenatal exercise was 18%. The fear of movement needs to be tackled if prenatal activity is to be increased among Indian women.

During interviews, the doctors mentioned multiple times that, in the Indian population, research is considered risky and signing consent forms sparks fear. Doctors reiterated that, due to this family influence, they have struggled with recruiting for their research studies the same way I did. Though this study was non-invasive, the fear that the hospital and the researcher were experimenting on pregnant women was present. Especially in this patient population, as they have struggled to

conceive, they would not want to try anything out of the ordinary even when made aware of the benefits. This is a new finding as nothing similar is reported in literature.

The doctors reiterated the strong power of society and family on the pregnant mother as a problem they face in their practice. Misinformation based on experience or hearsay is passed to mothers by friends and family, and guidelines given by doctors are not always followed.

In the current cultural context, the only way to successfully recruit and retain pregnant mothers in a research study, is to convince their family that the topic being spoken about or tested, is beneficial to her and will help with the pregnancy.

Mental health remains as one of the hidden disease burdens in India due to stigma and discrimination (Venkatesh *et al.*, 2015). There is both public stigma and self-stigma where the patient internalises the negative views held by the general public. This was corroborated during the trial and the qualitative study. Although I was careful to portray trial information as relating to positive mental health not mental illness the trial was still portrayed as a study which could support mental health. In hindsight, this could have been a deterrent to recruitment due to the negative connotations associated with talking to any outsider about mental health. Until there are steps taken to reduce the stigma associated with mental health, getting participants for any study looking into mental health will be difficult.

12.1.5.2 Women

The fear and anxiety reported to be common among women with infertility in literature in Chapters 2 and 6, was well represented during interviews with patients, family, and doctors. Social seclusion among infertility patients was a pattern identified during the qualitative research. Due to embarrassment, women avoid family events or socialising with peers. It seems like the obvious thing an individual in that situation might do, however, creating an environment of seclusion can affect her mental wellbeing.

From the interviews I conducted, it shows that there is a lack of knowledge and an ignorance about the effects of mental health on physical outcomes. The pregnant women I spoke to in India seemed to know that stress and anxiety were 'bad' during pregnancy or that 'it has an effect', but they did not know in what way. They are not knowledgeable on the specific effects this could have on the foetus, their pregnancy, the birth, and even lesser knowledge of the long-term effects on the child. I was unable to find any study that looked at the mother's knowledge of the effects of perinatal mental health in India.

As presented in Chapter 4, there is evidence on short- and long-term health outcomes on the mother (hypertension), foetus (preterm birth), labour and birth (duration, pain, request for analgesics, vaginal births vs caesarean sections) and child development (behavioural disorders). If the mothers were aware of these effects, potentially they might be more inclined to seek out and participate in approaches to protect and support mental health. One factor that potentially causes this gap in knowledge among pregnant women, is lack of the same knowledge among doctors and is addressed in the following section.

If a further trial were to be undertaken, it would be beneficial to conduct a Patient and Public Involvement (PPI) session first, to understand the knowledge and opinions of pregnant women on short- and long-term effects of mental wellbeing during pregnancy, their opinion on research, how best to communicate research, and ideas to maximise participation.

12.1.5.3 Doctors

There is a large body of research stretching back over at least two decades to show that maternal stress in pregnancy has a negative effect on the pregnancy and the baby. The majority of doctors interviewed in India were not aware of this, whereas the doctors interviewed in the UK were. It is intriguing that awareness levels are so low despite the strong research on this topic; however, it is not clear as to why there is such a disparity between the knowledge of the obstetricians in India and in the UK concerning this topic.

However even in the UK, the main focus amongst those who were aware of the links was on clinical outcomes of pregnancy labour. Mental health and its longer-term effects are not a priority. Those interviewed did not know that interventions to support emotional health could improve pregnancy outcomes, as well as longer term developmental outcomes for the child. A report by Bauer et al., (2014) discusses the wide range of effects of perinatal mental health issues on the child. Some of them being, special educational needs, leaving school without qualifications, conduct problems, emotional problems, chronic abdominal pain and child temperament.

It also became clear in both India and the UK that clinicians were worried about a lack of physical activity in this population and consequent obesity. Activity advice was thought to be most important for women with a high BMI. In discussing appropriate physical activity some doctors did mention Yoga. Given that there is little concern about mental health problems and there is concern about physical activity, the promotional literature about Yoga in support of a trial should arguably emphasise physical activity over mental health.

However, for clinicians to fully support research in improving mental health of mothers and to recruit mothers into the study, it is critical that both the groups are aware of the effects of mental health on the mother and baby. The range of inputs we received, from zero awareness to views informed by latest research, indicates a discrepancy in knowledge between clinicians in the same healthcare facility. If a doctor believes that positive mental health in pregnancy is not important that belief is likely to be passed explicitly or implicitly to pregnant women.

When doctors in India were asked about stress relief, counselling seemed to be the favourite option. There was a discrepancy as to whether they themselves should be responsible for counselling patients or psychologists should take that up. Lack of availability of psychologists to support the doctors and lack of time in obstetric practice mean that in reality this is not entirely practical. Participants of the trial highlighted that they had not been offered any counselling or alternative methods for stress relief.

It was expected that patients and doctors in India would be more knowledgeable and open to the practice of prenatal Yoga. In a survey of 238 doctors in an Indian teaching hospital, 70.7% believed Yoga to be effective (Kong *et al.*, 2013), and Yoga and diet based therapy was most commonly recommended for chronic illnesses. The reality on the ground was very different. Both patients and doctors had very limited knowledge about Yoga and almost no knowledge about prenatal Yoga. Since Yoga is a complementary therapy and not part of medical education or care protocols, most doctors have only been exposed to information about Yoga if they have personal experience of the practice. In the interviews and the focus group, the doctors who had experience of the practice were comparatively more open to the potential value of Yoga in pregnancy, a theme that is echoed in literature (Kong *et al.*, 2013; Roy *et al.*, 2015).

In both India and the UK, doctors reported that hardly any patients asked them about practising Yoga during pregnancy. If patients enquired about Yoga more frequently, doctors would possibly become better informed so they could answer their questions. For example, doctors should discourage unsupervised practice of Yoga by both pregnant women who have never practised Yoga, and people with experience of Yoga who have no understanding of how postures need to be changed during pregnancy.

Doctors in the UK thought Yoga was beneficial because it provided group-based support and community. They thought that this was similar to other antenatal classes. However, the literature shows that women prefer Yoga sessions, find them more interesting and believe that the Yoga sessions help to build a bond with the growing baby. Regular, longer sessions from pregnancy to

postpartum, supported by clinicians, appeal to women. A preference from women towards Yoga might aid in convincing the care providers to suggest Yoga to women.

Though patient education is important for successful recruitment and retention in a research study, changing doctors' knowledge, attitudes, and behaviour changes towards Yoga would be necessary before this trial would be feasible. A key point to be noted is that a single CPD session with the doctors in the UK changed attitudes of some of the participants, and possibly even had an influence on their practice. This shows that it is possible to change attitudes and opinions of doctors which will help in involving them in future studies. From my feasibility study I concluded that recruitment would be likely to continue to be a problem unless doctors themselves were involved in promoting the trial to their patients. This requires them to be concerned about the outcomes and genuinely interested in whether Yoga makes a difference.

12.1.6 Cultural Factors- Key to Success of a Further Trial

The above sections present in various ways, one common thread – a cultural change is necessary for a similar trial to be conducted within this population. In the Indian culture, patriarchy has a strong role, the primary role of a woman is to bear children and rear the children. Daughter-in-laws have a subservient status in the house, there are strict codes of conduct for females and an unfortunate preference for the male child (Sharma & Pathak, 2015). Marital disharmony and inadequate social support have been associated with increased risk of postnatal depression. A study from China suggests that the distress caused to women by factors such as arranged marriages, in-law troubles and enforced nurturing role can precipitate psychological disorders (World Health Organization, 2002), which could be suggested to be a problem in India as well.

For a pregnant mother, the current position of gender roles in a typical Indian family leads to a lack of autonomy and agency. The WHO has presented evidence that the feeling of a lack of autonomy and control over their own life is known to be associated with depression (World Health Organization, 2002). The literature (Chapter 2) and the results of qualitative research (Chapter 10) reflect the dependencies and the difficult experiences of women. Pregnancy being a family affair leads to the woman constantly being watched through a lens of abiding to the cultural beliefs and gender roles. Decisions are not taken by the mother or at times even the father. The in-laws have higher authority than the pregnant couple themselves. Fear is instilled in the mother regarding potential harm to the baby if cultural guidelines are not followed, as those beliefs are stronger within the larger community the family lives in. A small example being driving. While recruiting for this trial, travel to the hospital was a problem for many women as they did not have anyone to drop and pick them up. They weren't allowed to drive as it is considered dangerous. A chaperone was sent to the Yoga sessions to

observe what was happening. Sharma and Pathak (2015) suggest that culture is a strong factor that affects the occurrence, manifestations, treatment, and outcome of mental disorders in Indian women. The examples presented here and throughout this thesis demonstrate a lack of trust in the process of research, and a strong fear of giving independence to the mother. It would be interesting if future research assesses if these could be suggestive of situations that affect a pregnant woman's wellbeing.

The cultural change needed is going to take a long time. For a trial to be successful in the future, this aspect needs to be tackled, but with sensitivity. As individual researchers, it is difficult to bring about change by going against the family members and the wider community. It is important to remember that the pregnant mother spends a few minutes with the care provider but lives with her family. They need to be part of the process. Education involving the larger family through discussions, reading material and videos will be helpful. However, the key individual here is the obstetrician caring for the mother. Families will listen to their doctors most of the time and that medium of information dissemination will hold the highest value and respect. A trial design addressing these has been suggested later in this chapter.

12.2 STRENGTHS OF THIS THESIS

12.2.1 Overall Strengths

I reviewed a wide range of research on the health benefits and risks of yoga, including qualitative observational studies and trials. I have been able to collate, analyse and present evidence on suggestive benefits of Yoga for pregnant women. An updated systematic review has been conducted which is an addition of knowledge to the field and will be submitted for publication.

I learnt that the feasibility of complex intervention trials is not always directly linked to the intervention itself. The societal and cultural influences can strongly influence the viability of research. Educating the mothers and involving family members in care discussions are essential for potential health outcomes in the mother and the baby. The knowledge and attitudes of doctors is also very important. The enthusiasm of the chief obstetrician was essential in undertaking this research but was not in itself sufficient to overcome the lack of enthusiasm of the other doctors. This is important because doctors are a critical part of cultural change

This thesis provides evidence to future researchers on steps to take while designing a study recruiting pregnant women, in the context of an Indian population. The lessons learnt, the key findings discussed, and the suggestions gained from all participants are valuable preparation material for

researchers. I plan to write a paper on the learnings from this thesis as during the literature review, I identified that many of the findings discussed are original in the Indian context.

12.2.2 Positive aspects of the trial

Although it was concluded that several factors- cultural and trial design need to be addressed before a larger trial can be conducted, there were aspects of the feasibility study that worked well. Although multiple hospitals had to be approached, Fernandez hospital agreed to conduct the trial with their patients. Ethical approval to go ahead with the trial was granted by the BSREC in both countries, at Warwick University, and at Fernandez Hospital. Fernandez hospital was very supportive of the trial and the topic of Yoga in pregnancy. Fernandez is the only hospital in the state to provide midwifery care along with obstetric care. They currently offer Yoga classes, antenatal classes and doula care. The owner of the hospital is a keen advocate of supportive care and complementary therapies which helped me secure the alliance with the hospital. As the hospital is research oriented, it provided me with a supportive environment. My experience with setting up the trial can be an indicator that there is a slow change leading towards holistic care delivery in hospitals.

Whilst recruiting for the trial, doctors attended meetings and information sessions. Some women consented to the trial and turned up for the Yoga classes and the ones who did found the sessions to be very helpful. They reiterated during interviews that Yoga had an effect on how they felt and how their labour progressed. Post the trial, information from birth records was easy to obtain through the hospital administration. These show that it is possible from an administrative standpoint, to conduct a trial with a supportive hospital.

12.3 WEAKNESSES OF THIS THESIS

12.3.1 Negative aspects of the trial

12.3.1.1 Lack of resources and time

My scholarship covered tuition and provided a monthly stipend but did not have research expenses or any other additional allowance. This limited my capacity to offer more Yoga classes during the trial as I was paying the Yoga instructor for each class whether participants showed up or not. Lack of funding also limited my capacity to conduct PPI sessions with potential participants as part of the qualitative research.

The funding period also limited the time available as my funding ended at 3.5 years (March 2020), I had a very limited time period of 1 year to complete ethics processes and recruit participants into the study. The window was shorter as the longitudinal study design was 20 weeks long comprising of

two 10-week blocks. That design was based on previous successful studies using a 10-week intervention period. A design incorporating a shorter Yoga intervention might not have been sufficient to provide benefit, if the recruitment had succeeded. I did undergo training on Good Consent Practice, but, in hindsight, additional training on optimal recruiting methods and strategies could have been helpful.

Out of the five hospitals approached for this study, two hospitals had asked that I pay a sum of approximately £800 to be allowed to conduct the study in their facility. This amount was exclusive of research expenses like printing, travel and Yoga instructor costs. In another two, the doctors were not interested to support the study.

