

# A randomised controlled trial of frenotomy or breastfeeding support for babies with tongue-tie

<b>Submission date</b> 04/02/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/02/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/07/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This is a study for babies with breastfeeding difficulties who are thought to have tongue-tie. Many mothers and babies experience difficulties in establishing breastfeeding. In some babies it is thought that their difficulties may be linked to a condition called tongue-tie, in which a piece of skin tightly joins the middle part of the underside of the tongue to the base of the baby's mouth. This can be treated by an operation to divide the tight part/skin in the middle of the underneath of the tongue. It is usually carried out as an outpatient by either a midwife or doctor and babies typically go home the same day. However, there are other reasons for breastfeeding difficulties, including poor positioning and attachment of the baby to the breast. These difficulties can be solved by support from skilled infant feeding counsellors, and it may be that being given this support is more useful to help mothers and babies to continue to breastfeed when the baby is thought to have a tongue-tie and an operation is not needed. The aim of this study is to see whether an operation makes a difference to mothers and their babies. The study will compare babies in the group who have the operation and breastfeeding support to babies in the group who only receive breastfeeding support but not an operation. The main outcome is to compare how many babies in each group are still breastfeeding at three months.

### Who can participate?

Babies aged up to 10 weeks with breastfeeding difficulties diagnosed with a tongue-tie are eligible for inclusion, as long as their parents give consent to do so. Some babies will not be able to take part in the trial, for example babies born at less than 34 weeks' gestation, or if they have a known bleeding disorder, or if they have another condition known to affect breastfeeding (e.g. cleft palate, Down syndrome).

### What does the study involve?

After parents have been given information about the trial and decided that they would like their baby to take part, the baby is allocated at random (similar to tossing a coin) to either have an operation or not. All babies receive breastfeeding support whether or not they have an operation. When all the babies in the study are three months old, their mothers are asked whether they are still breastfeeding. Information is also collected about the age of the baby at

his/her last breastfeed, the baby's weight, any problems the baby had after the operation, whether the mothers have any breastfeeding difficulties e.g. pain or are anxious or depressed, and how confident they feel about breastfeeding. This information is compared between the two groups to see if there are any differences between the babies in the group who had an operation straightaway and those in the group that had breastfeeding support alone, or had an operation later. After six months, mothers are contacted again to see if they are still breastfeeding.

What are the possible benefits and risks of participating?

The findings will help guide care for women and their babies who are trying to breastfeed in the future. There are some risks associated with the frenotomy procedure. These include bleeding, a small risk of infection, and a small risk of salivary duct damage. However, both breastfeeding support and the frenotomy are standard care practices. Therefore the researchers do not believe there are any additional risks as a result of taking part in this study.

Where is the study run from?

The study is co-ordinated from the National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU), based at the University of Oxford. Participants will be recruited from around 22 hospitals throughout the UK.

When is the study starting and how long is it expected to run for?

April 2018 to May 2021

Who is funding the study?

National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (UK)

Who is the main contact?

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## Contact information

**Type(s)**

Scientific

**Contact name**

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**Type(s)**

Public

**Contact name**

Ms Victoria Stalker

**Contact details**

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

38654; HTA 16/143/01

**Study information****Scientific Title**

FROSTTIE: A randomised controlled trial of Frenotomy and breastfeeding support Or breastfeeding Support without frenotomy to investigate continuation of breastfeeding for babies with Tongue-TIE

**Acronym**

FROSTTIE

**Study objectives**

To investigate whether frenotomy is clinically and cost effective to promote continuation of breastfeeding at three months in infants with breastfeeding difficulties diagnosed with tongue-tie.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South Central - Oxford B Research Ethics Committee, The Health Research Authority, Whitefriars, Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT, Tel: +44 (0)207 1048058, Email: nrescommittee.southcentral-oxfordb@nhs.net, 10/12/2018, REC ref: 18/SC/0580

**Study design**

Randomised; Interventional; Design type: Treatment, Process of Care, Management of Care, Surgery

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Tongue-tie

## **Interventions**

The infants entered into the trial will be randomised 1:1 to either:

1. Frenotomy with standard breastfeeding support (intervention arm)
2. No frenotomy with standard breastfeeding support (comparator arm)

### **Intervention arm:**

Infants who are eligible for the trial and whose parents consent for them to participate and who are randomised to frenotomy with breastfeeding support will undergo the procedure according to usual hospital practice. Frenotomy will be carried out by the usual trained practitioner for participating hospitals using their normal technique. Frenotomy is usually a quick procedure in which the tongue is lifted and the frenulum (the tissue between the underside of the tongue and the base of the mouth) is divided. Breastfeeding may be conducted immediately post-procedure, and the baby will undergo an immediate post-frenotomy observed feed. Parents will receive further advice on positioning and attachment together with standard post-frenotomy advice concerning bleeding and other post-frenotomy adverse events. Parents will be provided with details about how to access rapid breastfeeding support in the event of ongoing feeding difficulties and an appointment for at least one follow-up visit.

### **Previous comparator arm:**

Infants who are eligible for the trial and whose parents consent for them to participate and who are randomised to breastfeeding support only will not undergo frenotomy, but at the frenotomy clinic will undergo an immediate observed feed and will receive further advice on positioning and attachment together with standard post-frenotomy advice concerning bleeding and other post-frenotomy adverse events. Parents will be provided with details about how to access rapid breastfeeding support in the event of ongoing feeding difficulties and an appointment for at least one follow-up visit.

### **Current comparator arm as of 16/09/2019 (amended with protocol dated 28/06/2019):**

Infants who are eligible for the trial and whose parents consent for them to participate and who are randomised to breastfeeding support only will not undergo frenotomy. Parents will be provided with details about how to access rapid breastfeeding support in the event of ongoing feeding difficulties and an appointment for at least one follow-up visit.

The study will compare how many babies are still breastfeeding at aged 3 months in the two groups, and will also look at the level of breastfeeding, the support provided, any further surgery on the tongue-tie and the mother's quality of life and perceptions of the level of breastfeeding of their baby. Information will be collected from the medical records by the

clinical research team at the feeding support hospitals. The trialists will also ask the mothers to complete short questionnaires through a secure web-based data collection platform, or by post or phone if preferred.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

Any breastmilk feeding at 3 months according to maternal self-report, defined as any breastmilk feeding in the 24 hours prior to the infant reaching three months of age. A positive response is indicative of continuation of breastfeeding.

## **Key secondary outcome(s)**

Measured by specific question unless noted, at first follow-up visit and 3 months of age:

1. Mother's pain while feeding during the previous 24 hours
2. Exclusive breastmilk feeding
3. Exclusive direct breastfeeding
4. Frenotomy in comparator group
5. Repeat frenotomy
6. Bleeding (following frenotomy or frenulum tear)
7. Post-procedure adverse events (tongue cut, scarring, salivary duct damage)
8. Maternal anxiety and depression dimension of EQ-5D-5L
9. Maternal health-related quality of life measured using EQ-5D-5L

Measured by specific question unless noted, at 3 months of age:

1. Mother's breastfeeding self-efficacy, measured using Breastfeeding Self-Efficacy Scale – Short Form
2. Amount of breastfeeding support used, measured by total number of contacts with any breastfeeding supporter since the FROSTTIE procedure (whether face to face, or by telephone)  
Updated 16/09/2019 (amended with protocol dated 28/06/2019): Amount of breastfeeding support used, measured by total number of contacts with any breastfeeding supporter since the infant joined the trial (whether face to face, or by telephone)
3. Infant weight gain from birth
4. Infant post-randomisation weight gain
5. Age of child when s/he last received breastmilk
6. Time spent breastfeeding in previous 24 hours
7. Maternal health-related quality of life, measured using EQ-5D-5L
8. Maternal and infant NHS healthcare resource use

Measured by specific question at 6 months:

1. Any breastmilk feeding

## **Completion date**

13/05/2021

## **Eligibility**

### **Key inclusion criteria**

1. Infant aged less than 10 weeks referred (by parent or other breastfeeding support service) to an infant feeding service with breastfeeding difficulties and judged to have tongue-tie
2. Parent has given informed consent for participation

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Total final enrolment**

169

**Key exclusion criteria**

1. Infants who have breastfeeding difficulties but are not judged to have tongue-tie
  2. Babies born at less than 34 weeks' gestation
  3. Babies with a congenital anomaly known to interfere with breastfeeding e.g. cleft palate, Down syndrome
  4. Babies with a known bleeding diathesis
- Added 16/09/2019 (amended with protocol dated 25/03/2019): 5. Infant has had a frenotomy prior to recruitment

