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Touch-based treatments and infantile colic - Parental perceptions of treatment outcomes

Submission date
15/05/2025

Recruitment status
No longer recruiting

Registration date
19/05/2025

Overall study status
Completed

Last Edited
21/11/2025

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Infantile colic is a common condition affecting many newborns, characterized by excessive crying and discomfort, often without a clear cause. This study aims to evaluate the effectiveness of different touch-based therapies—osteopathy, reflexology, and affective touch—in alleviating colic symptoms in infants.

Who can participate?
The study includes full-term infants aged 10 weeks or younger at the time of recruitment who exhibit symptoms consistent with colic, such as prolonged periods of crying. Parents or legal guardians must provide informed consent for their child's participation.

What does the study involve?
Participating infants were allocated to one of four groups—osteopathy, reflexology, affective touch, or standard care provided by child health clinic nurses—using a non-randomised assignment procedure.
Each intervention consists of multiple sessions over a period of 2–3 weeks. Parents are asked to maintain symptom diaries and complete questionnaires to report on their infant's crying patterns, sleep quality, and overall well-being. Additionally, some parents participate in semi-structured interviews to share their experiences with the assigned therapy.

What are the possible benefits and risks of participating?
Potential benefits include a reduction in colic symptoms, improved sleep patterns for the infant, and decreased parental stress. As the interventions are non-invasive and administered by trained professionals, risks are minimal. However, there may be a possibility that the therapy does not alleviate symptoms for all participants.

Where is the study run from?
The study recruitment is conducted in public child health clinics in Helsinki, the interventions are coordinated from the Metropolia University of Applied Sciences campus (Finland).

When is the study starting and how long is it expected to run for?
January 2020 to October 2022

Who is funding the study?
The study is funded by the Child and Nature Foundation and the Jenny and Antti Wihuri Foundation (Finland)

Who is the main contact?
Tiina Väänänen, tiina.vaananen@tuni.fi

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Leena Hannula

Contact details
PL 4000
00079 Metropolia
Helsinki / Finland
Helsinki
Finland
00079
+358 (0)974245000
leena.hannula@metropolia.fi

Type(s)
Public

Contact name
Ms Sandra Rinne

Contact details
Pobox 4000
00079 Metropolia
Helsinki
Finland
00079
+358 (0)401591759
sandra.rinne@metropolia.fi

Type(s)
Scientific

Contact name
Ms Tiina Väänänen

Contact details
Salastintie 66
Ruokolahti
Finland

56210
+358 (0)500764350
tiina.vaananen@tuni.fi

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HUS-2351-2020-7, HEL 2020-012399 T 13 02 01

Study information

Scientific Title
Touch-based treatments and infantile colic - Parental perceptions of treatment outcomes

Study objectives
Our hypotheses were that:
1. Osteopathy and reflexology have a greater effect in reducing parent-reported infant crying hours and increasing the parent-reported infant sleeping hours than conventional care alone (H1a)
2. Affective touch has a greater effect in reducing these parent-reported colic symptoms than conventional care alone (H1b), osteopathy and reflexology are more effective than affective touch (H2)

Our research questions were:
1. What effects do osteopathic treatment and reflexology have on infant colic symptoms, such as crying and sleep, as assessed by parents and practitioners, compared to affective touch or conventional child health clinic care only?
2. How do osteopathy and reflexology, in comparison to affective touch or conventional child health clinic care only, affect parental stress and fatigue, according to parents' self-reported experience?
3. How do parents perceive the benefits and usability of osteopathy and reflexology during and after the colic phase, in comparison to affective touch or conventional child health clinic care only?

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 28/10/2020, HUS ethical committee (HUS Tutkimuseettinen toimikunta PL 705, Helsinki, 000290, Finland; +358 (0)40 359 4618; eettinen.toimikunta@hus.fi), ref: HUS/2351/2020

2. approved 08/01/2021, City of Helsinki (Pohjoisesplanadi 11-13, Helsinki, 00099, Finland; +358 (0)310 13700; tutkimusluvat.sote@hel.fi), ref: HEL 2020-012399 T 13 02 01

3. approved 01/11/2021, City of Vantaa (Vantaan kaupungin kirjaamo, PL 1100, Vantaa, 01030, Finland; +358 (0)983911; kirjaamo@vantaa.fi), ref: VD/10228/13.00.00/2021

Study design
Single-centre mixed-methods interventional non-randomized single-blinded study

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life, Treatment

Health condition(s) or problem(s) studied
Infantile colic

Interventions
The study compared four intervention groups for infantile colic: (1) osteopathic treatment, (2) reflexology, (3) affective touch, and (4) child health clinic care only provided by child health clinic nurses. Each infant received one type of touch-based intervention, delivered by trained professionals or nurses over a series of sessions. Parents were instructed to observe and report outcomes such as crying, sleep, and overall well-being.

All participating infants received three free-of-charge treatments over a 2- to 3-week period at the treatment centre of Metropolia University. Each appointment for osteopathy, reflexology, and affective touch lasted a full hour, including time for discussion and breaks. The manual procedure itself lasted approximately 20–30 minutes.

Four follow-up questionnaires were sent to the osteopathy, reflexology and affective touch group parents: before the beginning of the experimental treatments (T0), within a day after the first treatment (T1), 1 week after the third treatment (T2) and 4 weeks after final treatment of the intervention (T3). Conventional care group parents were sent questionnaires T0, T2 and T3 at the same time points. The duration for treatment was 2-3 weeks and the follow-up lasted 4 weeks after the treatments, totalling a 7-week period.

Intervention Type
Other

Primary outcome(s)
1. Infant crying and sleeping patterns are measured using structured symptom diaries and questionnaires completed by parents at T0, T1, T2, and T3 for intervention groups and at T0, T2, and T3 for the conventional care group
2. Parental stress levels are measured using validated self-report questionnaires at T0, T1, T2, and T3 for intervention groups and at T0, T2, and T3 for the conventional care group
3. Parental fatigue levels are measured using validated self-report questionnaires at T0, T1, T2, and T3 for intervention groups and at T0, T2, and T3 for the conventional care group
4. Infant sleep duration and quality are measured using structured sleep diaries and questionnaires completed by parents at T0, T1, T2, and T3 for intervention groups and at T0, T2, and T3 for the conventional care group
5. Parental perceptions of the benefits and usability of the assigned intervention are measured using post-intervention surveys at T3 for all groups

Key secondary outcome(s))
1. Infant crying time is measured using parent-reported structured diaries in hours per day at T0, T2, and T3
2. Infant sleeping time is measured using parent-reported structured diaries in hours per day at T0, T2, and T3
3. Parent-perceived effectiveness of the intervention in reducing infant crying and improving sleep quality is measured using parent self-assessment questionnaires at T2 and T3
4. Parental post-natal stress is measured using the Postnatal Stress Questionnaire (Park et al. 2015) at T0, T2, and T3
5. Parenting-related stress is measured using the Parenting Stress Index Short Form (Berry and Jones 1995) at T0, T2, and T3
6. Perceived general stress is measured using the Perceived Stress Scale (Cohen 1983) at T0, T2, and T3
7. Infant colic symptoms are measured using parent-reported symptom diaries and questionnaires covering the preceding 24 hours and preceding week at T0, T2, and T3
8. Parental experiences of therapeutic touch are measured using semi-structured interviews analyzed with thematic analysis at T3

Completion date
31/10/2022

Eligibility

Key inclusion criteria
1. Full-term infants (gestational age ≥37 weeks)
2. Aged 10 weeks or younger at the time of recruitment
3. Presence of infantile colic symptoms, defined as crying for more than 3 hours per day, at least 3 days per week, consistent with Wessel's criteria.
4. Written informed consent obtained from parent(s) or legal guardian(s)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
0 days

Upper age limit
10 weeks

Sex
All

Total final enrolment
177

Key exclusion criteria
1. Preterm infants (gestational age <37 weeks)
2. Infants with additional medical diagnoses

Date of first enrolment
15/02/2021

Date of final enrolment
30/10/2022

Locations

Countries of recruitment
Finland

Study participating centre
Metropolia University of Applied Science
Myllypurontie 1 00920 Helsinki Finland
Helsinki
Finland
00920

Sponsor information

Organisation
Helsinki Metropolia University of Applied Sciences

ROR
https://ror.org/03hdaef25

Funder(s)

Funder type
Charity

Funder Name
Child and Nature Foundation

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The research data of the project will be retained by stored on Metropolia University's secure online disk for as long as necessary for the analysis and reporting of the research data and for five years after the end of the study until 2028. Manual data (consent forms and symptom diaries) will be disposed of appropriately in the shredder of the data protection container. After the study has been completed, when identifying information has been removed from the literature and the survey data has been anonymized, the data can be handed over for storage, for example, to the tietoarkisto.fi (Data Archive) https://www.fsd.tuni.fi/fi/.
Data type: De-identified individual participant data (IPD), including parent-reported symptom diaries, questionnaire responses, and relevant demographic information.
Availability: Data will be accessible starting six months after the publication of the final study results and will remain available for a period of five years.
Access criteria: Researchers interested in accessing the data must submit a formal request to the principal investigator, including a brief proposal outlining the intended use of the data.
Mechanism: Upon approval of the request, a data sharing agreement will be established to ensure compliance with ethical standards and data protection regulations.
Consent and anonymization: Participants' legal guardians provided informed consent for the use of de-identified data in future research. All shared data will be anonymized to protect participant confidentiality.
Ethical considerations: Data sharing will adhere to applicable ethical guidelines and legal requirements, ensuring that the rights and privacy of participants are safeguarded.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/11/2025	21/11/2025	Yes	No
Participant information sheet	version 3	14/10/2020	19/05/2025	No	Yes
Participant information sheet		18/09/2020	19/05/2025	No	Yes
Participant information sheet		18/09/2020	19/05/2025	No	Yes
Protocol file	version 3	15/10/2020	19/05/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes