

Jim Thornton's prediction of the FROSTTIE trial result. (#36228)

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1) Have any data been collected for this study already?

It's complicated. We have already collected some data but explain in Question 8 why readers may consider this a valid pre-registration nevertheless.

2) What's the main question being asked or hypothesis being tested in this study?

That frenotomy, cutting the fold of skin under the front of the tongue, improves breast feeding in babies with ankyloglossia or tongue tie. The FROSTTIE trial is registered here. <http://www.isrctn.com/ISRCTN10268851>

3) Describe the key dependent variable(s) specifying how they will be measured.

Any breast feeding at age three months according to maternal self-report.

4) How many and which conditions will participants be assigned to?

Intervention – Frenotomy plus standard breast feeding support.

Control – Standard breast feeding support alone.

5) Specify exactly which analyses you will conduct to examine the main question/hypothesis.

The analysis plan has not, as far as I am aware, been published. However, the group running this trial are experienced clinical trialists of high repute. I have no doubt that the analysis plan will be written and signed off before the treatment code is broken.

6) Describe exactly how outliers will be defined and handled, and your precise rule(s) for excluding observations.

See above. Analysis will be by intention to treat.

7) How many observations will be collected or what will determine sample size? No need to justify decision, but be precise about exactly how the number will be determined.

870 mother baby dyads in total. 435 per group.

8) Anything else you would like to pre-register? (e.g., secondary analyses, variables collected for exploratory purposes, unusual analyses planned?)

The FROSTTIE trial has already started. I know some of the trialists, but otherwise have nothing to do with it. My own centre, Nottingham University Hospitals NHS Trust is not even recruiting participants.

I have no criticism of the trial design. I predict that the result will be negative.

My issue is with the underlying rationale for the trial, which I believe, is non-existent. If by chance, or due to some unforeseen bias, the result is positive, I will still disbelieve it. I have explained the reasons for my scepticism more fully here. <https://ripe-tomato.org/2020/02/25/my-frosttie-prediction/>