



## **C**RYING, **U**NSETTLED, **DIS**TRESSED **I**NFANTS: **E**FFECTIVENESS **S**TUDY

**Infants' unsettled crying; Swiss part of an international controlled clinical trial to evaluate the effectiveness of an osteopathic treatment**

Fribourg, 25 Mai 2021

Dear Parent,

We would like to inform you about our clinical trial. As your child is still a minor, they cannot give their consent for the planned project. Therefore, we are sending you this information sheet, which will enable you to check whether you and your child agree to participate. Indeed, you can give your consent as a parent.

Below, we present the project: first, with a summary to give you a quick overview, then with a more detailed description.

Prof. Paul Vaucher  
Principal Investigator for Switzerland



## ***Application for participation in a research project in osteopathic care :***

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### **CUTIES-CH - Unsettled crying and osteopathic care**

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Dear parents,

Here we propose that you give us your consent for your child's participation in our project.

Participation is entirely free. All data collected within the framework of this project is subject to strict data protection rules.

The CUTIES project is run in Switzerland by the School of Health Fribourg and the University College of Osteopathy, two universities involved in osteopathic research. We will communicate the results to you if you wish.

In an interview, we will introduce you to the essentials and answer your questions. To give you an overview of the project, here are the key points to remember. You will find more detailed information below.

#### **Why are we conducting this research project?**

- In Switzerland, having unsettled crying (infant colic) is a frequent reason to consult an osteopath, without it being known what the real benefit of the manual part of osteopathic treatment is.
- This research project aims to investigate whether a usual osteopathic treatment, with a specific gentle manual component, reduces crying more than a usual osteopathic treatment with a generic gentle treatment.

#### **What are the conditions to participate?**

- Be available during the next two weeks to consult an osteopath with your child.
- Have access to the internet to answer the questionnaires online (if you do not have access, you can ask the osteopath for it)
- Be able to read French, German, Italian or English.
- Having a child under 10 weeks old with unsettled crying (infant colic) for at least 3 hours a day, 3 days a week.
- Your child has no other conditions that explain the crying.
- Apart from crying, your child is healthy.

#### **What will happen to you and your child if you participate?**

- Your participation consists of accompanying your child for a follow-up visit to an osteopath.
- If you give us your consent for you and your child to participate, you will have to complete two electronic questionnaires that will take 5-10 minutes each. You should also keep a daily diary of your child's crying time for a fortnight. Finally, you will be asked to identify and report any undesirable events that might occur during those two weeks.
- After completing the first questionnaire, your child will be randomly allocated to one of two groups. In addition to the usual care, your child will receive either a specific osteopathic treatment with gentle techniques, or a generic osteopathic treatment that also includes gentle techniques. If you decide to

participate in the study with your baby, you will have to accept that you DO NOT know which gentle 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 opinion about whether one treatment may have more effect than another. You will of course be able to attend the treatments. After completing the second questionnaire and returning a copy of your crying diary, you can ask your osteopath what treatment your baby has received.

- Duration: two weeks
- 1-4 consultations of 30-45 minutes

### What are the benefits and risks of participating in the project?

#### Benefits for participants

- You will receive information, advice and support from an osteopath to help you deal with your child's crying.
- The 1-4 osteopathic consultations are free of charge.
- Through your participation, you are helping future patients to be guided towards the best possible treatment.

#### Risks and constraints

- Literature reviews on the subject have not identified any risks associated with the proposed treatment for your child. However, it cannot be ruled out that the treatment may cause behavioural changes such as alterations of sleeping patterns or mealtimes. Even if studies exist to suggest that the osteopathic approach reduces the amount of crying, it cannot be excluded that the treatment may have the opposite effect.

By signing at the end of the document, you certify that you have understood all its contents and freely give your consent for the patient's participation in the project.

For further information you can contact the following people:

The osteopath with whom you will have an appointment:

NAME OF THE OSTEOPATH                      e-mail address

Person responsible for the study in Switzerland  
(available by telephone on Wednesday and Thursday during office hours) :

Prof. Paul Vaucher+41                      78 788 33 66                      [paul.vaucher@hes-so.ch](mailto:paul.vaucher@hes-so.ch)

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## Detailed information

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### 1. Aim of the project and selection of participants

This project aims to examine and measure the effectiveness, performance and safety of manual osteopathic treatment consisting of a "soft" touch over the duration of crying in infants with colic. This study also evaluates the occurrence of adverse effects in order to better understand and communicate the risks and benefits of manual osteopathic treatment. You are solicited for your role as the child's parent/legal representative.

