



CRYING, UNSETTLED, DISTRESSED INFANTS: EFFECTIVENESS STUDY

Osteopath Information Leaflet

Invitation

We would like to invite you to take part in our research study looking at the effectiveness of osteopathic care for infants with colic. Before you decide we would like you to understand why the research is being done and what it would involve for you and your practice. You are welcome to discuss any questions you have with a member of the study team. 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.

Why have I been invited?

You have been invited to join this study because you are a registered osteopath with experience of treating infants (around one per week) and because you have at least one year of post graduate experience. We are looking for around 100 osteopaths to recruit 202 babies to take part in the trial.

Do I have to take part?

No, it is up to you to decide whether you would 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 an agreement form and attend a one day training course to introduce you to the study and train you in Good Clinical Practice for research and to deliver the interventions / treatments. If you choose to be part of the study, you can still change your mind at any time and withdraw from being part of it.

What will it involve?

You will be asked to recruit 2 infants into the study. Each infant 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 treatment techniques will be used in this study. Half of the babies in the CUTIES Study will receive Targeted Tension Release

(TTR) manual osteopathic treatment and the other half will receive a Generic Tension Release (GTR) manual treatment. The babies in both groups will receive gentle touch techniques only. In the TTR group the techniques are guided by the osteopath's examination and in the other to pre-specified areas of the baby's body.

What will I have to do?

The study recruitment period will take up to 1 year, the duration of your involvement will depend on how many infants you treat with colic in your clinic and how willing the parents' are to participate. You will be asked to invite all parents with eligible infants into the study, who call to make an appointment with you or at your clinic.

We ask that you send parents information about the study and seek their consent to be in the study.

Once recruited, each infant will remain in the study for a 2 week period, during which time you will provide care for the infant, this may take from 1 – 4 consultations depending on the needs of the infant and parent. The care you provide after this period will be up to you and the parent to discuss and agree.

You will also be asked to give the parent a crying diary to complete.

Osteopaths will be asked to complete a questionnaire about the treatment they give the infants and the advice and support they give parents at each consultation, this takes around 5 minutes.

If you decide to take part in the study you would have to agree NOT to tell the parent which 'treatment' their baby has received until the end of the study. This is because we need to make sure that the results of the study are not affected by the parents views about whether one treatment might have more effect than the other.

What does the study involve for the parents?

Parents will be asked to complete a trial consent form, fill in two questionnaires, one at the start of the study (the osteopath will send the parent the URL link to the parent's email address) and one after 14 days. The questionnaires ask the parent about their baby's health, parenting confidence and experience of the care provided. These questionnaires take approximately 5 minutes to fill in.

They will also be asked to complete a 14 day crying diary to record how many minutes their baby cries in each hour over a 14 day period, this should take no longer than 5-10 minutes per day.

What are the possible disadvantages and risks of taking part?

All treatment must be given free of charge to the parent, although we ask them to fill in the questionnaires and the crying diary for us in return. This means that we are asking you to 'donate' the treatment consultation fee of the study infants and some of your time towards the study.

What are the possible benefits of taking part?

The aim of the study is to see if this treatment works, therefore the results of this study will, in the future, provide information to help osteopaths and parents make informed choices about the care of their babies and help the profession to reflect about services provided to new parents.

What will happen to the information (data) collected about the babies?

All of the information (data) given to 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 will give you information about what we find in this study in 2021. The results will also be published in medical journals and presented at medical conferences.

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 the information sheet.