A feasibility study for a randomised controlled trial to measure the impact of frenotomy in breastfed infants with tongue tie.

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**Background:** Around 3% of babies are born with a tongue tie (TT), which can result in failure of breastfeeding. Cutting the tongue-tie (frenotomy) to free up tongue movement and improve breastfeeding is becoming widespread. NICE recommends the procedure but calls for better evidence on which to base the practice. One small RCT suggested frenotomy improved sucking and reduced maternal pain on breastfeeding, but the follow up was short and the outcomes subjective. It is unclear if all infants with TT, or only those with the most severe form, should be offered frenotomy. We will assess the feasibility of a trial of treatment of mild to moderate TT comparing immediate frenotomy with usual care (breastfeeding support), to inform the design and assess the acceptability of a protocol for a full RCT.

**Aims:** The feasibility study will aim to:

- Determine recruitment and retention rates to the trial
- Explore outcome measures that are appropriate and important for mothers
- Estimate ability to obtain effectiveness measures
- Estimate confidence intervals for the size of the effect between trial groups
- Produce a protocol for a larger multi-centre clinical trial.

At the end of the feasibility study, we aim to know whether a large RCT is needed, if it is feasible to recruit and retain participants, and which methods to use. The principal aim of the main RCT will be to compare the impact of frenotomy on breastfeeding efficiency after 5 days.

**Plan of investigation:**

Mothers of **term** infants with breastfeeding problems due to tongue tie will be referred to the service at Southmead and assessed by one of the lactation specialists. Infants who have lost more than 10% of their birthweight will not be included, but will be discussed with a neonatologist.

Informed consent will be obtained to participate in the trial. Where possible details will be sent 24 hours or more prior to the trial, but as this will be a pragmatic trail involving individuals coming to an established service with an expectation of treatment this may not always be possible in advance.
On the first visit (Day 0), efficacy of breastfeeding will be assessed by the LATCH Breastfeeding assessment tool and IBFAT (Infant Breastfeeding Assessment Tool), which record the breastfeed in slightly different formats; severity of tongue tie using the Hazelbaker Assessment Tool for Lingual Frenulum Function (HATLFF); breastfeeding confidence using the Breastfeeding Self Efficacy Scale (BSES) (short form) and the infant will be weighed naked.

The LATCH scale was modelled on the Apgar score with a range of 0-10 with 5 parameters (latch, audible swallowing, nipple type, comfort, hold) each scored 0-2. IBFAT has 4 parameters (readiness to breastfeed, rooting, latch, sucking pattern) each scored 0-3.

The HATLFF has 5 appearance items and the short form has 3 function items each scored 0-2 giving a total of 16 (least severe). Significant ankyloglossia is diagnosed with a total score of 12 or less. Clinical use suggests that babies with scores of 6 or less would be severely compromised by their TT, so will be excluded from the trial and we will include those with scores of 6-12.

The BSES assesses the mother’s confidence in her ability to breastfeed with 14 questions (self rated from 1-5) and a total score of 70.

Breastfeeding will also be scored using a second validated tool, the Infant Breastfeeding Assessment Tool (IBFAT), to provide a comparative assessment.

Mothers of infants with a mild to moderate tongue tie (HATLFF score 6-12) with breastfeeding difficulties (LATCH score ≤8) will be invited to take part in the study.

Participants will be randomised to two groups:

A: Intervention

B: Usual care

A. Intervention group:

Mothers will be offered immediate frenotomy for their baby, followed by breastfeeding support and advice from the lactation specialist in the hospital. Mothers and babies will receive usual breastfeeding care at home and return to the clinic for reassessment on Day 5, using the same methods as on Day 0. Normal care will continue until the 8 week telephone contact.

B. Usual care group:

Breastfeeding support and advice will be given by the lactation specialist in the hospital, and by community midwives (trained in Baby Friendly breastfeeding support) at home. After 5 days the mother and baby will return to the clinic to be re-assessed by the trial manager and one of the lactation specialists, using the same methods as on Day 0. If the infant is feeding adequately and gaining weight, normal care will continue until the 8 week telephone assessment. If the infant is still having difficulties with breastfeeding, the mother will be offered the option of frenulotomy for her baby.
In BOTH groups at day 5 the feeding assessment (LATCH/IBFAT score) will be made by the trial manager prior to the baby being seen by the lactation specialist, so that this assessment will be blinded to whether the child has been treated by frenotomy or not.

At 8 weeks of age, all mothers will be telephoned to find out how they are feeding their baby and those who are still breastfeeding will be offered a home visit so that the trial manager can watch a breastfeed and obtain another LATCH/IBFAT score. The baby’s weight will be obtained from the infants’ red book or requested by telephone from those who are not visited.

**Inclusion criteria**

Term infants with a functionally significant tongue tie (HATLFF function score between 6-12) with breastfeeding difficulties (LATCH score ≤8) will be eligible for the study.

Infants who have lost >10% of their birth weight will be assessed by a neonatologist to determine whether they are ill and if not, they can be included in the trial.

**Exclusion criteria**

Preterm infants, infants with serious congenital anomalies, infants with a HATLFF score of <6, and those over 2 weeks old will be excluded from the study. Also mothers who do not want their baby to have surgery will be excluded.

Infants who have not received vitamin K will be excluded unless their mother agrees to an injection of vitamin K at least one hour before entering the study.

**Randomisation**

Patients will be block randomised equally to 2 groups by an independent web-based randomisation service provided by Bristol Randomised Trials Collaboration, minimising for sex of infant and by birth order, to ensure equal numbers of first born children in each arm.

**Sample size**

As this is a feasibility study a formal sample size calculation is not appropriate.

We will measure the variability in the outcome measures being collected to inform the outcomes for the future trial. We will recruit for a total of 16 months starting in September 2011, during which time we estimate that 50 participants will be randomised to each group and complete the study (total of 100), and allow 6 months at the end of recruitment for collection, cleaning and validation of outcome measures. We estimate that this will provide sufficient information to meet the aims of the study. Currently 280 babies under 7 days old with breastfeeding difficulties are referred to the service each year, 60% of whom (168 infants) will be eligible on the basis of their HATLFF score being between 6 and 12. If 75% of these mothers agree to take part and no more than 25% subsequently drop out that will give 110 babies completing the feasibility study.
Primary outcome measure

We will record the numbers of participants who are eligible for the trial, monitor recruitment and retention rates to inform the future trial. The predicted outcome for the main trial is expected to be the LATCH score 5 days after entering the trial.

The primary comparison will between mothers whose baby had frenotomy on day 0 and those who received usual care, with the primary outcome of breastfeeding efficacy on day 5 using the LATCH score.

Secondary outcomes:

LATCH, HATLFF and IBFAT scores and BSES (breastfeeding self efficacy score) collected at Day 0 and Day 5; BSES and LATCH collected at the 8 week visit for those who are still breastfeeding. Further outcomes collected at the 8 week contact will be breastfeeding status (exclusive, any, none) and babies’ weights to calculate conditional weight gain from day 0 to 8 weeks.

Process measures.

The numbers of babies with tongue-tie will be documented and the reasons given by mothers who decline to take part in the trial will be recorded. Those who are willing to be involved in the trial in some way, but do not want surgery will be followed up to find out both the reasons for not wanting surgery and the impact this decision has on breastfeeding. Those who give up breastfeeding after randomisation will be followed up.

Qualitative process interviews.

At the 8 week telephone contact mothers will be invited to be interviewed by an independent researcher. 20 participants who have agreed will be interviewed in more depth to explore their views on the trial, the intervention process, the acceptability of randomisation and their attitude to frenotomy.

Purposive sampling will be used to recruit mothers with a range of ages and ages of baby from those who agree to be interviewed. The interviews will take place after the 8 week outcome measures. The two lactation specialists will also be interviewed to document their views on the trial procedures.

The interviews will be digitally recorded, transcribed and analysed using standard thematic methods of building codes into themes and sub-themes using the process of constant comparison. The analysis will be facilitated using NVIVO8 software. These interviews will inform the design of a larger multi-centre trial.

Statistical methods.

As this is a feasibility study the analyses will mainly be descriptive in nature. Statistics concerning the recruitment rate, number of available subjects per month, completeness of outcome data, reliability of outcome data, number of patients who had frenulotomy and number of ineligible
participants recruited will be presented. 95% confidence intervals for these percentages will be calculated using the exact binomial method as required to estimate possible effect sizes.

**Health economics.**

If the intervention is successful, the changes in breastfeeding patterns will bring benefits in health related quality of life for these babies stretching well beyond the time frame of the study. These benefits are notoriously difficult to quantify and value.

However, the cost differences between the interventions in the two arms of the present trial are, at greatest, very small. If a future definitive trial were to show significant differences in outcome, the arm showing a better outcome would be dominant. In light of the within-trial dominance of one of the arms, the cost-effectiveness decision would not be altered by modelling the longer term cost-effectiveness of the intervention.

For these reasons we feel that it is not necessary to collect economic data in this feasibility trial.

**Data management.**

The trial manager will supervise data collection by the lactation consultants, and key data from questionnaires onto a database held securely at the University of Bristol. She/he will contact the mothers at 8 weeks and make the 8 week visit. An independent qualitative researcher will conduct the longer process interviews.