Participation is open to parents who :

- Have a child who cries incessantly for more than 3 hours a day, 3 days a week.
- Let there be no other explanation for this crying.
- That apart from crying, the child is healthy.
- That the child is less than 10 weeks old.

### 2. General information on the project

In Switzerland, one in two infants is seen by an osteopath, a significant proportion of them for unsettled crying (infant colic). Unsettled infant crying, or infant colic, is a disorder that affects children between 0 and 6 months of age. The disorder manifests itself by crying for more than 3 hours a day, for more than 3 days in a week and is not explained by any other condition. This disorder is transient and usually disappears with the maturation of the nervous and digestive systems. The underlying causes remain unknown. Crying mainly affects the health of the parents and can lead to a lack of sleep, a feeling of helplessness and a loss of confidence in parenting skills.

In Switzerland, osteopathy has become a health profession since 2019. In order to practise, osteopaths must meet the requirements to safely treat patients in the first line of treatment. Within the framework of this project, all practising osteopaths receive a basic training equivalent to 5 years of full-time training and two years of post-graduate training. They all have experience in infant care and paediatrics. They are therefore already used to taking care of parents and infants suffering from colic.

There are about ten small clinical studies that have already evaluated the effects of osteopathic treatment for incessant crying. However, these studies are small and do not allow us to know the effect of the manual osteopathic component of the treatment on this condition. We would therefore like to evaluate the effect of a personalised osteopathic gentle treatment on the duration of crying compared to a generic gentle treatment with no desire to modify the tissues.

This study is part of an international project. A total of about 120 parents with their child will be followed up in the study, of which 40 will be in Switzerland. The other participants come from Great Britain and Australia.

If you and your child participate in the study, you will therefore be randomly assigned (one chance in two) to either a specific targeted manual treatment or a generic manual treatment without you knowing which treatment your child will receive.

The intervention studied is a usual osteopathic treatment involving light touch for 10-20 minutes, one to four times over two weeks. The touch is directed to specific areas of the baby's body, as the osteopath deems appropriate, with the aim of modifying tissue function or fluid dynamics.

The control intervention also consists of the usual osteopathic treatment. However, the usual manual treatment is replaced by a non-specific generic light touch on the skull, thorax, abdomen and sacral region

in any order without the osteopath attempting to move or adjust the soft tissues or change the fluid mechanisms. There is therefore no intention to relieve the tensions found. The duration is also 10-20 minutes, 1-4 times over two weeks.

You and your child will receive all the other components of normal care, i.e. listening, advice and support. You will therefore benefit from the standard treatment recommended in Switzerland. Each consultation usually lasts between 30 and 45 minutes. The follow-up is over two weeks.

This study is carried out in accordance with the requirements of Swiss legislation. In addition, we follow all internationally recognised guidelines. The study was reviewed and approved by the competent ethics committees at the international (NHS - UK) and national (Swissethics) levels. A description of the study can also be found on the website of the [Federal Office of Public Health](#) under the SNCTP register number [000004452].

### **3. Procedure for participants**

#### *Contribution to the study*

You will participate in the study over a period of two weeks with 1-4 osteopathic consultations of 30-45 minutes depending on your needs. You will be asked to fill out a crying diary to record how many minutes your baby cries during each hour of the day over a period of 14 days. This should not take you more than 5-10 minutes per day. You will also be asked to complete two electronic questionnaires, one at the beginning of the study when you first visit the osteopath and the other after 14 days. These ask questions about your baby's health, your confidence as a parent and your experience of care. These questionnaires should take about 5 minutes to complete.

#### *Course of events*

All of the osteopaths participating in this study have previous experience of treating babies, they are all registered health professionals who have been specially trained and selected to participate in this study. During treatment, you will be with your baby at all times and if your baby is in distress, you will be free to comfort and reassure them at any time.

Consultations will take place at the address you were given when you made your appointment:

[NAME OF THE OSTEOPATH]  
[NAME OF THE PRACTICE]  
[STREET AND STREET NO.]  
[POSTCODE] [PLACE]  
[PHONE NUMBER]

During the first consultation, you will have the opportunity to ask questions and make sure you agree to participate. The care is the same as the one usually proposed. You will therefore receive advice and support from the osteopath. The only difference is that your child will receive one of the two forms of gentle manual treatment offered: a specific form or a generic form.

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

You are also asked to be particularly attentive to the signs your child may present after treatment (e.g. drowsiness, agitation, change in appetite rhythm, crying) in order to report any form of adverse event. You can report them orally to the osteopath during a scheduled visit or in the questionnaire on the 14th day.