If I had the support of a grant and a longer time span, there is a possibility that the results of the trial would have been different. Literature does not show any feasibility study done in this subject in India. However, full trials have been conducted in India and have shown varying results as discussed in Chapter 8. Those trials have had a minimum recruitment period of a year, were built around home-based sessions with few face-to-face sessions or had many sessions in a short span of time.

12.3.1.2 Location

I chose India as my location for field work due to my field experience and interest. In hindsight, recruitment might have been easier in the UK. Prior to beginning the trial in India, I was positive about getting responses from doctors and patients. As per my systematic review, there were successful large trials of Yoga and pregnancy conducted in India, therefore, I did not expect trouble with a small sized feasibility study.

In this event, I overestimated the extent of medical knowledge in India relating to stress in the study population and its impact on pregnancy outcomes. I also overestimated the clinician's knowledge of Yoga and its benefits. I also underestimated the highly significant negative impact of family culture and knowledge with regard to the needs of pregnant women post infertility treatment.

12.3.1.3 Population

The combination of location with the chosen population could be another factor that led to low levels of recruitment. I had chosen to conduct this trial with pregnant women who conceived post infertility treatments because it was relevant, novel and no such trial had been conducted previously. In hindsight, it may not have been the best idea in a project with limited time. If the project was based on pregnant women post spontaneous conception and/or treatment led, the total sample possibly would have been larger.

12.3.1.4 Involvement of Obstetricians

In a topic like Yoga and pregnancy, where new and alternative interventions are being studied, it is critical to have the support of obstetricians and midwives. Active involvement of obstetricians and midwives will help in increasing recruitment rates. However, for them to be interested in a study of this nature, they need to understand the impact, and care about the wider implications of stress in pregnancy.

Doctors in India had mixed opinions. I did not get any referrals from individual obstetricians. Small numbers of referrals can make an RCT impossible with a long and expensive trial period (Greenfield, 1989).

The majority of the doctors in India were ignorant about the effects of stress in pregnancy. It was the opposite in the UK. This is where I feel that if I had conducted the trial in the UK, I might have had different results.

It would be ideal if a single obstetrician or midwife who believes that the subject is worth studying can actively participate in recruiting women into the study. The alternative option is to educate doctors about the impact of stress on pregnancy, and Yoga as an option to reduce it. Educating doctors through emails or flyers is convenient but can be done only on a very small scale. Doctors can be provided with a few weeks of Yoga sessions to help them personally understand the practice and raise questions or queries.

Getting into Continual Professional Development (CPD) sessions is a better and more credible option, but this is difficult to achieve and beyond the scope for a PhD student. In comparison, it will be better to identify and collaborate with one single doctor/midwife or a team who believes in the topic and its relevance.

12.3.2 Overall Weaknesses

The limited response to the feasibility trial and the interviews affects the generalisability of this study. Higher participation in the qualitative research would have permitted data saturation. Though there are strong learnings from this thesis especially in terms of the cultural influences on Indian women's pregnancies and the clinicians and patients' lack of knowledge on effect of mental wellbeing, the results need to be taken in context with the environment and the limitations under which it was conducted.

12.4 ALTERNATIVE APPROACHES TO RESEARCH ON THIS TOPIC

Doctors are educated and trained to accept RCTs as the highest standard of research. It is what helps them decide what shows net benefit or net harm and accordingly supports their decision making. But although RCTs hold the highest position in research designs, there are problems with RCTs. Designing and conducting a well powered, good quality RCT is costly, requires larger number of human resources to run and takes time.

Yoga cannot work without patient engagement as active participation is required. In Chapter 6, It was noted that when patients were allowed to self-select groups, there was a higher number in the Yoga group as opposed to the control group. If that can be replicated in larger numbers, there would be an argument that Yoga intervention-based studies should be conducted in a self-selected group design as patient preference plays a role. In an RCT, the patients do not get to choose. Allowing participants to choose to participate will help identify the types of individuals who like the therapy or are open to it, and the benefits of the practice on those. RCTs are not the best design for pragmatic trials where information is sought, not just on efficacy of treatment, but also on its practical effectiveness (Kowalski & Mrdjenovich, 2013; Torgerson et al., 1996).

The body of non-RCT research in the last two decades on Yoga and pregnancy: pilots, pre-test-post-test designs and qualitative studies, show evidence of benefit. These are more numerous than RCTs perhaps because of lack of funding, lack of evidence of feasibility and lack of support from doctors. This is a Catch-22 situation where doctors require RCTs to support the practice, but we need doctors to support the practice in order to conduct RCTs. In India and in the UK, the majority of doctors interviewed were adamant that RCTs were necessary, but a minority were not sure that they were needed. The latter, on the basis of evidence of no harm, were open to suggesting Yoga to their patients and thought that social benefits would be sufficient to justify the suggestion.

Given the practical difficulties associated with conducting an RCT, it is debatable whether it is the ideal methodology to use in order to establish the benefits of Yoga for pregnant women. As presented in Chapter 7, there has been an argument that RCTs are useful in a 'single cause-single treatment' approach but not in today's complex health scenario.

As there is enough data to establish evidence of no harm, there is an argument to suggest that evidence of benefit can be proven through other research designs like pre-test/post-tests experimental studies, cohort studies and preference trials instead of an RCT. Existing systematic reviews and the latest evidence from all research designs do provide evidence to demonstrate likely benefits of Yoga in post infertility treatment populations.

In Section 12.6.3 of this chapter, I have recommended a potential preference trial design. Though the above said non-RCT designs can prove evidence of benefit, clinicians are firm on their need for RCTS. A preference trial in an apt in-between design.

12.5 Role of Patient Preferences

In a typical RCT, patient preferences are not taken into consideration. It is common for patients to refuse randomisation in trials because they have strong preferences of intervention/treatment options (Howard & Thornicroft, 2006; Torgerson & Sibbald, 1998; Wasmann et al., 2019). Absence of these patients from trials leads to a misrepresented population compromising external validity. Hence the results cannot be generalised. (Torgerson & Sibbald, 1998).

There is a belief that patient preferences influence intervention outcomes and have an effect on the prognosis (Howard & Thornicroft, 2006). The negative aspect of preference trials is that the characteristics of the patients who choose one arm might be different in a way which influences outcomes from those who consent to the other arm (McPherson and Britton (2001).

When patients with strong preferences are recruited and randomised in interventions where blinding is not possible, they can suffer from demoralisation which then has implications on compliance and affects the internal validity of the study (Howard & Thornicroft, 2006; Wasmann et al., 2019). In situations where choice and control has a therapeutic benefit, randomisation can lead to biased results and hurt patients by denying the power of choice (Kowalski & Mrdjenovich, 2013).

Patients receiving their preferred treatments may comply better than others. There is potential for treatment effects that result from patient preferences and not only the therapeutic efficacy of the intervention/treatment being tested (Torgerson & Sibbald, 1998). Wasmann et al (2019) report that consciously choosing a treatment arm leads to dedication and a certain amount of tolerance for the treatment. Since recruitment and dropout are primary hurdles for running a successful RCT, preference-based trials are attractive in this regard.

A systematic review and meta-analysis by Wasmann et al (2019) reported that the participation rate in preference trials is higher than RCTs; higher education, female patients, age and prior experience with the treatment arm were common characteristics of patients declining randomisation in RCTs. Loss to follow up and cross over was also higher in RCTs and primary outcomes were comparable between both RCTs and Preference Trials.

Another review by Group and McPherson (2009) reported a higher treatment effect in patients who had their preferred treatment in comparison to patients who had no preference. Participants allocated to undesired treatments had outcomes similar to participants who were indifferent about their

preferences, and no difference was found in attrition levels. The increased treatment effect size in preference groups was estimated to be a genuine effect in the sense that treatments work better among patients who got their desired treatment.

The patient preference RCT design by Brewin and Bradley (1989) gives the option for patients with preferences to be allocated to their choice of intervention and the ones with no preferences to be randomised the usual way.

In this method, there is at least one comparison conducted between the randomised arms alone. But it does lead to a need for a higher sample size as the study will have four distinct groups (shown in Figure 10). There needs to be comparison between the characteristics of individuals who choose to be randomised versus the individuals who have preferences, between the intervention and control groups in each arm and between the intervention groups of both arms. Though it is a statistically complex design, there is a potential for rich data collection that can aid clinicians and patients alike.

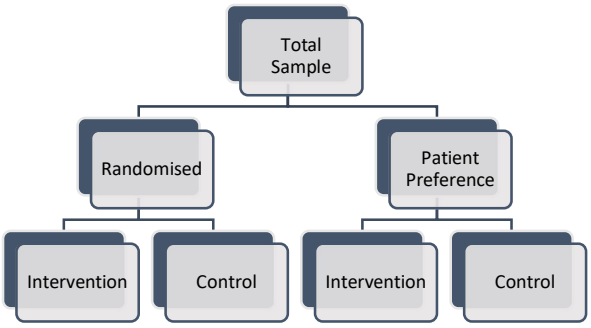


Figure 10: Patient Preference Trials

A patient preference trial complements randomised trials but does not completely replace them. It has many advantages. It aids in recruiting patients who otherwise would not be part of the trial due to randomisation. Secondly, as these account for patient preferences, it helps establish the external validity of the intervention being evaluated. This data can potentially be useful for clinicians who are attempting to understand why some interventions are preferred or have higher compliance over others.

The limitations of preference trials are that not randomising individuals fails to take into account confounding factors. Also, patient preferences can change with time, and clinicians may play a role in the decision making of the patient. Lastly, it is very difficult to predict patient behaviour with respect

to choosing which arm they would like to go ahead with, leading to unpredictable time and costs. A short term pilot study is required to determine this information prior to a complete patient preference trial (Howard & Thornicroft, 2006).

In the context of mental health Howard and Thornicroft (2006) have suggested that although it is inconclusive whether preference has an effect on outcomes, data from patient preference trials can be useful in evaluating mental health services as this is an area with complex interventions where preferences play a strong role in compliance and retention.

Although many doctors believe the results to be inferior to RCTs, patient preference trials give doctors key information including evidence of no harm and evidence of extent of benefit, that will help them in their practice. They show which interventions are more likely to be accepted by patients and the characteristics of patients who prefer one intervention in comparison to the other. An intervention may work well in an RCT but if there is no willingness to engage in the intervention following the RCT, the RCT would be a loss of money and time as it takes several years and large amounts of healthcare research costs to be completed. Medicine is now focusing on patient centric care and shared decision making. We need to know if what we design will be accepted by patients.

12.6 FUTURE RESEARCH

For future research in this subject, I suggest a three-step process to be followed. Step 1 and 2 form part of the short-term plan and Step 3 is a long-term plan.

12.6.1 Short Term and Long-Term Plans

In the short term, there is nothing substantial that can be done by me to make a trial work in India. The cultural norms and expectations are not easy to overcome in the short term. Educating doctors is particularly difficult if one is not a doctor themselves. A scenario in which doctors may get interested in this research is if I am awarded a large grant that will give them the platform for research and publicity. It might be possible to then design a research addressing cultural barriers and run a trial. At this stage of my career, this is highly unlikely. In the short term, arguably, the research would be better situated in the UK. The doctors have a higher knowledge level, there are no cultural norms to fight against, doctors are in favour of the research and willing to support a study.

Step 1 and 2 below form part of my short-term plan.

In the long term, once I have a stronger academic and research career, I aim to apply for grants and funding that will allow me to would move to Step 3- both in India and the UK. Also, in reflection, if I

started this study again, I would have gone for a preference design to begin with and hence that is what I am proposing here.

12.6.2 Step 1: Improve awareness about the topic

It is important to increase awareness about Yoga and pregnancy amongst the clinical staff, patients and family members. Writing papers in obstetric journals and presenting at obstetric conferences, starting with the Systematic Review that was conducted as part of this thesis, will be the first step in increasing awareness. Writing joint CPD papers with my PhD supervisor is a parallel path to follow.

A third option is to try and enable access to Yoga sessions for the hospital staff. It can be a method of improving the wellbeing of the doctors. It has been discussed previously that doctors with experience of Yoga practice were more open to the practice. Giving the doctors a chance to experience Yoga sessions for themselves, can help in improving acceptance of the practice while improving their wellbeing at the same time. As I have a start-up in India that works in the area of maternity wellness, I can use that medium to enable access to Yoga sessions in India while I parallelly work with doctors in the UK. It will be an efficient use of my time and resources.

To improve awareness among patients and family members, creating visually attractive material in the form of leaflets, waiting room posters, videos and workshops will be useful. Adding a short section of prenatal Yoga during the existing antenatal classes will be the quickest first step in this direction. This option was reiterated by the doctors as an ideal next step during the interviews. The information needs to be easily comprehensible and created in collaboration with the doctors. Involving the doctors in creation of and approval of the material will give them the confidence to disseminate it amongst their patients. Testimonials from women who participate in prenatal Yoga in social media pages of the hospital will help spread awareness and create publicity. All the strategies discussed in this paragraph can also be conducted parallelly in India and the UK. As there is no research data collection at this stage, there will be no conflict of interest between the start-up and my academic work.

12.6.3 Step 2: Pilot Yoga sessions in Hospitals for Patients

On the basis of how Step 1 goes, I can make a decision as to which location would be preferable for Step 2- India or the UK. In an ideal situation, I would like to do a cross-country study where a doctor can be the chief investigator in India and I can lead the study in the UK with the support of a midwifery unit.

