



CRYING, **U**NSETTLED, **DIS**TRESSED **I**NFANTS: **E**FFECTIVENESS **S**TUDY

Participant Information Leaflet

Invitation

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you and your baby. Your osteopath or a member of the study team can go through the information sheet with you and answer any questions you have. You do not have to make your mind up now, please take your time and talk to others as you need.

What is the purpose of this study?

This study aims to find out if osteopathic manual therapy (hands-on) care is effective for reducing the crying time of babies who are difficult to console and settle.

Around 1 in 6 babies are very unsettled, distressed and cry excessively despite being otherwise healthy and well cared for. These babies are often referred to as babies with colic or silent reflux.

We still do not know why some babies cry more than others, why some can be consoled and others not. There are some treatments available for babies and their parents but there is little high quality evidence to show whether they are helpful or not.

This study is funded by The National Council for Osteopathic Research (www.ncor.org.uk) and sponsored by University College of Osteopathy.

You have been invited to join this study because you and/or your osteopath thinks your baby might have been excessively crying, unsettled and distressed (more than 3 hours per day for 3 days or more, for one week or more). We are looking for 112 babies to take part in the trial.

Do I have to take part?

No, it is up to you to decide whether you would like your baby to take part in the study. This information sheet will provide you with information to help you decide. If you agree to take part, we will ask you to sign a consent form. If you choose to be part of the study, you can still change your mind at any time. This will not affect the quality care that you or your baby are given in the future. If you do decide to leave the study, a researcher (not the osteopath) will contact you confidentially to check that you and your baby are well and your reason for leaving the study (although you do not have to say if you do not want to). If you decide not to join the study this will also not affect the quality of care that you or your baby are given in the future.

What will happen to me and my baby if we take part?

Your baby will receive a minimum of 1 and a maximum of 4 treatment sessions lasting approximately 30-45 minutes per treatment session.

Every baby will receive a health screening. Two different types of light touch techniques will be used in this study. Half of the babies in the CUTIES Study will receive Targeted Tension Release (TTR). This is light touch osteopathic treatment guided by the osteopath's examination applied to where the baby's tensions are perceived to be (usual osteopathic care). The other half will receive a Generic Tension Release (GTR) light touch which will be applied to pre-specified areas of your baby's body and not guided by the osteopath's examination or directed at any specific tissues. Babies in both groups will receive gentle light touch applied to the baby's head, shoulders, chest, tummy and/or base of their back. This design will help us test whether there is any difference between the two methods of light touch.

What will I have to do?

The study will involve you taking part over a 2-week period. You will be asked to complete a crying diary to record how many minutes your baby cries in each hour, 24 hours before your first appointment and afterwards for 14 days. This should take no longer than 5-10 minutes per day.

You will also be asked to fill in two questionnaires, one at the start of the study and one after 14 days, about your baby's health, your parenting confidence and your experience of the care provided. These questionnaires should take approximately 5 minutes to fill in.

Every parent/carer will be given advice and support from their osteopath.

If you decide to take part in the study with your baby, you would have to agree NOT to know which light touch your baby will receive. This is because we need to make sure that the results of the study are not affected by your own views about whether one treatment might have more effect than the other.

All treatment is given free of charge, we just ask you to fill in the questionnaires and the crying diary for us. Once this stage is complete you can ask your osteopath which treatment your baby received.

What are the possible disadvantages and risks of taking part?

You will be asked to bring your baby to the osteopath up to a maximum of 4 times over a 2-week period, this will involve time and possible travel costs. During the treatment you will be with your baby at all times and should your baby get distressed you will be free to console and comfort your baby at any point.

We know from other research that reactions after treatment (also known as adverse events) are very rare for this type of gentle therapy given to babies.

All osteopaths in this study have previous experience of treating babies, they are all registered healthcare professionals who have been specially trained and selected to be involved in this study.

Osteopathy is a statutory regulated health profession, meaning that when you visit an osteopath you are afforded the same protection as you have when you visit your GP (General Osteopathic Council www.osteopathy.org.uk).

What are the possible benefits of taking part?

We appreciate that when babies are inconsolable it can be very difficult for parents. By being involved you will get help and support which is often not possible in an already overburdened health care system.

The aim of the study is to see if this treatment works, we do not know if it will help your baby directly, therefore the results of this study will, in the future, provide information to help parents make informed choices about the care of their babies and about services provided to new parents.

Will my taking part in the study remain confidential?

Yes, all the information you give to your osteopath and the study will remain confidential to your osteopath and the study team only.

When you join the study your baby will be given a unique identification number and all of the information you give us will be associated with the baby's number. Your names will not be used. This will protect your identities. Only your osteopath and some of the study team will know which baby is associated with which number.

What will happen to the information (data) collected about me and my baby?

All of the information (data) you give us will be studied and analysed by treatment groups so individuals will not be identifiable. All data will be stored securely at the University College of Osteopathy and will be destroyed after 6 years.

What will happen to the results from the study?

The data from both of the treatment groups will be compared to see which treatment is associated with a greater reduction in crying time. We can give you information about what we find in this study, you can contact your osteopath or the study team in May 2021. The results will also be published in medical journals and presented at medical conferences. You and your baby will not be identified in any of the information about the study.

What if I have a complaint or if there is a problem?

If you are unhappy in any way during your time in the study you can either discuss this with your osteopath or a member of the study team.

If you require further information, please contact the Study team manager:

Professor Dawn Carnes

University College Osteopathy

273 Borough High St, London

Telephone: 00 44 (0) 20 7085 5330. Email: dawn.carnes@uco.ac.uk

If, however you would like to contact someone independent from the running of the trial please contact:

Dr Carol Fawkes

National Council for Osteopathic Research

Queen Mary University of London, Centre for Primary Care and Public Health

58 Turner St, London

Telephone: 00 44 (0) 20 7882 6131. Email: c.fawkes@qmul.ac.uk

Thank you for taking the time to read this information sheet, if you have any questions please tell ESO Reception Staff and they will put you in touch with a member of the study team.

Treatment sessions will take place at the ESO Clinic on a Wednesday morning and at a private osteopathic clinic in Kingshill.

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