An Exploration of Mother's Experiences of Antenatal Hand Expression of Colostrum, and the Effects upon Breastfeeding Continuation and Maternal Emotional Health.

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Main Sponsor: University of Liverpool

Study Team

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Sponsor

The University of Liverpool is the research Sponsor for this Study. For further information regarding the sponsorship conditions, please contact:

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University of Liverpool, School of Psychology

STUDY SUMMARY

This protocol describes the Exploration of Antenatal Hand Expression Study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the Study. Problems relating to this Study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research (v3.2 10th October 2017). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

TITLE: An Exploration of Mother's Experiences of Antenatal Hand Expression of Colostrum, and the Effects upon Breastfeeding Continuation and Maternal Emotional Health. (An Exploration of Antenatal Hand Expression.)

DESIGN: Qualitative research

AIMS: To explore how antenatal hand expression of colostrum impacts on breastfeeding continuation and on maternal emotional health. Women's experiences of antenatal hand expression will be explored during semi-structured interviews and analysed using modified grounded theory analysis.

POPULATION ELIGIBILITY: Women over the age of 18; Women who have experience of antenatal hand expression within the last three months; Women with a good grasp of the English Language; Women with no clinical mental health diagnosis; Women of infants born >37 weeks gestation.

DURATION: September 2018- May 2019

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1. INTRODUCTION

1.1 BACKGROUND

This study aims to explore mother's experiences of antenatal hand expression of colostrum and its impact upon breastfeeding continuation and maternal emotional health. Antenatal hand expression was initially used with diabetic women during the final weeks of pregnancy to collect colostrum prior to their baby's birth. Babies of diabetic mothers sometimes require supplementary feeds during the first few days after birth to maintain blood sugar levels. In order to reduce the need to rely on formula for these supplementary feeds this practice was developed to build up a store of colostrum. The DAME (Diabetes and Antenatal Milk Expressing) Trial found that babies of mothers who hand expressed colostrum during late pregnancy were less likely to receive formula in the first 24 hours of life (Forster et al, 2017).

Due to its efficacy, this intervention was extended at Liverpool Women's Hospital to include all pregnant women. During antenatal classes, women are taught how to hand express and are given syringes to collect their colostrum and store in a freezer. Health care professionals have anecdotally found this practice to be reassuring to women at Liverpool Women's Hospital, however there has been no research examining the experiences of the women themselves. It is thought that antenatal hand expression increases confidence with breastfeeding and supports women to establish breastfeeding. This study will help identify the effects of antenatal hand expression on breastfeeding continuation and on maternal emotional health.

The aim is to recruit 12 women over the age of 18 through Liverpool Women's Hospital who have recent experience of this practice. The study has the support of the Infant Feeding Coordinator at the hospital who will identify participants and provide them with information about the study. The study will involve conducting a semi-structured interview which will assess participant's views and experiences of antenatal hand expression. These interviews can be conducted at the participant's homes, at the University of Liverpool Infant Feeding Laboratory or via telephone or Skype, as specified as the most convenient by the participant. Interviews will be digitally recorded and transcribed by the student researcher, and a Grounded Theory Analysis will be used to analyse the data. It is anticipated that the views and experiences of these women will aid future planning of maternity care services at Liverpool Women's Hospital and, if beneficial, the intervention may be extended to other trusts.

1.2 RATIONALE FOR CURRENT STUDY

To explore how antenatal hand expression impacts of colostrum on breastfeeding continuation and on maternal emotional health. Breastfeeding offers numerous health benefits to both mother and infant (Victoria et al, 2016) and initiation of breastfeeding within an hour of birth is a key recommendation made by the World Health Organisation (WHO, 2017) to avoid early supplementation with formula. Given low breastfeeding rates, particularly in Liverpool, and barriers to breastfeeding which some women experience, this can be difficult to achieve. Preparing colostrum in advance of the birth helps to avoid early supplementation with formula and has been successfully used at Liverpool Women's Hospital to ensure that infants receive breastmilk after birth. The impact of this strategy has not been explored.

2. STUDY OBJECTIVES

The primary objective is to explore mother's experiences of antenatal hand expression of colostrum during the late stages of pregnancy, including any difficulties or benefits and the mother's perception of this experience. The secondary objective is to explore the impact of antenatal hand expression on breastfeeding continuation and maternal emotional health. Other study objectives include; identifying if any further support could be given to women hand expressing antenatally, to promote recommended feeding practices and to support their emotional health, and; exploring whether antenatal hand expression builds breastfeeding confidence.