If I can find a doctor who is interested in this topic, along with sessions for doctors, piloting sessions for the patients in that unit will be the second step. As part of this step, I will work on further public

education as once the doctors have better knowledge, they can talk to the patients in a different way about Yoga. For this, I will use the health education resources used in Step1, such as reading material, booklets and videos to support these conversations.

An important conversation to have with the doctors is how they would like to sell Yoga to their patients. Whether as an exercise that can support labour and birth, and physical outcomes, or whether they would like to approach the mental health conversation. Unless I can find a doctor, who champions mental health awareness and outcomes, it will be tactical to start with research focusing on physical outcomes as in Chapters 10 and 11, it was recognised that obstetricians prioritise physical outcomes.

In India, it is very important for the message to be conveyed by the doctor as the family trusts the doctor's decision. If doctors communicate the suggested benefits and ask the women to join a study, the chances of family members being supportive are higher. Without the support of the family members, it will be almost impossible for such research to be successful.

While conducting the pilot sessions for the patients, it will be beneficial to set up a reporting system for doctors to use to report any negative effects or harms due to Yoga. This will be an effective method to prove no harm from the practice. In conversation with obstetricians and midwives if this still seems necessary after steps 1 and 2, in Step 3, I have designed a preference trial to be conducted in India and the UK, along the lines that the doctors at UHCW proposed.

12.6.4 Step 3: Conduct a Pilot Preference Trial

In the subject area of Yoga and pregnancy, a preference trial is potentially the best midway option between an RCT and other research designs. Although it is statistically complex, the benefits of a preference trial discussed above make it the best design to prove the efficacy and efficiency of the intervention. I suggest that a grant is applied for which would allow for a preference trial. If resources permit, a bi-country pilot would be a direction to pursue.

The priority however, would be to conduct a pilot study on a simpler format of the preference trial design in India, preferably in the same hospital. If we can go further, the same is to be duplicated in the UK. As discussed before, there has been interest expressed by clinicians in the UK to run a study on Yoga and pregnancy. They know and understand the effects of stress on the mother and baby and are willing to explore solutions to address the same.

This pilot study design will reflect the benefits of Yoga on Blood Pressure During Pregnancy. In literature, the effect of mental health on preeclampsia was reviewed and hypertension was an area

of interest among the clinicians during the focus group discussion, and preeclampsia and hypertension are prevalent in India.

My thesis has been focused on mental health but through the course of the last 4 years, I have recognised that, to involve clinicians and engage them to play an active role in the study, it is important to have a physiological outcome as a primary outcome followed by mental health as a secondary outcome. In this study, variations in blood pressure levels of mothers during pregnancy will be the primary outcome measure followed by changes in mental wellbeing as one of the secondary outcomes. In this way, it is a win-win situation for everyone involved.

In terms of the sample population, for this study, I suggest that all pregnant women are considered. This is in contrast to the feasibility study I conducted for my thesis where I focused on women pregnant post infertility treatments. I believe that in the current circumstances, it is important to establish evidence of benefit of Yoga during pregnancy. Restricting the population will make it increasingly difficult to conduct a study.

All pregnant women undergo blood pressure checks during their antenatal check-ups, making it easy to record and monitor the impact of Yoga practice. As a pilot study, along with checking the impact of Yoga, it is important to investigate the following: which form of Yoga delivery is preferred by women, and which works best, or if there is a difference between them at all. Unlike the full preference trial where there is a randomised arm, in this short-term pilot study, there is only a preference arm.

As shown in Figure 11, the study design is a preference trial where women can choose to be on one of three arms. The first decision is their preference of wanting to do Yoga or not. The women who choose not to participate form the control group, i.e., Group 2. If they choose to participate, i.e., Group 1, they have two options; a weekly group class at the hospital (1a) or a maximum of three one-to-one sessions combined with self-practice at home (1b). To mimic trials conducted in other countries, a 10-week intervention period is suggested. This trial design will allow for multiple comparisons between Yoga and controls, and within the two Yoga groups as well.

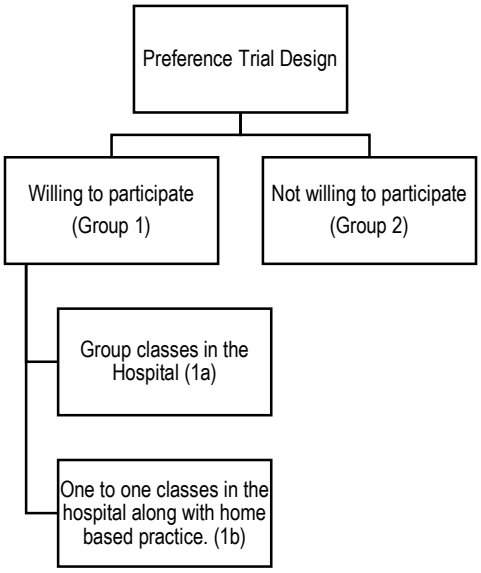


Figure 11: Preference Trial Design

The quantitative outcomes to be measured will be:

1) Blood pressure levels throughout the intervention period
2) Diagnosis of Preeclampsia
3) Preference rates between Yoga and standard care, and between the two intervention delivery options
4) Mental wellbeing through WEMWBS

The qualitative outcomes to be measured will be:

1) Reasons for no participation
2) Reasons for dropouts
3) Reason for choice of intervention delivery option

For this study, a minimum of three members will be required. A doctor/midwife who will recruit patients into the study, a Yoga instructor who will conduct classes in the hospital (group and one on one) and a researcher who will collect and analyse all the data. Irrespective of location, the direct involvement of the doctor/midwife in recruitment and the pre-recruitment groundwork of spreading awareness about this topic will be crucial to success of the trial.

I would suggest that it be conducted in the form of a short term 6-month study where two months are used for recruitment and four months are allocated for the intervention. From a practical standpoint, the group sessions would start on a fixed date and be held on weekends to increase the potential of

working women joining the study. The one-on-one sessions can be booked along with their antenatal appointments. If they do not have an antenatal appointment within four weeks, a separate appointment for the one-on-one session will be made. Group 1b will be given a diary to record number and duration of practice sessions.

This study can potentially deliver multiple results on both evidence of benefit of Yoga practice, and the potential practicality of attending sessions or continuing self-practice from the perspective of a patient. There are other variables that can be looked at like mode of delivery, gestational age, birth weight etcetera, depending on the research team priorities. The above-mentioned variables do not require additional steps as it will be taken from birth records, like the blood pressure figures, and will add value to the results. A pilot study looking into all these variables, in the above-mentioned preference trial manner, has not been conducted until now and will be a novel approach with potentially practical results. The next chapter concludes this thesis.

13 CONCLUSION

This PhD thesis looked into the feasibility of conducting a trial in India, investigating the effect of Yoga among pregnant women who conceived after infertility treatments. The study used mixed methods including a feasibility trial and qualitative studies investigating the outcomes of the trial.

The conclusion of these studies is that many hurdles would need to be overcome before an RCT of Yoga in pregnancy could be run in India. They uncovered multiple external factors that influence participation in trials, especially in India. These factors would need to be tackled either prior to, or during the design and recruitment, for a trial to be successful.

Although it is well established that women in this particular population experience mental health problems and that there is short- and long-term effects of these mental health problems on the mother and the baby, this information is not widely appreciated among either patients or doctors in India. As a result, there is little incentive to establish research on solutions. At the same time there is a strong prevalent belief in the general public that exercise is harmful in pregnancy. Pregnant women in India have limited autonomy and agency and even those who were interested in Yoga met with strong family opposition. There is also considerable public suspicion of research in general and stigma involved in research addressing mental health.

In order for an RCT of Yoga in pregnancy post infertility to be feasible there is a need for professional education about mental health in pregnancy and the potential role of Yoga as a solution, and public education about the value of exercise in pregnancy, and the safety and importance of clinical research. All family members would need to be involved in recruitment which would ideally be done by obstetricians involved in the women's care. Designing a trial with obstetric and physical health outcomes as the focus of interest and measuring mental health as a secondary outcome might help to overcome the stigma related to mental health.

In comparison to India, UK doctors recognise the impact caused by mental health problems in pregnancy and appreciate the need for interventions to reduce potential negative effects. Currently, Cognitive Behavioural Therapy (CBT) is the preferred first line of treatment. Although there is reasonable evidence that Yoga provides both mental and physical health benefits in pregnancy, the potential value of Yoga is not well known. Doctors who had participated in Yoga classes themselves were better informed and more interested in Yoga for their patients than those who had not. In general, they were more interested in understanding the evidence of benefit of Yoga on physiological outcomes as compared to mental health outcomes.

RCT's are still the preferred style of research for high quality evidence amongst doctors, but there was some interest among UK doctors in other approaches including cohort studies. The doctors in the UK study were influenced by the results of the systematic review I presented, and some changed their views on the value of Yoga in pregnancy. The importance of evidence showing no harm from Yoga was reiterated several times and this evidence was thought to be sufficient to respond positively to patients who asked about the safety of Yoga in pregnancy. But many doctors felt RCT evidence of benefits was necessary for them to actively advocate Yoga.

RCTs can present problems for health promoting interventions like Yoga and preference trials may be a better design. A study focusing on Yoga as a physical activity and looking at obstetric risk factors, such as hypertension, as primary outcomes, and mental health issues as secondary outcomes, might be easier to run. Collaboration with doctors and midwives, especially their involvement in recruitment, would make a difference to feasibility.

The evidence on the benefits of Yoga and pregnancy is growing but more research on different sub populations depending on mode of conception, effect on co-morbidities, and influence of mental health outcomes on physical outcomes, are needed.

With the learnings of this thesis, I have suggested a three-step process to approach this need. The process is inclusive of patients and care providers. The steps are building awareness, health education and a pilot preference trial on the effect of Yoga on blood pressure during pregnancy.

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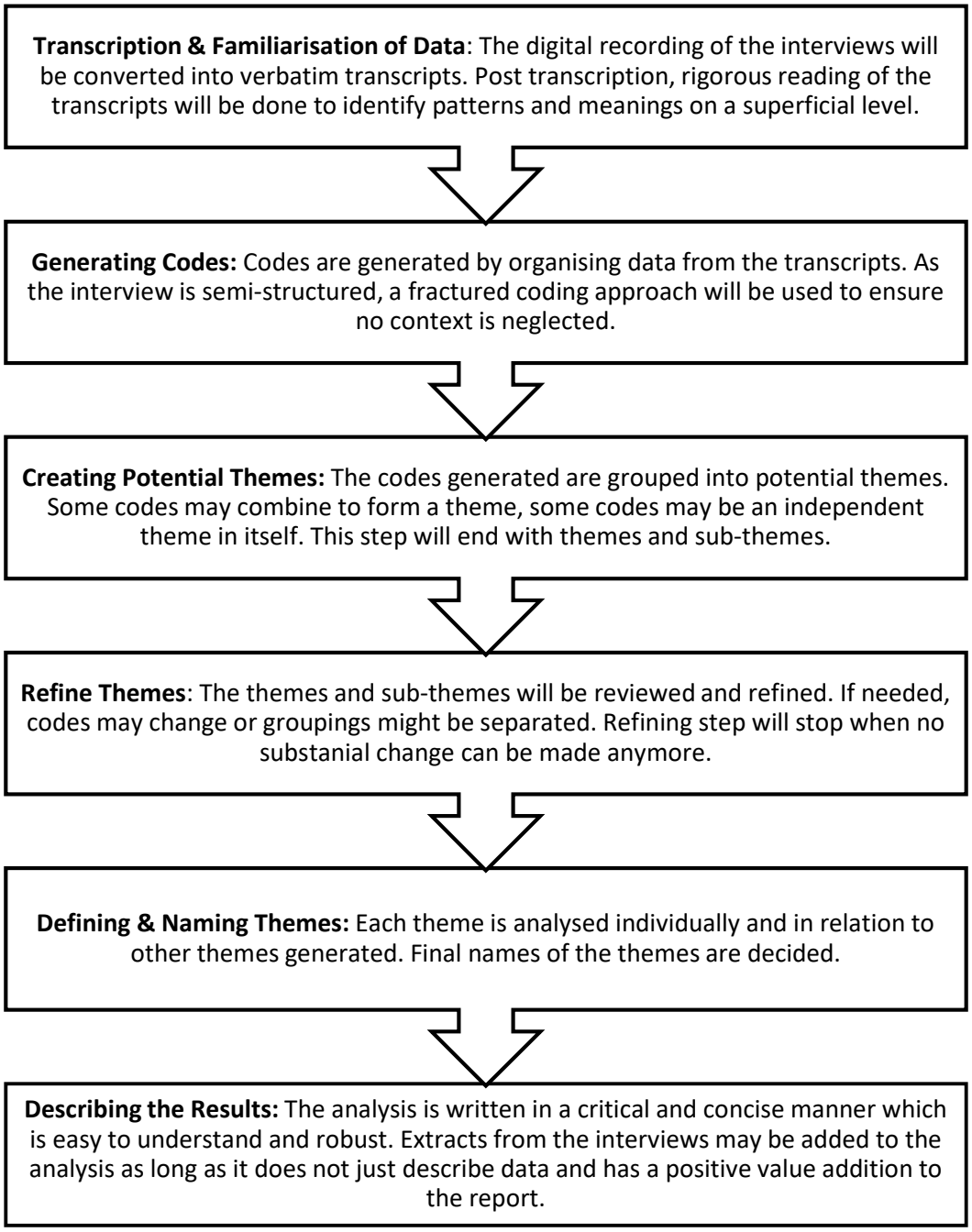
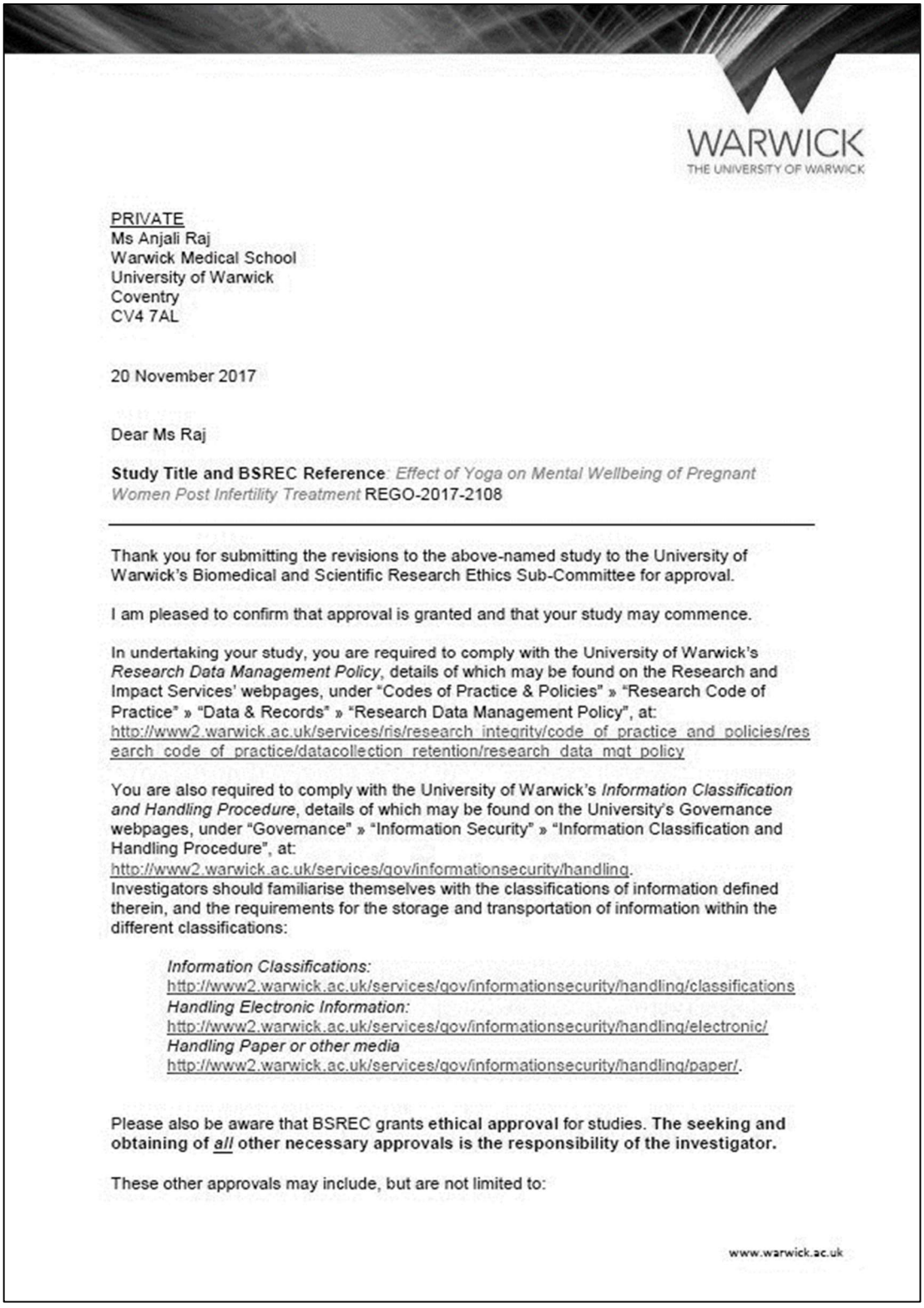
15 APPENDIX

15.1 STAGES OF THEMATIC ANALYSIS



15.2 BSREC APPROVAL – WARWICK MEDICAL SCHOOL



WARWICK
THE UNIVERSITY OF WARWICK

PRIVATE
Ms Anjali Raj
Warwick Medical School
University of Warwick
Coventry
CV4 7AL

20 November 2017

Dear Ms Raj

Study Title and BSREC Reference: *Effect of Yoga on Mental Wellbeing of Pregnant Women Post Infertility Treatment* REGO-2017-2108

Thank you for submitting the revisions to the above-named study to the University of Warwick's Biomedical and Scientific Research Ethics Sub-Committee for approval.

I am pleased to confirm that approval is granted and that your study may commence.

In undertaking your study, you are required to comply with the University of Warwick's *Research Data Management Policy*, details of which may be found on the Research and Impact Services' webpages, under "Codes of Practice & Policies" » "Research Code of Practice" » "Data & Records" » "Research Data Management Policy", at:
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http://www2.warwick.ac.uk/services/gov/informationsecurity/handling.
Investigators should familiarise themselves with the classifications of information defined therein, and the requirements for the storage and transportation of information within the different classifications:

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http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/paper/.

Please also be aware that BSREC grants **ethical approval** for studies. **The seeking and obtaining of *all* other necessary approvals is the responsibility of the investigator.**

These other approvals may include, but are not limited to:

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1. Any necessary agreements, approvals, or permissions required in order to comply with the University of Warwick's Financial Regulations and Procedures.
2. Any necessary approval or permission required in order to comply with the University of Warwick's Quality Management System and Standard Operating Procedures for the governance, acquisition, storage, use, and disposal of human samples for research.
3. All relevant University, Faculty, and Divisional/Departmental approvals, if an employee or student of the University of Warwick.
4. Approval from the applicant's academic supervisor and course/module leader (as appropriate), if a student of the University of Warwick.
5. NHS Trust R&D Management Approval, for research studies undertaken in NHS Trusts.
6. NHS Trust Clinical Audit Approval, for clinical audit studies undertaken in NHS Trusts.
7. Approval from Departmental or Divisional Heads, as required under local procedures, within Health and Social Care organisations hosting the study.
8. Local ethical approval for studies undertaken overseas, or in other HE institutions in the UK.
9. Approval from Heads (or delegates thereof) of UK Medical Schools, for studies involving medical students as participants.
10. Permission from Warwick Medical School to access medical students or medical student data for research or evaluation purposes.
11. NHS Trust Caldicott Guardian Approval, for studies where identifiable data is being transferred outside of the direct clinical care team. Individual NHS Trust procedures vary in their implementation of Caldicott guidance, and local guidance must be sought.
12. Any other approval required by the institution hosting the study, or by the applicant's employer.

There is no requirement to supply documentary evidence of any of the above to BSREC, but applicants should hold such evidence in their Study Master File for University of Warwick auditing and monitoring purposes. You may be required to supply evidence of any necessary approvals to other University functions, e.g. The Finance Office, Research & Impact Services (RIS), or your Department/School.

May I take this opportunity to wish you success with your study, and to remind you that any Substantial Amendments to your study require approval from BSREC before they may be implemented.

Yours sincerely

pp. [redacted]

Dr David Ellard
Chair
Biomedical and Scientific
Research Ethics Sub-Committee

Biomedical and Scientific
Research Ethics Sub-Committee
Research & Impact Services
University of Warwick
Coventry, CV4 8UW.
E: BSREC@Warwick.ac.uk

http://www2.warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/biomed

15.3 BSREC APPROVAL- FERNANDEZ HOSPITAL

FERNANDEZ HOSPITAL
Health Care for Women & Newborn

Date: 14th February, 2018

To
Ms. Anjali Raj
PhD student
University of Warwick, UK

Sub: Protocol Titled **"Effect of Yoga on Mental Wellbeing of Pregnant Women Post Infertility Treatment- A Feasibility Study", EC Ref # 31_2017**

Dear **Ms. Anjali,**

We have received the following documents:

1. Protocol Titled **"Effect of Yoga on Mental Wellbeing of Pregnant Women Post Infertility Treatment- A Feasibility Study", EC Ref # 31_2017**
2. Consent Form and Patient Information Leaflet in English
3. Questionnaire Booklet (4 Questionnaires)
4. Safe Yoga Postures by Polis et al., (2015)
5. Scientific Committee Approval Letter
6. Scientific Committee Summary

At the Ethics committee meeting held on **Friday, 19th January, 2018 at 8 am, Ground Floor, LJF Block. Abids,** the above mentioned documents were reviewed. Further to their suggestions, your revised documents were resubmitted online. After consideration, the committee has decided to approve the study for a period of one-year only.

Please note:

a) Any amendments in the protocol must be promptly informed to the Ethics committee and new approval of the protocol has to be taken.

b) Any serious adverse event must be reported to the ethics committee within 48 hours in writing.

c) Any advertisement placed in the newspapers, magazines must be submitted for approval.

d) Your project will be due for renewal in February 2019.

e) You are requested to submit the interim report at 6 months to evaluate the rate for complications if any.

f) Any deviations /violation from the protocol has to be reported to the ethics committee.

It is hereby confirmed that neither you nor any of the members of the study team participated in the decision making / voting procedures.

Please quote the **EC Reference No. 31_2017** in all future correspondence. Best wishes from the Committee for the success of this project.

Yours sincerely,

[redacted]

Dr. Kameswari S., FRCOG
Member Secretary
Ethics Committee

NABH Accredited
Awarded to Units 1 & 2

Fernandez Hospital Pvt. Ltd. (Regd. Office), 4-1-1229/1, Bogulkunta, Hyderabad – 500001. Telangana, India.
Fax : +91 40 24753482 Email : info@fernandezhospital.com Web : www.fernandezhospital.com
Centralized Tel. No. : +91 40 40222300 CIN No. U85110TG1991PTC013233

Certified No. M - 0831
NABL ACCREDITED

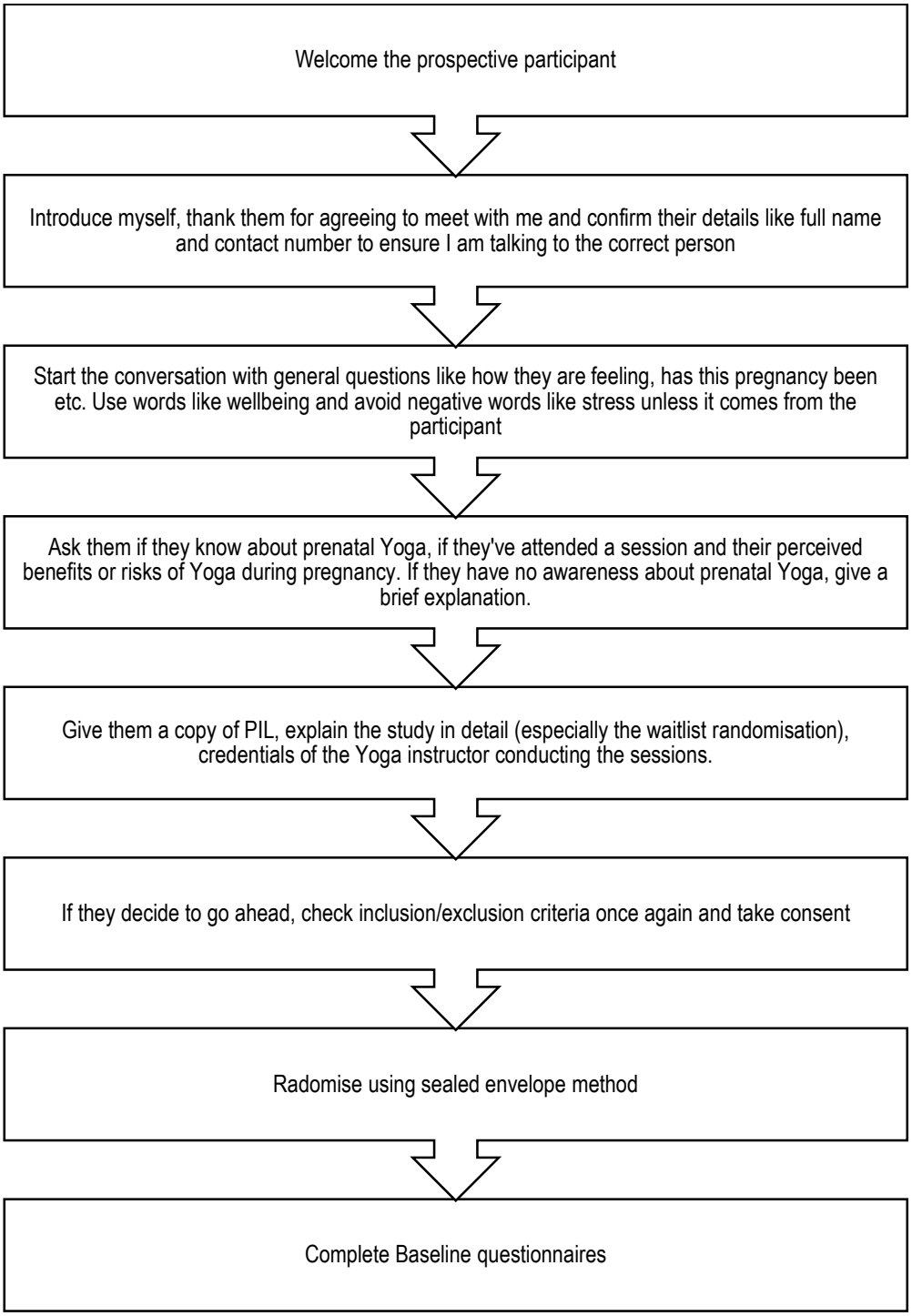
UNIT 1 – BOGULKUNTA
4-1-1230, Off Abid Road,
Bogulkunta, Hyderabad – 500001

UNIT 2 – HYDERGUDA
3-6-282, Opp. Old MLA Quarters,
Hyderguda, Hyderabad – 500029

UNIT 3 – JUBILEE HILLS
Plot 769, Road 44, Jubilee Hills,
Hyderabad – 500033

UNIT 4 – HYDERGUDA
3-5-874/1, Opp. Toyota Showroom,
Hyderguda, Hyderabad – 500029

15.4 CONSENT TAKING PROCESS



15.5 PARTICIPATION INFORMATION LEAFLET- FEASIBILITY STUDY

Participant Information Leaflet

Study Title:	Effect of Yoga on mental wellbeing and stress level of pregnant women post infertility treatments- Feasibility Study
Investigator(s):	Anjali Raj

Introduction

You are invited to take part in a study. Before you decide, you need to understand why the study is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

(Part 1 tells you the purpose of the study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study)

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

What is the study about?

In this study, we are trying to study the effect of yoga on mental wellbeing and stress levels of pregnant

women. We are trying to establish whether it is feasible to undertake a controlled trial of Yoga as a complementary method to aid women in having a stress-free and happy pregnancy asking questions like do women want to take part, how do they feel about the experience of the Yoga classes and also about taking part in the research

Do I have to take part?

It is entirely up to you to decide. We will describe the study and go through this information sheet, which we will give you to keep. If you choose to participate, we will ask you to sign a consent form to confirm that you have agreed to take part. You will be free to withdraw at any time, without giving a reason and this will not affect you or your circumstances in any way.

What will happen to me if I take part?

If you consent to the study, you will be randomly assigned to either the Group A- or Group B. The randomization will be done through a sealed envelope method to avoid bias and errors. Both groups will be asked to complete a number of questionnaires. Total time commitment to fill the questionnaires is 15 minutes. In the 60-minute session, 10 minutes are allotted to group discussion. On the 5th and 10th session, the questionnaires will be given at that time to ensure minimum additional time post their 60 minutes.

Group A will be assigned to a prenatal group yoga class starting straight away. The yoga class will run once a week for 10 weeks. A handout will be given to you to record home practice of prenatal yoga. If you also consent for interview, you will be interviewed after the completion of the yoga class

Group B will be assigned to a Yoga class starting 10 weeks after recruitment. The yoga class will run once a week for 10 weeks. A handout will be given you to record home practice of prenatal yoga. If you have consented for interview you will be interviewed after the completion of the yoga intervention.

After the birth of the baby, the baby's birth weight and mode of delivery will be recorded from their medical records and you will be asked to complete a few simpler quick questionnaires.

What are the possible disadvantages, side effects, risks, and/or discomforts of taking part in this study?

Yoga during pregnancy has been proven to be safe under guidance of a certified yoga instructor. All routines used during this study have been researched and authenticated as safe. However, in case the participant develops any discomfort, they will be given immediate medical care and can withdraw from the study as per their decision.

What are the possible benefits of taking part in this study?

This study aims at enabling benefits of Yoga to improve mental wellbeing of women going through a stressful time to be studies. By participating in this study, you are aiding in creating evidence-based programs for the wellbeing of women and their babies.

Expenses and payments

There is no extra incentive- monetary or otherwise, provided to the participants. The yoga classes are offered free of charge.

What will happen when the study ends?

Once the study ends, the data will be used for analysis and post consolidation of results, any identifiable data (the link between the patient name and participant study code number) will be deleted after a period of 6 months. Post 6 months, if the participant decides to withdraw, they will have to provide the participant study code number.

Will my taking part be kept confidential?

Yes. We will follow strict ethical and legal practice and all information about you will be handled in confidence. Further details are included in Part 2.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm that you might suffer will be addressed. Detailed information is given in Part 2.

This concludes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

Who is organising and funding the study?

The study is being organised and funded by the University of Warwick, UK.

What will happen if I don't want to carry on being part of the study?

Participation in this study is entirely voluntary. Refusal to participate will not affect you in any way. If you decide to take part in the study, you will need to sign a consent form, which states that you have given your consent to participate.

If you agree to participate, you may nevertheless withdraw from the study at any time without affecting you in any way. You have the right to withdraw from the study completely and decline any further contact by study staff after you withdraw.

Withdrawal from the study will not affect your usual hospital care or any benefits to which you would otherwise be entitled.

What if there is a problem?

This study is covered by the University of Warwick's insurance and indemnity cover. If you have an issue, please contact the Chief Investigator of the study:

Name: Sarah Stewart Brown

Email address: Sarah.Stewart-Brown@warwick.ac.uk

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study

Head of Research Governance

Research & Impact Services

University House

University of Warwick

Coventry

CV4 8UW

Tel: 024 76 522746

Email: researchgovernance@warwick.ac.uk

Will my taking part be kept confidential?

The data collected, including participation preference will be completely confidential. Every participant will be allocated a code known only to the researcher. All data will be linked to a code to maintain patient confidentiality. Unless a legal issue arises, the hospital authorities will have no access to your questionnaires or responses. The data will be secure in a digital format within the University of Warwick server.

What will happen to the results of the study?

After the study is complete, the consolidated results of this study will be used for the following:

1. Publish academic papers
2. Abstracts/Posters in conferences
3. Magazine/Newspaper articles
4. Hospital media communications

If you would like a copy of the results, you could request for that while filling up the consent form.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC): REGO-2017-2108 (Approval Granted on 20 November 2017) & Fernandez Hospital BSREC in January 2018.

What if I want more information about the study?

If you have any questions about any aspect of the study, or your participation in it, not answered by this participant information leaflet, please contact:

Anjali Raj

[redacted]uk

Sarah Stewart Brown

[redacted]

Siobhan Quenby

[redacted]

Thank you for taking the time to read this participant information leaflet.

15.6 CONSENT FORM- FEASIBILITY STUDY

Study Consent Form

Patient Identification Number for this study:

Title of Project: Effect of Yoga on mental wellbeing of pregnant women post infertility treatments- Feasibility Study

Name of Researcher(s): Anjali Raj

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 02/09/2017 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

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

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from The University of Warwick, from the hospital authorities, where it is relevant to my taking part in this study. I give permission for these individuals to have access to my records. ☐

    a. Mode of delivery- vaginal or c-section

    b. Gestational age and birth weight of baby

4. I agree to take part in the qualitative part of the above study. The interviews will be conducted during your subsequent antenatal visit to the hospital after the 10th week intervention session. ☐

5. I would like a copy of the study results to be sent to ☐

_____

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

15.7 DEMOGRAPHIC QUESTIONNAIRE

Demographic Questionnaire

Participant ID:

(For the following, please tick the relevant option)

A. Age of the Participant:
    1. <20
    2. 21-25
    3. 26-30
    4. 31-35
    5. >36

B. Highest Education Level
    1. High School
    2. Diploma
    3. Vocational Training
    4. Bachelors
    5. Masters
    6. Doctorate

C. Marital Status

1. Single
2. Married
3. Divorced

D. Employment Status

1. Student
2. Homemaker
3. Employed
4. Self Employed
5. Other (please specify) _____

E. Prior Experience of Yoga

1. Yes

   If Yes,

   a. How many years? _____
   b. Are you currently practising? _____
2. No

F. Current Lifestyle

1. Very Active (On your feet for greater than 4 hours a day)
2. Active (On your feet for 3-4 hours a day)
3. Sedentary (Predominantly desk bound)

G. Are you on a specific diet?

1. If Yes,
   i. Given by a nutritionist
   ii. Self-prescribed
2. No

Any other information you would like to give us?

_____
_____
_____
_____

Signature of Participant

15.8 EDINBURGH POSTNATAL DEPRESSION SCORE

We would like to know how you are feeling. Please tick the answer that comes closes to how you have felt in the PAST 7 DAYS, not just how you feel today

In the past 7 days:

1. I have been able to laugh and see the funny side of things
    a. As much as I always could
    b. Not quite so much now
    c. Definitely not so much now
    d. Not at all

2. I have looked forward with enjoyment to things
    a. As much as I ever did
    b. Rather less than I used to
    c. Definitely less than I used to
    d. Hardly at all

3. I have blamed myself unnecessarily when things went wrong
    a. Yes, most of the time
    b. Yes, some of the time

c. Not very often
d. No, never

4. I have been anxious or worried for no good reason
    a. No, not at all
    b. Hardly ever
    c. Yes, sometimes
    d. Yes, very often

5. I have felt scared or panicky for no good reason
    a. Yes, quite a lot
    b. Yes, sometimes
    c. No, not much
    d. No, not at all

6. Things have been getting on top of me
    a. Yes, most of the time I haven't been able to cope at all
    b. Yes, sometimes I haven't been coping as well as usual
    c. No, most of the time I have coped quite well
    d. No, I have been coping as well as ever
7. I have been so unhappy that I have had difficulty sleeping
    a. Yes, most of the time
    b. Yes, sometimes
    c. Not very often
    d. No, not at all

8. I have felt sad or miserable
    a. Yes, most of the time
    b. Yes, quite often
    c. Not very often
    d. No, not at all

9. I have been so unhappy that I have been crying
    a. Yes, most of the time
    b. Yes, quite often
    c. Only occasionally
    d. No, never

10. The thought of harming myself has occurred to me
    a. Yes, quite often
    b. Sometimes
    c. Hardly ever
    d. Never

15.9 WARWICK EDINBURGH MENTAL WELLBEING SCALE

Below are some statements about feeling and thoughts. Please tick the box that best describes your experiences of each feeling/thought over last 2 weeks.

Statements	None of the Time	Rarely	Some of the Time	Often	All of the Time
I've been feeling optimistic about the future					
I've been feeling useful					
I've been feeling relaxed					
I've been feeling interested in other people					
I've had energy to spare					
I've been dealing with problems well					
I've been thinking clearly					
I've been feeling good about myself					

I've been feeling close to other people					
I've been feeling confident					
I've been able to make up my own mind about things					
I've been feeling loved					
I've been interested in new things					
I've been feeling cheerful					

15.10 PERCEIVED STRESS SCORE

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way.

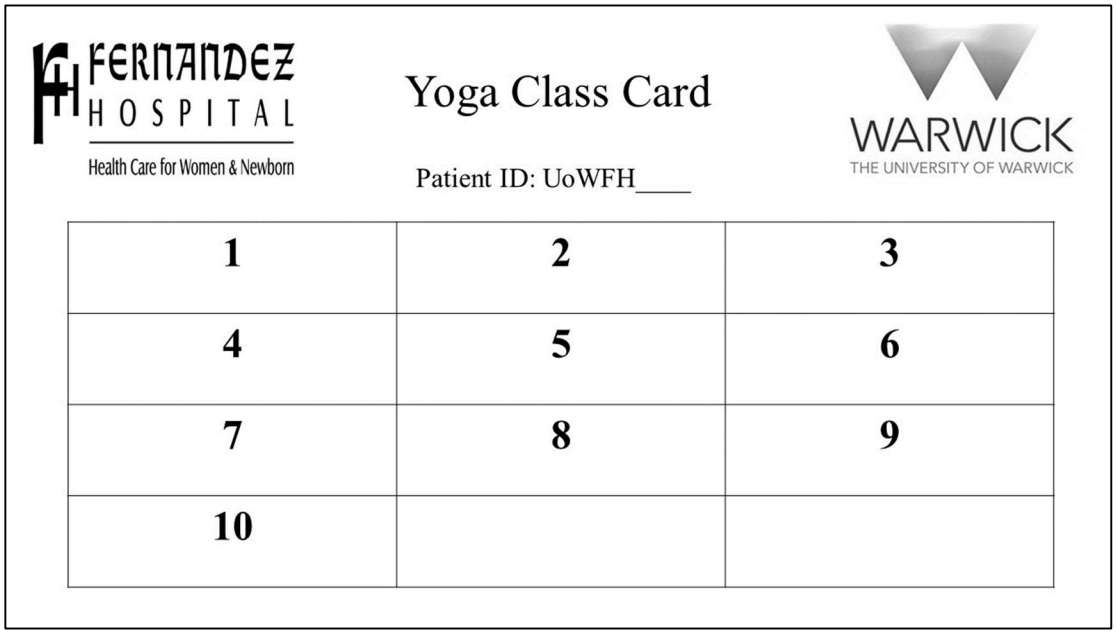
Please draw a X in the option you feel matched your feelings/thoughts.

0= Never 1= Almost Never 2= Sometimes 3=Fairly Often 4= Very Often

Sno.	Question	0	1	2	3	4
1	In the last month, how often have you been upset because of something that happened unexpectedly?					
2	In the last month, how often have you have you felt that you were unable to control the important things in your life?					
3	In the last month, how often have you felt nervous and “stressed”?					
4	In the last month, how often have you felt confident about your ability to handle personal problems?					
5	In the last month, how often have you felt that things were going your way?					
6	In the last month, how often have you could not cope with all the things that you had to do?					
7	In the last month, how often have you been able to control irritations in your life?					
8	In the last month, how often have you felt that you were on top of things?					

9	In the last month, how often have you been angered because of things that were outside your control?					
10	In the last month, how often have you felt that difficulties were piling up so high that you could not overcome them?					

15.11 YOGA CLASS CARD FOR PARTICIPANTS



15.12 RECRUITMENT PROCESS

1	Interested. To be met on 18th Feb at JH Unit between 1030-1130	**18th Feb**	17/02/2018	Call Made. Meeting at 11am confirmed	18-Feb	Consent Signed. Intervention group
2	Could not get through		12/02/2018	Interested. To meet in SH on 22nd	**18th Feb**	Did not pick up. Message Sent
3	Could not get through		12/02/2018	Message Sent. Husband Called and will meet on 18th JH	17/02/2018	Wife travelling. Not possible to attend.
4	Could not get through		12/02/2018	Message Sent	17/02/2018	No Response
5	Interested.To meet during Scan follow up HG	**21st Feb**	**18th Feb**	Reminder Call Made. Interested but will talk to husband and get back.	21/02/2018	Consent Signed. Control group
6	Interested.To meet during Scan follow up HG	**27th Feb**	26/02/2018	Reminder Call Made. Scan at 9:30am in HG Unit	27/02/2018	They came and met. Consent Signed. Intervention Group
7	Interested.To meet during Scan follow up JH	**24th Feb**	23/02/2018	Reminder Call Made. Scan at 240pm in JH Unit	24/02/2018	Consent Signed. Control group
8	Not Interested					
9	Not Interested					
10	Not Interested					
11	Could not get through		12/02/2018	Did not pick up phone. Message Sent	17/02/2018	No Response
12	Husband Picked Up. Will talk to wife and get back		12/02/2018	Message Sent. Husband will talk and get back.	17/02/2018	Reminder Message Sent
13	NA .Language Problem					
14	Will consult with husband. To call on Sunday	**18th Feb**	18/02/2018	Spoke to husband. Explained in detail. Not interested.		
15	Could not get through. Sent message	**18th Feb**	18/02/2018	No response	20/02/2018	No Response
16	Call got disconnected. Sent message.	**18th Feb**	18/02/2018	Call Made. Meeting confirmed at 11am on 24th HG Unit	23/02/3018	Reminder Call done. Meeting at 11am HG Unit
17	Not Interested					
18	Could not get through. 2 attempts made	**18th Feb**	18/02/2018	Call Made. Not interested.		
19	Interested. To meet during Scan follow up HG	**20th Feb**	**18th Feb**	Send Reminder to meet on 19th. They have postponed their consult appointment to 20th.	20/02/2018	No Show. No Response to Phone Calls
20	Interested. To meet during follow up in BG Unit on 28th	**28th Feb**	27/02/2018	Reminder Call made. Her appointmade preponed to 27th.	27/02/2018	Consent Signed. Intervention group
21	Interested. She will get back on appointment date by 19th.	**19th Feb**	19th Feb	Meeting set for 11:30am on 25th at JH Unit	24/02/2018	Reminder call done. Meeting at 11:30am on 25th at JH
22	She is located in Kurnool. Will not be able to participate					
23	Very Interested. Will meet at JH Unit on 25th for Consent	**24th Feb**	24/02/2018	Meeting set for 12:00 pm on 25th at JH Unit	25/02/2018	No Show. No Response to Phone Calls
24	Spoke to husband. Will ask wife to call back	**24th Feb**	24/02/2018	Husband took the call. They need time to decide.	26/02/2018	No Response
25	Will consult with husband. To call on Friday/Saturday	**23rd Feb**	23/02/2018	No response	24/02/2018	No Response. SMS Sent
26	No Response	**23rd Feb**	23/02/2018	No response	24/02/2018	No Response
27	Interested. Will meet on 25th for Consent at JH Unit	**24th Feb**	24/02/2018	Allotted a new project work. Cannot attend sessions.		
28	Not Interested					
29	Language Problem. Cannot speak/understand English					
30	Interested. Will call back on 19th to fix appointment for consent	**19th Feb**	**19th Feb**	Called back and fixed meeting on 24th at HG Unit	23/02/2018	Tried calling. Didn't get through. Reminder SMS sent
31	Living in another town away from Hyderabad					
32	Working hours. Not interested anyways					
33	Language Problem. Cannot speak/understand English					
34	Not reachable.	**23rd Feb**	23/02/2018	Not Interested in Yoga and working too		
35	Language Problem. Cannot speak/understand English					
36	Not reachable.	**23rd Feb**	23/02/2018	No response	24/02/2018	No Response

Recruitment calls to participants 1-36, Part 1 of 2

1						
2	23/02/2018	No Response	25/02/2018	No Response	26/02/2018	Travelling out of the country. NA
3						
4	20/02/2018	No Response	24/02/2018	Spoke to her. She will visit HG Unit on 27th	26/02/2018	No Response
5						
6						
7						
8						
9						
10						
11	23/02/2018	No Response	24/02/2018	No Response		
12	21/02/2018	Husband replied. Wife not interested.				
13						
14						
15	23/02/2018	No Response	24/02/2018	Husband picked up. Will consult wife and get back		
16	24/02/2018	Feeling unwell. Rescheduled to 27th	26/02/2018	Feeling unwell. Rescheduled to 28th HG Post Lunch	02/03/2018	Consent Signed. Intervention Group
17						
18						
19	23/02/2018	No Response	24/02/2018	Visited HG Unit and Signed Consent. Control Group		
20						
21	25/02/2018	Consent Signed. Intervention Group				
22						
23	26/02/2018	Cannot attend. Family commitments				
24	26/02/2018	No Response	28/02/2018	No Response		
25	26/02/2018	No Response	28/02/2018	No Response		
26	26/02/2018	No Response	28/02/2018	No Response		
27						
28						
29						
30	24/02/2018	Phone not reachable since 2 days	28/02/2018	Visited HG Unit. Consent Signed. Intervention Group		
31						
32						
33						
34						
35						
36	26/02/2018	No Response	28/02/2018	No Response		

Recruitment calls to participants 1-36, Part 2 of 2

37	No Response	24/03/2018	No Response	18/04/2018	No Response	25/04/2018	No Response	02/05/2018	No Response
38	Switched Off	24/03/2018	Switched Off	18/04/2018	Switched Off	25/04/2018	No Response	07/05/2018	No Response
39	Does not live in Hyderabad								
40	Does not live in Hyderabad								
41	Interested. Will consult with Husband and get back	24/03/2018	Language Problem, Cant speak English						
42	Interested. Will meet on Saturday 2pm	24/03/2018	Consent Signed. Control Group						
43	Not Interested. Working woman and unsupportive family regarding physical exercise								
44	Does not live in Hyderabad								
45	Does not live in Hyderabad								
46	Switched Off	24/03/2018	Interested. In 8th Week now. Will meet on April 20 at JH Unit for 12 week Scan	17/04/2018	Scan time to be informed on 19th	19/04/2018	Waited for 3 hours. Didn't turn up	20/04/2018	No Response
47	Switched Off	18/04/2018	Switched Off	18/04/2018	Switched Off	25/04/2018	Switched Off	07/05/2018	Switched Off
48	No Response	18/04/2018	Working at the moment. Shifts are unsupportive.						
49	Interested. Scan appointment on 7th May Hyderguda	06/05/2018	Appointment shifted to 12th May at Abids unit	11/05/2018	Called and said called cant make it.				
50	Interested. 12 week Scan appointment on 5th May Hyderguda at 10am.	04/05/2018	Appointment shifted to 7th May at 10am in Unit 4	07/05/2018	Appointment completed on 3rd May. Will meet on June 2nd in SH Unit	01/06/2018			
51	Switched Off	18/04/2018	No Response	25/04/2018	No Response	07/05/2018	No Response	11/05/2018	Switched Off
52	No Contact Info on File								
53	Interested. Currently 6 week scan going on. Need to contact after 4 weeks	07/05/2018	No Response	11/05/2018	No Response	14/05/2018			
54	Does not live in Hyderabad								
55	Switched Off	18/04/2018	Switched Off	25/04/2018	Switched Off	07/05/2018	Switched Off	11/05/2018	Switched Off
56	Language Problem. Lives away								
57	Not Interested.								
58	Working. Cant make it for the class.								
59	Interested. Will consult with Husband and get back	14/05/2018							
60	Switched Off	14/05/2018							
61	Interested. Will consult with Husband and get back	14/05/2018							

Recruitment calls to participants 37-61, Part 1 of 1

15.13 BSREC AMENDMENT APPROVAL- WARWICK MEDICAL SCHOOL

WARWICK
THE UNIVERSITY OF WARWICK

PRIVATE
Ms Anjali Raj
Warwick Medical School
University of Warwick
Coventry
CV4 7AL

Monday, 09 July 2018

Dear Ms Raj

Study Title and BSREC Reference: *Effect of Yoga on Mental Wellbeing of Pregnant Women Post Infertility Treatment* REGO-2017-2108

Thank you for submitting a substantial amendment application for the above-named project to the University of Warwick's Biomedical and Scientific Research Ethics Sub-Committee.

I am pleased to confirm that the changes that you wish to make to this study have been approved.

Please keep a copy of the signed version of this letter with your study documentation.

Yours sincerely

pp. [redacted]

Dr David Ellard
Chair
Biomedical and Scientific
Research Ethics Sub-Committee

Biomedical and Scientific Research Ethics Sub-Committee
Research & Impact Services
University of Warwick
Coventry, CV4 8UW.
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http://www2.warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/biomed

www.warwick.ac.uk

15.14 BSREC AMENDMENT APPROVAL- FERNANDEZ HOSPITAL

FERNANDEZ HOSPITAL
Health Care for Women & Newborn

Institutional Ethics Committee, Fernandez Hospital
Reg.No: ECR/933/Inst/TG/2017

Regd. Office: 4-1-1230, Fernandez Hospital, Bogulkunta, Hyderabad – 500001
T: +91 40 222460, F : +91 40 24753482, E : irb@fernandezhospital.com

Justice T.N.C. Rangarajan
Chairperson
Former Judge,
High Courts of Madras & A.P

Dr. Kameswari Surampudi
Member Secretary (Clinician)
Head, Department of Academics

Dr. Srinivas Samavedam
Member (Clinician)

Dr. Anupama Reddy
Member (Clinician)

Dr. Shanti Y.
Member (Clinician)

Mr. Kishore Kumar Vunnamatla
Member (Social Scientist)

Dr. Latha Sashi
Member (Scientific)

Ms. Rachna S. Waddepalli
Member (Lawyer)

Dr. Sarvothaman H.
Member (Scientific)

Dr. Sesikeran B.
Member (Basic Medical Scientist)

Dr. Shamanna Bindiganavale
Member (Clinician)

Ms Lakshmi Venuturupalli
Member (Layperson)

Date: 31st August, 2018

To
Ms. Anjali Raj
Researcher
Health Sciences
Warwick Medical SchoolUniversity of Warwick,Coventry, CV47AL

Sub: Protocol Titled "Effect of yoga on mental wellbeing of pregnant women post infertility treatment- A Feasibility Study." EC Ref No. 31_2017

Dear Ms.Anjali Raj,

We have received the following documents:

1. Amended Protocol (Version 1: date: 10.07.2018)
2. Consent Form in English (Appendix 10.1, Version 1: date: 10.07.2018)
3. Participant Information Sheet (Appendix 10.2, Version 1: date: 10.07.2018).
4. Demographic Questionnaire (Appendix 10.3, Version 1: date: 10.07.2018).
5. 26 Safe Yoga Postures by POLIS et. al., (2015)(Appendix 10.4, Version 1: date: 10.07.2018).
6. Invite E-mail for Interviews (Appendix 10.5, Version 1: date: 10.07.2018).
7. PIL -Interviews (Appendix 10.6, Version 1: date: 10.07.2018).
8. Consent Form Interviews (Appendix 10.7, Version 1: date: 10.07.2018).

At the Ethics committee meeting held on Friday, 31 August, 2018 at 8 am, LJF Block. Abids, the above mentioned documents were reviewed. After consideration, the committee has decided to approve the study.

Please note:

1. Any amendments in the protocol must be promptly informed to the Ethics committee and new approval of the protocol has to be taken.
2. Any serious adverse event must be reported to the ethics committee within 48 hours in writing.
3. Any advertisement placed in the newspapers, magazines must be submitted for approval.
4. You are requested to **submit the interim report at 6 months** to evaluate progress of study.
5. Any deviations /violation from the protocol has to be reported to the ethics committee.

It is hereby confirmed that neither you nor any of the members of the study team participated in the decision making / voting procedures.

Please quote the **EC Ref No. 31_2017** in all future correspondence. Best wishes from the Committee for the success of this project.

Yours sincerely,

[redacted]
Dr. Kameswari S.;
FRCOG Member
Secretary
Ethics Committee

FERNANDEZ HOSPITAL PVT. LTD. SCIENTIFIC COMMITTEE HYDERABAD 500 001

FERNANDEZ HOSPITAL PVT. LTD. ETHICS COMMITTEE HYDERABAD 500 001

15.15 PARTICIPATION INFORMATION LEAFLET- INTERVIEWS

Participant Information Leaflet- Interviews

dated 01/06/2018

Study Title:	Effect of Yoga on mental wellbeing of pregnant women post infertility treatments- Feasibility Study
Investigator(s):	Anjali Raj

Introduction

You are invited to take part in a study. Before you decide, you need to understand why the study is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

(Part 1 tells you the purpose of the study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study)

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

What is the study about?

We are interested in ways of reducing the stress levels of women who are pregnant after infertility treatment. This study is trying to establish whether it would be feasible to undertake a controlled trial of studying the effect of yoga on mental wellbeing and stress levels of pregnant women who have conceived post infertility treatments.

Do I have to take part?

It is entirely up to you to decide. We will describe the study and go through this information sheet, which we will give you to keep. If you choose to participate, we will ask you to sign a consent form to confirm that you have agreed to take part. You will be free to withdraw at any time, without giving a reason and this will not affect you or your circumstances in any way.

What will happen to me if I take part?

If you consent to the study, an interview will be scheduled at a timing of your convenience. The interview will be directed towards understanding your experience, opinions and beliefs on the topic.

The session will last approximately 20-30 minutes. The session will be audio recorded and the data will be completely confidential.

What are the possible disadvantages, side effects, risks, and/or discomforts of taking part in this study?

As a simple one on one interview, there are no known possible side effects, risks and/or discomforts from taking part.

What are the possible benefits of taking part in this study?

By participating in this study, you are aiding in creating evidence-based programs for the wellbeing of women and their babies.

Expenses and payments

There is no extra incentive- monetary or otherwise, provided to the participants.

What will happen when the study ends?

Once all the interviews are complete, the data will be analysed. Six months after analyses are completed any data of the interview that can be traced back to you will be deleted and data will be identified only by participant study code number. If you wish your data to be withdrawn at this stage you will need to provide me with this code number, which you will find on your consent form. .

Will my taking part be kept confidential?

Yes. We will follow strict ethical and legal practice and all information about you will be handled in confidence. Further details are included in Part 2.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm that you might suffer will be addressed. Detailed information is given in Part 2.

This concludes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

Who is organising and funding the study?

The study is being organised and funded by the University of Warwick, UK.

What will happen if I don't want to carry on being part of the study?

Participation in this study is entirely voluntary. Refusal to participate will not affect you in any way. If you decide to take part in the study, you will need to sign a consent form, which states that you have given your consent to participate.

If you agree to participate, you may nevertheless withdraw from the study at any time without affecting you in any way. You have the right to withdraw from the study completely and decline any further contact by study staff after you withdraw.

Withdrawal from the study will not affect your usual hospital care or any benefits to which you would otherwise be entitled.

What if there is a problem?

This study is covered by the University of Warwick's insurance and indemnity cover. If you have an issue, please contact the Chief Investigator of the study:

Name: Sarah Stewart Brown

Email address: Sarah.Stewart-Brown@warwick.ac.uk

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance

Research & Impact Services

University House

University of Warwick

Coventry

CV4 8UW

Tel: 024 76 522746

Email: researchgovernance@warwick.ac.uk

Will my taking part be kept confidential?

The data collected, including participation preference will be completely confidential. Every participant will be allocated a code known only to the researcher. All data will be linked to a code to maintain participant confidentiality. Unless a legal issue arises, the hospital authorities will have no access to your interview recordings. The data will be secure in a digital format within the University of Warwick server.

What will happen to the results of the study?

After the study is complete, the consolidated results of this study will be used for the following:

1. Publish academic papers
2. Abstracts/Posters in conferences
3. Magazine/Newspaper articles
4. Hospital media communications

If you would like a copy of the results, you could request for that while filling up the consent form.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC): REGO-2017-2108 (Approval Granted on 20 November 2017) & Fernandez Hospital BSREC in January 2018. The substantial amendment details

What if I want more information about the study?

If you have any questions about any aspect of the study, or your participation in it, not answered by this participant information leaflet, please contact:

Anjali Raj

[redacted]

[redacted]

Sarah Stewart Brown

[redacted]

Siobhan Quenby

[redacted]

Thank you for taking the time to read this participant information leaflet.

15.16 INTERVIEW QUESTIONS- DOCTORS

Stress Post ART

1. What are the issues you see facing women who conceive post ART In your opinion, what are the underlying causes for stress? (If stress doesn't come up, a secondary question to be asked)
2. Clinically speaking, what could be possible complications of high levels of stress among these women?
3. What do you currently advocate as a stress-reliever or stress buster?

Wellness

1. Is the term wellness useful in the context of pregnancy. If yes what does it mean to you?
2. What is your view on Yoga during pregnancy?
3. Open question if it hasn't come up in the previous one-What are the pros and cons of Yoga during ART induced pregnancy
4. How do you think Yoga can help women deal with stress and anxiety levels?
5. How do you think (using what they have said in the previous sentence) that works?
6. Have you experienced this happening with any of your patients?

Patient Behaviour

1. If they have come up with positives re Yoga in ART pregnancy, what sort of studies do you think should be done to research yoga in pregnancy and demonstrate benefits if there are any?
2. What do you think are the factors influencing recruitment to the study?
3. Do you think women would be more or less likely to come to a class which was not part of a trial?
4. What sort of level of adherence would you feel made provision of Yoga classes in the hospital worthwhile?
5. What are the likely reasons for high drop out?
6. What might improve things? (Probe on the family if it doesn't come up)

Interventions

1. What are possible interventions that can be done for this specific patient group?
2. What are key factors/people to be considered for success of the interventions?
3. What could be motivating factors to increase participation?
4. Do you think hospital-based interventions or external/at home interventions will work better?

General

1. Any other comments?

15.17 Interview Questions- Husbands

Stress Post ART

1. Can you tell me about any issues you as a couple, faced in this pregnancy? (Then probe on stress if it doesn't come up)
2. Why do you think this pregnancy was stressful?
3. Do you think others in your situation find pregnancy a stressful time?
4. How does stress affect you; do you think it affects the baby?
5. What have you found makes things better and what worse?

Wellness

1. What do you know about Yoga?
2. Have you ever practiced?
3. Do you know anyone who practices?
4. Might Yoga be helpful for you wife in this situation? How?
5. What led to this belief?

Patient Behaviour

1. What did you think when you both were approached about this trial? I am interested in both positive and negative things
    a) What were the barriers to joining and how did you overcome those?
    b) What would make the offer more attractive?
    c) What might help overcome barriers?
2. What motivated your wife to attend the classes?
    a) What were the barriers to joining and how did you overcome those?

b) What would make the offer more attractive?
c) What might help overcome barriers?

3. What role do you think the family plays in women attending or using interventions to reduce stress during pregnancy? (If family doesn't come up)

Interventions

1. Do you think this intervention has been beneficial?
2. If it was a regular class and not a controlled trial where you have been randomised into groups, would you have preferred that or not?
3. What are other possible interventions that can be done in your opinion?
4. What are key factors/people to be considered for success of future interventions?
5. What could be motivating factors to increase participation?
6. Do you think hospital-based interventions or external/at home interventions will work better?

General

1. Any other comments?

15.18 INTERVIEW QUESTIONS- PARTICIPANTS

Stress Post ART

1. Can you tell me about any issues you faced in this pregnancy? (Then probe on stress if it doesn't come up)
2. Why do you think this pregnancy was stressful?
3. Do you think others in your situation find pregnancy a stressful time?
4. How does stress affect you; does it affect the baby?
5. What have you found makes things better and what worse?

Wellness

1. Before we met, and you heard about the trial, what did you know about Yoga?
2. Have you ever practiced?
3. Do you know anyone who practices?
4. Might Yoga be helpful in your situation? How?

5. What led to this belief?

Patient Behaviour- (Attendees)

1. What did you think when you were approached about this trial? I am interested in both positive and negative things
    a) What were the barriers to joining and how did you overcome those?
    b) What would make the offer more attractive?
    c) What might help overcome barriers?
2. What motivated you to attend the classes?
    a) What were the barriers to joining and how did you overcome those?
    b) What would make the offer more attractive?
    c) What might help overcome barriers?
3. What role do you think the family plays in women attending or using interventions to reduce stress during pregnancy? (If family doesn't come up)
4. What is your opinion on the sessions that were conducted?
    a) How did it feel after the sessions?
    b) Can we improve anything to make this better next time?
    c) What were the good and bad parts of the intervention?

Patient Behaviour- (Non-Attendees)

1. What did you think when you were approached about this trial? I am interested in both positive and negative things
    a. What were the barriers to joining and how did you overcome those?
    b. What would make the offer more attractive?
    c. What might help overcome barriers?
2. Post consent, what made it impossible for you to attend the class?
    a. Could we have done something different to motivate you to attend classes?
3. What role do you think the family plays in women attending or using interventions to reduce stress during pregnancy? (if family doesn't come up)

Interventions

1. Do you think this intervention would have been beneficial?
2. If it was a regular class and not a controlled trial where you have been randomised into groups, would you have preferred that or not?

3. What are other possible interventions that can be done in your opinion?
4. What are key factors/people to be considered for success of future interventions?
5. What could be motivating factors to increase participation?
6. Do you think hospital-based interventions or external/at home interventions will work better?

General

1. Any other comments?

15.19 INTERVIEW QUESTIONS- YOGA INSTRUCTORS

Stress Post ART

1. Could you comment on stress, anxiety and depression among women conceived post ART?
2. In your opinion, what are the underlying causes for stress?
3. As a practising doula, in your experience, what could be possible complications of high levels of stress among these women?
4. In your dual role as a doula & a yoga instructor, what do you currently advocate as a stress-reliever or stress buster?

Wellness

1. What is your opinion on wellness during pregnancy?
2. In the past, what benefits have your clients mentioned while practising yoga during pregnancy?
3. Which aspect of Yoga can help women deal with stress and anxiety levels?

Patient Behaviour

1. We had trouble recruiting women into the study. From your experience, what do you think could be the major causes for women not consenting to be part of this study?
2. Adherence was another major concern. Post consent almost 75% of women dropped out. In your opinion what could have led to that?
3. What role do you think the family plays in women attending or using interventions to reduce stress during pregnancy?

Interventions

1. What are possible interventions that can be done for this specific patient group?
2. What are key factors/people to be considered for success of the interventions?
3. What could be motivating factors to increase participation?
4. Do you think hospital-based interventions or external/at home interventions will work better?

General

1. Any other comments?

15.20 CONSENT FORM- INTERVIEWS

Study Consent Form

Participant Identification Number for this study:

Title of Project: Effect of Yoga on mental wellbeing of pregnant women post infertility treatments- Feasibility Study

Name of Researcher(s): Anjali Raj

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 01/06/2018 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐
3. I agree to take part in the qualitative part of the study by participating in the interview ☐
4. I would like a copy of the study results to be sent to ☐

_____

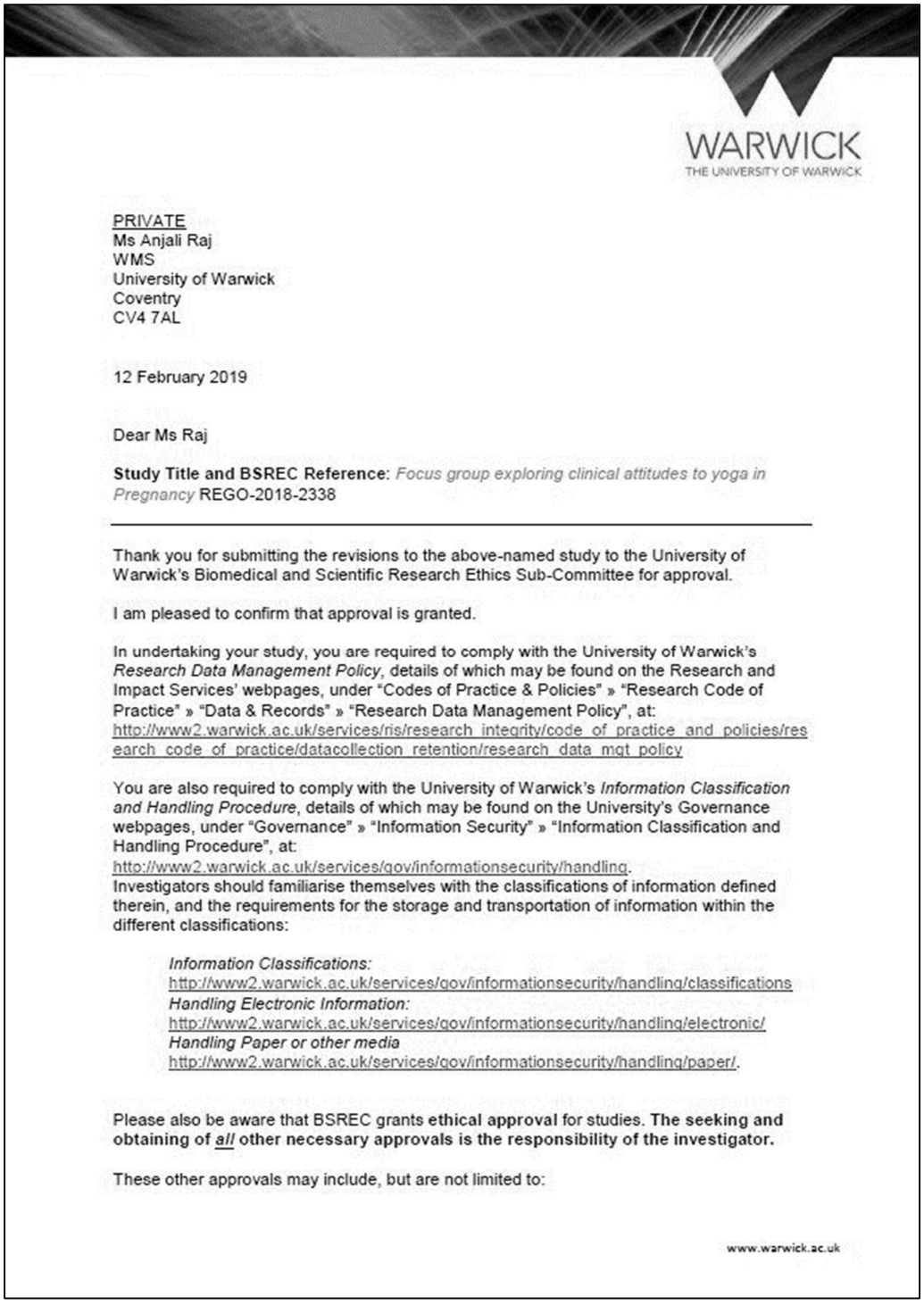
_____ _____ _____

Name of Participant Date Signature

_____ _____ _____

Name of Person taking consent	Date	Signature

15.21 BSREC APPROVAL FOR FOCUS GROUPS- WARWICK MEDICAL SCHOOL



WARWICK
THE UNIVERSITY OF WARWICK

PRIVATE
Ms Anjali Raj
WMS
University of Warwick
Coventry
CV4 7AL

12 February 2019

Dear Ms Raj

Study Title and BSREC Reference: *Focus group exploring clinical attitudes to yoga in Pregnancy* REGO-2018-2338

Thank you for submitting the revisions to the above-named study to the University of Warwick's Biomedical and Scientific Research Ethics Sub-Committee for approval.