It is also possible that the osteopath may propose to film the consultation for quality control reasons. These videos are analysed by the principal investigator before being destroyed. You are entirely free to refuse to be filmed or to make the video accessible to the investigator without having to justify yourself.

All treatments are free of charge, we just ask you to fill in the questionnaires and the crying diary for us. Once this is completed, you can ask your osteopath what treatment your baby has received.

#### **4. Benefits for participants**

If you participate in the study, usual care (i.e. explanations, reassurance, advice, etc.) and osteopathic care may help to reduce crying and your quality of life. But you may not benefit from it at all. However, the results of the study can still be used to better inform other parents of children with unsettled crying.

#### **5. Voluntary nature of participation and obligations**

Participation in the study is entirely free. If you do not wish to participate or if you, as a parent, later reconsider your decision on this matter, you will not have to justify your decision. This decision will not have any negative repercussions on your or your child's future care.

Participation in the study implies the following obligations:

- You are required to complete the questionnaires and the Crying Diary as accurately as possible.
- The osteopath who follows you must be informed of the evolution of your child's health and any new symptoms, any new disorder and any change in your child's condition should be reported to him/her, including after the end / cessation of the study and until the mitigation of a possible adverse effect.
- The osteopath must be informed of any treatment or therapy prescribed or followed by a doctor/practitioner as well as all medicines taken by your child, including complementary or alternative medicine treatments.

Your child can of course benefit from the proposed specific techniques:

- Outside the study, which however implies exclusion from the study.
- After the study, if your child has been randomised to the control group.
- After the study, if you see an interest in continuing the treatment.

#### **6. Risks and constraints for participants**

We know from other research that post-treatment reactions (also called "adverse events") are very rare for this type of gentle therapy given to babies. However, it cannot be ruled out that the treatment induces undesirable events such as changes in sleeping or feeding rhythm or even an increase in crying. The proposed treatment has already been administered to hundreds of thousands of infants, and we are not aware of any cases of serious events induced by so-called "gentle" techniques. However, we cannot rule out the possibility that there may be an extremely rare unknown risk.

You will be asked to take your child to one of these osteopaths up to a maximum of 4 times over a period of 2 weeks, which implies time and possible travel expenses.

#### **7. Alternatives**

Participation in the study has both benefits and risks. By participating, you also have access to the usual treatment recommended by the guidelines in the field. There are, however, some alternatives, especially drugs. However, the evidence of their effectiveness remains uncertain. The osteopath and your child's paediatrician can provide you with information and advice on the use of these alternatives and the usual osteopathic treatment.

#### **8. Results**

During the course of the study, the osteopath-investigator will notify you, as a parent, of any new discoveries that are important for your child. If there is any doubt about the presence of another condition, you will be informed immediately. At that time your child may have to be excluded from the study.

The osteopath-investigator can also send you, at the end of the study, a synthesis of the global results which will also be published in free access for the public.

## **9. Confidentiality of data and samples**

### **9.1. Data processing and coding**

Within the framework of this study, data relating to your child's health and data concerning your role as a parent are collected and processed, in part automatically. This information is coded at the time of collection. Coding means that all identifying data (name, date of birth, etc.) are deleted and replaced by a code. It is not possible to link the data to the participants without the code, which remains in your possession and in that of the osteopath-investigator who followed you.

Only a limited number of people may access the data of participants in uncoded form, and only for the purpose of carrying out the tasks necessary for the study. These persons are bound by professional secrecy. As a parent, you have the right to access your own and your child's data. For this, it remains essential that you keep the code that was sent to you with the copy of your consent form.

### **9.2. Data protection**

All data protection guidelines are strictly adhered to. The data is stored on a certified secure server in the Netherlands which guarantees data protection equivalent to that guaranteed in Switzerland.

### **9.3. Data protection in case of re-use**

If health-related data are re-used for other research projects, such as analyses that combine the results of several studies together, the same security rules apply to your data as for this study. This may be important for answering other questions. Only non-personalised coded data is then used. By agreeing to participate in this study, you also agree that your coded data and your child's coded data may be reused for future scientific studies.

### **9.4. Right of consultation in the context of inspections**

The study may be subject to inspection. These may be carried out by the competent ethics commission, or by the sponsor who initiated the study. In certain very specific cases, the investigator must then communicate the data of the participants for the purposes of these inspections. All persons involved are bound by the strictest professional secrecy.

### **9.5. Withdrawal of the project**

The parent and his/her child can withdraw from the study at any time and end his/her participation if he/she wishes to do so or if you as a parent decide to do so. However, the data collected so far can still be analysed in coded form.

In the event of withdrawal, your data will continue to appear in encrypted form in the study documents, primarily to ensure medical safety. You should check whether you agree with this before giving your consent.

### **9.6. Compensation**

You will not receive any compensation for your participation in this study.

## **10. Responsibility**

Although there is no foreseeable risk involved in such research, the institution (the local promoter) is liable, under the legal provisions, for any damage that may occur in the course of the study. Any claim for compensation should be made to :

The HES-SO | FR, Rue des Arsenaux 16a, 1700 Freiburg, which is insured through the Bâloise, Aeschengraben 21 P.O. Box 4002 Basel (Police 2071361362).

## 11. Financing of the study

The study is financed by the School of Health Sciences Fribourg, the HES-SO, the Swiss Osteopathic Science Foundation, the University College of Osteopathy in London, the Institute of Osteopathy, and the National Council for Osteopathic Research.

## 12. Contact person(s)

You can ask questions about the study at any time. If you have any doubts, fears or emergencies during or after the study, you can contact the following contact person:

Principal investigator:  
(Switzerland)

Prof. Dr. Paul Vaucher  
[paul.vaucher@hes-so.ch](mailto:paul.vaucher@hes-so.ch)  
+41 78 788 33 66

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## Declaration of consent

### Written statement of consent for participation in a clinical study

Please read this form carefully. Do not hesitate to ask questions if you do not understand something or if you need clarification. Your written consent is required for the patient's participation.

<b>BASEC number of the research project:</b>	BASEC2021-00099
<b>Title :</b>	CUTIES-CH - Unsettled crying and osteopathic care
<b>Responsible institution :</b>	School of Health Sciences Fribourg Rue des Arsenaux 16a1700 Fribourg
<b>Investigator in charge</b>	Prof. Paul Vaucher
<b>Place of realization:</b>	To be completed according to the place of practice of each osteopath.
<b>Osteopath co-investigator/responsible investigator on the site:</b> Name and first name in block letters :	To be completed for each participating clinical osteopath
<b>Participant (child):</b> Printed name and surname : Date of birth :	To be completed during the first visit
<b>Identifier in the study:</b> Unique number allowing the link between your data and your identity (only accessible by you and your osteopath)	To be completed during the first visit

- In my capacity as parent/legal representative of the above-mentioned child, I have obtained written and oral information from the undersigned osteopath/investigator on the objectives and the course of the study evaluating a usual manual osteopathic treatment as well as the possible advantages and disadvantages and possible risks.
- I confirm that I am making the decision, on behalf of myself and my child, to participate to this clinical trial. On my own and my child's behalf, I accept the written and oral information. I have had sufficient time to make my decision.
- I have received answers to the questions I asked in relation to the study. I will keep the information sheet and receive a copy of my consent statement.
- I have been informed about therapeutic alternatives to the project, e.g. about the existence of other treatments and therapies.
- I agree that my child's paediatrician may be informed of my child's participation in the research project.
- In the event of subsequent treatment outside the location of this study, I authorise my child's paediatrician(s) to provide the osteopath-investigator with relevant post-treatment information for the study.
- I agree that the competent specialists named by the promoter and the competent ethics committee may consult the patient's unencrypted data in order to carry out checks and inspections, provided that the confidentiality of this data is strictly guaranteed.

- I am aware that personal data may be transmitted for research purposes within the scope of this study and only in encrypted form abroad as well. The promoter ensures data protection in accordance with Swiss standards and requirements.
- On behalf of my child, I may, at any time and without having to justify myself, revoke my consent to participation, without this decision having any adverse repercussions on the further care of my child. However, the data and samples collected up to the time of withdrawal will be analysed as part of the study.
- I have been informed that all damage attributable to the study is covered by the University of Applied Sciences Western Switzerland - Fribourg and its insurance (La Bâloise – Police 2071361362).

Place, date	Printed name and surname  <a href="#">To be completed during the first visit</a>  Relationship with the child (mother, father, legal representative, etc.) :  <a href="#">To be completed during the first visit</a>  Signature of parent :  <a href="#">To be completed during the first visit</a>
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**Co-investigator's attestation:**

I hereby certify that I have explained to the person representing the patient the importance and scope of the study. I declare that I fulfil all obligations in connection with this study in accordance with current Swiss law. If I should, at any time during the course of the study, become aware of anything that might influence the child's consent to take part in the project, I undertake to inform the parent immediately.

Place, date	Name and surname of the osteopath-investigator in block letters. <a href="#">To be completed during the first visit</a>  Signature of the osteopath/investigator <a href="#">To be completed during the first visit</a>
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