3. STUDY DESIGN

The study will use a qualitative design. The study will recruit 12 women who have experience of antenatal hand expression within the last three months, through an Infant Feeding Coordinator based at Liverpool Women's Hospital, with whom the Chief Investigator has strong links. The research team has a history of successfully implementing similar qualitative infant feeding studies. Semi-structured interviews will be carried out by the student researcher (accompanied by a member of the staff team) to stimulate thorough responses from the participants on their experience of antenatal hand expressing. Interviews will take place wherever it is easiest for the participant, either in their home, in the School of Psychology's Infant Feeding Laboratory or via Skype/phone call. Participants choosing to travel to the University will be reimbursed for travel expenses incurred. Interviews will be digitally recorded with permission from the participant and the student researcher will transcribe and analyse the data using a Grounded Theory Analysis.

3.1 STUDY OUTCOME MEASURES

The aim of this this study is to investigate mothers' experiences of antenatal hand expression of colostrum, the effects on maternal emotional state and the impact upon the continuation of breastfeeding, which has not previously been explored. It is hoped that this research will provide a better understanding of the experiences of mothers who have needed to hand express while pregnant, in order to identify how women can best be supported during this time, during the early weeks of motherhood, and in establishing breastfeeding.

4. PARTICIPANT ENTRY

4.1 PRE-REGISTRATION EVALUATIONS

The Infant Feeding Coordinator at Liverpool Women's Hospital will provide information to potential participants about the study and those who express interest in taking part will receive the research team's contact information. Upon contact with the research team, screening questions will be asked via phone or email to verify that the potential participant fulfils the inclusion criteria. Potential participants will then be sent information on the study and a provisional appointment made for informed consent and the interview. Participants will be made aware that they cannot take part in the interview unless informed consent has been given. There will be a 48-hour cooling-off period between the provision of the information sheet and the

process of informed consent, to give the participants time to read and digest the information. Participants who are being interviewed via Skype or telephone will be emailed the participant information sheet and consent form, and must sign and return prior to an interview being scheduled.

4.2 INCLUSION CRITERIA

Women over the age of 18 who have experience of antenatal hand expression within the last three months, and are available to take part in an interview about their experiences. Women must have a good grasp of the English Language, to ensure understanding, as the research team is monolingual.

4.3 EXCLUSION CRITERIA

Women with a diagnosed mental health condition and mothers of preterm babies (< 37 weeks), as these factors may confound experiences.

4.4 WITHDRAWAL CRITERIA

Participants will be made aware from the first contact with the research team, and throughout the process, that they are able to withdraw from the study at any time, without explanation and without their rights being affected in any way. In the event that a participant becomes distressed during interview, the interview and recording will be suspended immediately, and the participant accompanied to comfortable location to recover. Participants being interviewed on Skype or phone will be offered immediate support on the line. The participant and researcher will collaboratively decide whether to end the interview and for the participant to withdraw from the study.

5. ADVERSE EVENTS

5.1 DEFINITIONS

The risk of adverse events in this study involving interviews is very low.

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

5.2 REPORTING PROCEDURES

All adverse events will be reported directly to the Chief Investigator.

5.2.1 Non serious AEs

No serious adverse events are expected; however, some mothers may feel upset by some of the topics discussed. The information sheet outlines research activities, ensuring participants are aware of the materials and activities involved in the study (for example interview questions about birth experience or negative infant feeding experiences) and are able to make an informed decision about participation. A distress protocol has been devised to manage distress in the event of this occurring and the Chief Investigator is well trained in managing participant distress. In the event that a participant becomes distressed during interview, the interview and recording will be suspended immediately, and support offered. Participants being interviewed in person will be accompanied to a comfortable location and given a period of time to recover, whilst those on Skype or phone interviews will be supported over the line. The interviewer and participant will collaboratively decide upon their ability to continue the interview following this period.

On completion of the study or on withdrawal, participants will receive a full debrief, including sources of postpartum well-being support and the researchers contact information. Participants will not receive any specific advice on postpartum mental health directly from the researchers but will be directed to relevant websites and sources of information. Those who have experienced distress will be encouraged to contact their GP, if necessary. Alternatively, with participant consent, the researcher will carry this out for them, or contact a family member of friend if they wish. A courtesy call will be made (if the participant consents) in the following days, to ensure the participant is no longer distressed.

5.2.2 Serious AEs

An SAE form will be completed and emailed to the Chief Investigator within 24 hours. The Chief Investigator will notify the Sponsor of all SAEs.

6. STATISTICS AND DATA ANALYSIS

The sample size is small as the study's focus is on qualitative methods. We aim to recruit 12 eligible participants to interview, with research showing that data saturation can be achieved with these numbers (Guest, Bunce & Johnson, 2006). Participants will be recruited via purposive sampling, interviews transcribed, and data analysed using a Grounded Theory Method.

7. REGULATORY ISSUES

7.1 ETHICS APPROVAL

The Chief Investigator has obtained approval from the Research Ethics Committee and Health Research Authority (HRA) approval. The study will be submitted to each proposed research site for Confirmation of Capacity and Capability. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

7.2 CONSENT

Following expressions of interest, the researchers will verify that participants fulfil the inclusion criteria. Participants will be sent information on the study and a provisional appointment for informed consent and the interview. Participants will be made aware that they cannot take part in the interview unless informed consent has been given and that they are free to withdraw at any time, without giving reason. There will be a 48-hour cooling-off period between provision of the information sheet and the process of informed consent, to allow participants time to read and digest the information. Participants who are being interviewed via Skype or phone will be emailed the participation information sheet and consent form and must sign and return to the research team prior to an interview being scheduled.

7.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and will abide by the Data Protection Act.

Confidentiality will be ensured in accordance with the University of Liverpool information security policy. The Chief Investigator has been trained in the security of information appropriately. Confidentiality and anonymity will be maintained throughout the study and it will not be possible to identify the participant in any publications. To ensure anonymity of personal data, participants will be allocated pseudonyms which will be assigned before each recorded interview commences. During the transcription process, pseudonyms will be used to replace the names of any friends, family and health professionals mentioned in interviews by participants. Only researchers named on this application will have access to the audio files.

7.4 INDEMNITY

The University of Liverpool holds Indemnity and insurance cover with Marsh UK LTD, which apply to this study.

7.5 SPONSOR

The University of Liverpool will act as Sponsor for this study. It is recognised that as an employee of the University the Chief Investigator has been delegated specific duties, as detailed in the Sponsorship Approval letter.

7.6 FUNDING

The School of Psychology will be funding this study as it will be conducted as part of an Undergraduate third year project. Participants will receive a £5 voucher on completion of their interview and will be reimbursed for any travel expenses.

7.7 AUDITS

The study may be subject to inspection and audit by the University of Liverpool under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research (v3.2 10th October 2017).

8. STUDY MANAGEMENT

The day-to-day management of the study will be coordinated by Dr Vicky Fallon.

9. END OF STUDY

The study will end when the final study report is written

10. ARCHIVING

With permission from the participant, the interview will be digitally recorded using a Dictaphone and save as an audio file. Audio files will be kept on a secure University drive until publication, when it will be deleted, as transcripts will be kept. All transcribed data will be stored electronically on a secure University drive and kept for 10 years. This is in accordance with the University's data archiving procedures.

Documents including consent forms will be stored in a locked filing cabinet in the Chief Investigator's office and kept for 10 years. This is in accordance with the University's data archiving procedures.

11. PUBLICATION POLICY

Publication of study findings in the Maternal and Child Nutrition Journal will be pursued.

12. REFERENCES

Forster, D.A., Moorhead, A.M., Jacobs, S.E., Davis, P.G., Walker, S.P., McEgan, K.M., Opie, G.F., Donath, S.M., Gold, L., McNamara, C., Aylward, A., East, C., Ford, R., & Amir, L.H. (2017). Advising women with diabetes in pregnancy to express breastmilk in late pregnancy (Diabetes and Antenatal Milk Expressing [DAME]): a multicentre, unblinded, randomised controlled trial. *Lancet, 389,* 2204-13.

Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? an experiment with data saturation and variability. *Field Methods, 18(1),* 59-82.

Victoria, C.G., Bahl, R., Barros, A.J.D., Franca, G.V.A., Horton, S., Krasevec, J., Murch, S., Sankar, M.J., Walker, N., & Rollins, N.C. (2016). Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *Lancet, 387,* 475-90.

WHO (2017). Guideline: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services. *Geneva: World Health Organization.* Retrieved from http://www.who.int/nutrition/publications/guidelines/breastfeeding-facilities-maternity-newborn/en/