I am pleased to confirm that approval is granted.

In undertaking your study, you are required to comply with the University of Warwick's *Research Data Management Policy*, details of which may be found on the Research and Impact Services' webpages, under "Codes of Practice & Policies" » "Research Code of Practice" » "Data & Records" » "Research Data Management Policy", at:
http://www2.warwick.ac.uk/services/ris/research_integrity/code_of_practice_and_policies/research_code_of_practice/datacollection_retention/research_data_mgt_policy

You are also required to comply with the University of Warwick's *Information Classification and Handling Procedure*, details of which may be found on the University's Governance webpages, under "Governance" » "Information Security" » "Information Classification and Handling Procedure", at:
http://www2.warwick.ac.uk/services/gov/informationsecurity/handling.
Investigators should familiarise themselves with the classifications of information defined therein, and the requirements for the storage and transportation of information within the different classifications:

Information Classifications:
http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/classifications
Handling Electronic Information:
http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/electronic/
Handling Paper or other media
http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/paper/.

Please also be aware that BSREC grants **ethical approval** for studies. **The seeking and obtaining of *all* other necessary approvals is the responsibility of the investigator.**

These other approvals may include, but are not limited to:

www.warwick.ac.uk

1. Any necessary agreements, approvals, or permissions required in order to comply with the University of Warwick's Financial Regulations and Procedures.
2. Any necessary approval or permission required in order to comply with the University of Warwick's Quality Management System and Standard Operating Procedures for the governance, acquisition, storage, use, and disposal of human samples for research.
3. All relevant University, Faculty, and Divisional/Departmental approvals, if an employee or student of the University of Warwick.
4. Approval from the applicant's academic supervisor and course/module leader (as appropriate), if a student of the University of Warwick.
5. NHS Trust R&D Management Approval, for research studies undertaken in NHS Trusts.
6. NHS Trust Clinical Audit Approval, for clinical audit studies undertaken in NHS Trusts.
7. Approval from Departmental or Divisional Heads, as required under local procedures, within Health and Social Care organisations hosting the study.
8. Local ethical approval for studies undertaken overseas, or in other HE institutions in the UK.
9. Approval from Heads (or delegates thereof) of UK Medical Schools, for studies involving medical students as participants.
10. Permission from Warwick Medical School to access medical students or medical student data for research or evaluation purposes.
11. NHS Trust Caldicott Guardian Approval, for studies where identifiable data is being transferred outside of the direct clinical care team. Individual NHS Trust procedures vary in their implementation of Caldicott guidance, and local guidance must be sought.
12. Any other approval required by the institution hosting the study, or by the applicant's employer.

There is no requirement to supply documentary evidence of any of the above to BSREC, but applicants should hold such evidence in their Study Master File for University of Warwick auditing and monitoring purposes. You may be required to supply evidence of any necessary approvals to other University functions, e.g. The Finance Office, Research & Impact Services (RIS), or your Department/School.

May I take this opportunity to wish you success with your study, and to remind you that any Substantial Amendments to your study require approval from BSREC before they may be implemented.

Yours sincerely

pp. [redacted]

Dr David Ellard
Chair
Biomedical and Scientific
Research Ethics Sub-Committee

Biomedical and Scientific
Research Ethics Sub-Committee
Research & Impact Services
University of Warwick
Coventry, CV4 8UW.
E: BSREC@Warwick.ac.uk

http://www2.warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/biomed

15.22 PARTICIPATION INFORMATION LEAFLET- FOCUS GROUPS

Participant Information Leaflet

10/01/2019

Study Title: Focus Group Exploring Clinical Attitudes to Yoga in Pregnancy

Investigator(s): Anjali Raj, PhD 3rd Year, Supervisor: Prof. Siobhan Quenby

Introduction

You are invited to take part in a research study which is being conducted as part of a continuing professional development session. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Who is organising and funding the study?

This study is a part of the researcher's PhD project on "Effect of Yoga on Mental Well-being of Women Post Infertility Treatments". It is a self-funded study.

What is the study about?

Exploring the opinions of clinicians on the benefits, risks, feasibility and other problems related to advocating yoga to their pregnant patients and the nature of a credible evidence base.

What would taking part involve?

Taking part in this study involves:

- Attending a focus group discussion lasting a maximum of one hour which will be audio recorded
- Completing a brief questionnaire including questions on age gender experience of yoga and current position on giving advice about yoga in pregnancy

Do I have to take part?

No. Participation in this study is completely voluntary and choosing not to take part will not affect you in any way. You can also choose to withdraw your participation at any time, without giving a reason by contacting one of the research team. Further details about withdrawing from the study are provided later on in this document.

What are the possible benefits of taking part in this study?

Taking part in the focus group discussion can lead to increased knowledge of existing research on yoga in pregnancy and deeper appreciation of the nature of evidence. It will also increase understanding of how colleagues' views. The session will accrue CPD points.

What are the possible disadvantages, side effects or risks, of taking part in this study?

There are no possible disadvantages or risks of taking part in this study.

Expenses and payments

There is no monetary reimbursement or payment provided to the participants for agreeing to be part of this study.

Will my taking part be kept confidential?

Yes. All data collected will be kept confidential.

- Every participant will be given an anonymous code whose details are only known to the researcher
- The focus group discussion will be recorded on audio and the tape stored securely in the University of Warwick servers in a password protected file with access only to the researcher and project supervisors.

- Quotes used in the report and/or for publication will be attached to the participant codes and no names will be used to maintain confidentiality.

What will happen to the data collected about me?

As a publicly funded organisation, the University of Warwick have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, such as this, we will use your data in the ways needed to conduct and analyse the research study.

We will be using information from the focus group discussion in order to undertake this study and will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation. The University of Warwick will keep information on the focus group discussion for 5 years from data collection.

Research data will be pseudonymised as quickly as possible after data collection. This means all direct and indirect identifiers will be removed from the research data and will be replaced with a participant number. The key to identification will be stored separately and securely to the research data to safeguard your identity. You can withdraw from the study at any time up until June 2019. Beyond that, it will not be possible to withdraw from the study.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. The University of Warwick has in place policies and procedures to keep your data safe.

This data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

For further information, please refer to the University of Warwick Research Privacy Notice which is available here: https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?
Participation in this study is entirely voluntary. The focus group discussion is a one-time event. You are free to withdraw from the study till the discussion concludes.

Once the discussion is over and data is collected, you have up till June 2019 to withdraw your data from the study.

To safeguard your rights, we will keep the data secure in line with the University's Information and Data Compliance policies

What will happen to the results of the study?

Post data analysis, the report will be written up as part of the researcher's PhD project and submitted for publication independently as a qualitative study.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical & Scientific Research Ethics Committee (BSREC): REGO-2018-2338

Who should I contact if I want further information?

The lead researcher: Anjali Raj , [redacted]

Project supervisor: Siobhan Quenby, [redacted]

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 024 76 522746

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer, [redacted], Information and Data Director who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Thank you for taking the time to read this Participant Information Leaflet

15.23 CONSENT FORM- FOCUS GROUP

CONSENT FORM

Participant Identification Number for this study:

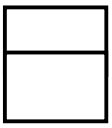
Title of Project: Focus Group Exploring Clinical Attitudes to Yoga in Pregnancy

Name of Researcher(s): Anjali Raj, PhD 3rd Year; Supervisor: Prof. Siobhan Quenby

Please initial all boxes

1. I confirm that I have read and understand the information sheet (Version 1, dated 10/01/2019) 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 up until June 2019 without giving any reason, without my professional standing being affected. ☐
3. I consent to the use anonymised verbatim quotations ☐
4. I consent to audio recording of the focus group discussion ☐
5. I understand that the audio recording data collected during the focus group discussion and my basic demographic characteristics, may be looked at by individuals from The University of Warwick. I give permission for these individuals to have access to my data. ☐

6. I am happy for my data to be used in future research.
7. I agree to take part in the above study.



8. I would like the results of this study to be emailed to

_____

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

15.24 FOCUS GROUP TOPIC GUIDE

1. Once all the participants arrive, they will be briefed about the study and their right to withdrawal. Following this, consent forms will be given out for signature.
2. Once consent is over and everyone is settled around the table and introductions are over, the moderator hands over a sheet of paper with a patient scenario and 3 questions (appendix I). The participants are given 10 minutes to think it over and answer the questions privately.
3. Discussion:
    a. Why did the participants answer Yes/No to the questions in the sheet? What was the reasoning behind it?
4. Presentation by the researcher on existing evidence of Yoga and Pregnancy, Results of the feasibility study and issues faced.
5. Discussion: (Following are questions to lead the discussion and to keep everyone in line with the topic)
    a. Personal experience of Yoga? Yes/No and details. Has that influenced how they think about Yoga during pregnancy?
    b. Have the participants had patients asking about Yoga and pregnancy? How much?
    c. If no good quality RCT's are available, what information would be required for them to confidently advocate Yoga during pregnancy?
    d. What information is required about harms?
    e. What specific evidence of benefit is required?

f. What type of medical history will hinder you from advocating yoga during pregnancy? Do conception post infertility treatments fall in that category?
g. With respect to infertility, will your opinions change with type of treatment i.e., OI, IUI, IVF etc.
h. Is advocating yoga or other complementary therapy as a clinician, a credibility issue?
i. Conclusion: Rank on what type of evidence you require to be convinced on benefits of Yoga during pregnancy:
    i. Pre-test-Post test
    ii. Experimental study
    iii. Observational study
    iv. Surveys
    v. Cohorts
    vi. Cross-Sectional Studies
    vii. Qualitative Study
    viii. Reviews
j. Go back to the case scenarios answered by the participants and ask them to now look at it again with the information received during the discussion and answer it once more.

16 GLOSSARY (A-Z)

1. Agoraphobia: A complex phobia manifesting itself as a collection of inter-linked conditions.

2. Amenorrhea: Absence of menstruation for a minimum of 3 cycles.

3. APGAR score: A scoring system for rapid assessment of the clinical status of a new-born infant at 1 minute and 3 minutes of age.

4. Asana: Physical postures practiced in a Yoga session.

5. Clinical Pregnancy: Presence of a foetal heartbeat at 6-7 weeks of pregnancy.

6. Embolism: A blocked artery caused by a foreign body such as a blood clot or an air bubble.

7. Fecundity: The ability to produce an offspring, commonly used synonymously with fertility.

8. Gametes: An organism's reproductive cells.

9. Haemorrhage: Blood loss from a ruptured blood vessel.

10. HbA1C: Average blood glucose levels for the last two to three months.

11. Hypoxia: A condition where the body or a part of the body is deprived of oxygen supply.

12. IUI: An assisted reproduction treatment which involved placing sperm inside a woman's uterus to facilitate fertilisation.

13. IVF: An assisted reproduction treatment where an egg is removed from the woman's ovaries and fertilised with sperm in a laboratory. The fertilised egg/embryo is returned to the woman's womb to grow and develop.

14. Multigravida: A woman who has been pregnant for at least a second time.

15. Non-Stress Test: A common prenatal test where the baby's heart rate is monitored to see how it responds to the baby's movements. It also records contractions, if any.

16. Nulliparous: A woman who has never given birth.

17. OI: An assisted reproduction treatment where ovulation is stimulated by medication.

18. Perinatal: The period immediately before and after birth.

19. Postprandial Blood Glucose: Blood glucose levels after a meal.

20. Pranayama: Breathing motions done during a Yoga session.

21. Primigravida: A woman who is pregnant for the first time.

22. Psychoneurosis: A neurosis based on emotional conflict in which an impulse that has been blocked seeks expression in a disguised response or symptoms.

23. Psychopharmacology: The scientific study of the effect's drugs has on mood, sensation, thinking and behaviour.

24. Pulse Oximetry: Test used to measure the oxygen level of the blood.

25. Uterine Tocometry: Test that measured force of uterine contractions.