**Date of first enrolment**

01/01/2019

**Date of final enrolment**

27/11/2020

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Royal Victoria Infirmary**

Queen Victoria Road  
Newcastle upon Tyne  
United Kingdom  
NE1 4LP

**Study participating centre**

**Norfolk and Norwich University Hospital**  
Colney Lane  
Norwich  
United Kingdom  
NR4 7UY

**Study participating centre**  
**Royal Albert Edward Infirmary**  
Wigan Lane  
Wigan  
United Kingdom  
WN1 2NN

**Study participating centre**  
**Royal Cornwall Hospital**  
Treliske  
Truro  
United Kingdom  
TR1 3LJ

**Study participating centre**  
**Royal Berkshire Hospital**  
London Road  
Reading  
United Kingdom  
RG1 5AN

**Study participating centre**  
**George Eliot Hospital**  
College Street  
Nuneaton  
United Kingdom  
CV10 7DJ

**Study participating centre**  
**Homerton University Hospital**  
Homerton Row  
London  
United Kingdom  
E9 6SR

**Study participating centre**  
**Bradford Royal Infirmary**  
Duckworth Lane  
Bradford  
United Kingdom  
BD9 6RJ

**Study participating centre**  
**Leeds General Infirmary**  
Great George Street  
Leeds  
United Kingdom  
LS1 3EX

**Study participating centre**  
**East Lancashire Hospital NHS Trust**  
Burnley General Teaching Hospital  
Casterton Avenue  
Burnley  
United Kingdom  
BB10 2PQ

**Study participating centre**  
**Great Western Hospital**  
Marlborough Road  
Swindon  
United Kingdom  
SN3 6BB

**Study participating centre**  
**Queen Alexandra Hospital**  
Southwick Hill Road  
Cosham  
Portsmouth  
United Kingdom  
PO6 3LY

**Study participating centre**

**The Cumberland Infirmary**

Infirmery Street  
Carlisle  
Cumbria  
United Kingdom  
CA2 7HY

**Study participating centre**

**Darlington Memorial Hospital**

Hollyhurst Road  
Darlington  
United Kingdom  
DL3 6HX

**Study participating centre**

**Sunderland Royal Hospital**

Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**

**University Hospital of North Durham**

North Road  
Durham  
United Kingdom  
DH1 5TW

**Study participating centre**

**Royal Blackburn Hospital**

Haslingden Road  
Blackburn  
United Kingdom  
BB2 3HH

**Study participating centre**

**Russells Hall Hospital**

Pensnett Road  
Dudley  
United Kingdom  
DY1 2HQ

**Study participating centre**  
**Worcestershire Royal Hospital**  
Charles Hastings Way  
Worcester  
United Kingdom  
WR5 1DD

**Study participating centre**  
**Royal Manchester Children's Hospital**  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Stoke Mandeville Hospital**  
Mandeville Road  
Aylesbury  
United Kingdom  
HP21 8AL

## **Sponsor information**

**Organisation**  
University of Oxford

**ROR**  
<https://ror.org/052gg0110>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/143/01

# Results and Publications

## Individual participant data (IPD) sharing plan

A statement on the management of participant data sharing can be found at <https://npeu.ox.ac.uk/ctu/privacy-notice>

## Previous publication and dissemination plan:

The protocol and other study documents will be made available on the website <https://www.npeu.ox.ac.uk/frosttie>

The trialists will submit for publication in a high impact peer-reviewed journal. They aim to present findings to academic and professional audiences at key conferences. They will also bring the trial results to the attention of the Cochrane review authors so that they may be considered for inclusion in an updated review.

It is NPEU policy to send results to all trial participants, unless they have opted out. The trialists will also share the results with other breastfeeding mothers through national organisations working to support breastfeeding, appropriate websites, social and traditional media as well as with organisations designing services and guidelines about breastfeeding and tongue-tie to help make sure that the services provided in the NHS are based on what they have found.

## IPD sharing statement

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		25/07/2023	26/07/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version v5	29/07/2020	06/01/2021	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes