

<b>Populärvetenskaplig resultatsammanfattning</b>	<b>International Safety study on Osteopathy in Children; the VOKO study</b>
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#### Resultatsammanfattning (På Svenska)

Användandet av Komplementär- och Alternativmedicinska (KAM) behandlingsmetoder ökat de senaste decennierna. Osteopati är en "manuell behandlingsmetod" inom KAM området. Internationella studier visar att mellan 7.5%-20% av barn med astma, allergier och psykiatriska besvär besöker en osteopat. Litet är känt om effektivitet, och säkerhetsaspekter avseende osteopatisk behandling bland barn. På grundval av denna brist av data initierade forskarteamet en internationell säkerhetsstudie, med syftet att undersöka förekomst av oönskade effekter/biverkningar associerade med osteopatisk behandling av barn (yngre än 17 år). Det undersöktes även vilka besvär barn erhåller behandling för, samt tillfredsställelse med behandlingen.

Metod: Data insamlades med hjälp av web-baserade enkäter i samband med att barnet kom osteopat för behandling. Vid första enkättilfället insamlades bakgrunddata och uppgifter om kontaktorsak, vid andra enkättilfället registrerades uppgifter om eventuella oönskade effekter. I studien var målet att inkludera 500 föräldrar till barn som genomgick behandling hos osteopat (250 vardera i Sverige och Norge).

Resultat: Under studieperioden inbjöds cirka 400 föräldrar/barn för deltagande, av dessa besvarade 73 första frågeformuläret och 34 det andra, vilket reflekterar en låg svarsfrekvens (18% och 8.5%).

Utifrån det insamlade datat finns indikationer på att det är säkert att behandla barn med osteopati, lätta oönskade effekter (trötthet, lokal ömhet) registrerades hos två (2.7%) av 73 barn. Barnen i studien behandlades främst för muskulo-skeletala besvär (65.8%) men även till viss del för psykosomatiska/stressrelaterad besvär (ospecifik magsmärta, migrän, sömnlösning) samt i hälsofrämjande syfte. Föräldrar uttrycker stora förväntningar på behandlingen, samt är mycket tillfredsställda med behandlingsresultatet.

Diskussion/konklusion: Syftet med denna studie har enbart *delvis* uppnåtts, *delvis* på grund av teamet ej har lyckats rekrytera deltagare planenligt. Orsakerna till den låga svarsfrekvensen är multifaktoriell och kan bero på studiedesignen, delegerandet av rekrytering till behandlande osteopater, att ha en web-baserad enkät istället för papper, en lägre andel av barn som behandlas än förväntat, bristande engagemang hos osteopater och mer.

Det förefaller som att osteopatisk behandling av barn inte är förenat med risker, dock är oönskade effekter relativt vanliga. Dock, utifrån den låga svarsfrekvensen så måste resultaten tolkas med försiktighet.

Utifrån våra erfarenheter i detta projekt rekommenderas att framtida projekt inom ämnet genomförs med striktare metodik, där forskarna bibehåller kontrollen över rekrytering av deltagare, och om möjligt samlar in uppgifter i direkt kontakt med deltagare.

Vetenskaplig rapport: Studien har ej, och kommer ej att skickas in till vetenskaplig tidskrift då forskargruppen bedömer att svårigheterna med att samla in valida data ej har lyckats.



## **International Safety study on Osteopathy in Children; the VOKO study**

### **1. Purpose and aims of the research project:**

The overall objective of this research project was to investigate the safety of osteopathic treatment in children of 17 years and younger.

The following research questions was planned to be addressed:

- Which side effects (adverse events) are reported by parents of children who are visiting and treated by an osteopath.
- What was the frequency of these side effects.
- What were possible predictors of side effects with osteopathic treatment (for example training of osteopath, age of children, type of complaint).
- For which complaints do children visit an osteopath
- What is the general satisfaction of parents with respect to the osteopathic treatment of their children.

An attempt to answer the research questions was made by implementation of an international surveillance study among children visiting an osteopath in Sweden, Norway and the Netherlands

***This present report refers to the Scandinavian part***

### **3. Background:**

The use of Complementary and Alternative Medicine (CAM) has increased during the last years. Depending on the exact definition and region, about 20-49% of the Swedish population uses some form of CAM therapy, including manual therapies such as massage, acupuncture, chiropractic, osteopathy and naprapathy (Eklöf, 2001). Osteopathy is for of CAM that is based on the principle that physiological dysfunction is associated with a disruption in the musculoskeletal system. Recently, it has become apparent that more and more children visit an osteopath for a wide range of conditions. Four studies in the Netherlands found that 7.5% up to 20% of children with a chronic condition such as asthma, allergies and psychiatric disorders visit an osteopath (Jong 2010, Jong 2012A, Jong 2012B, Vlieger 2008). Despite its frequent use, little is known about the effectiveness and safety of osteopathy in children. A Dutch review (Weggelaar, 2011) reported on 10 Randomized Controlled Trials (RCTs) in children dating from 2003 and later. These studies were performed in children with asthma (1), otitis media acuta (3), cerebral palsy (2), plagiocephalie (1), dentistry (1), infantile colic (1) and dysfunctional voiding (1). The reported RCTs demonstrated positive effects of osteopathic treatment, but studies were small in size, low in overall quality and lacked an appropriate control group. A report from Norway reported that osteopathic treatment in children is safe and not associated with any side effects or risk (Brugberg, 2009). In contrast, two reviews of Weggelaar et al (2011) and Dobson et al (2012) reported that too little data are known to conclude that osteopathic treatment (or other manual therapies) of children is safe. In 2009, a case was reported on the death of a young infant after manipulation of the neck and spine (Holla, 2009). This manipulation was labelled as craniosacral therapy in which the general guidelines of osteopathy were not followed. In an additional review of reported adverse

events of manual therapies a few other serious cases has been reported (Todd, 2015). Thus further studies on the course and safety of osteopathic treatment in children are warranted.

#### **4. Rational for the study**

Due to the absence of safety data on osteopathic treatment in children, the research group initiated an active large scale surveillance study to investigate the incidence of adverse events associated with osteopathic treatment in children.

A hypothesis was that osteopathic treatment of children by certified osteopaths would be well tolerated and to a high level of satisfaction of parents. We consider it strategically of utmost importance to first generate data on the safety and use of osteopathic treatment in children, before implementing any further studies on the efficacy of osteopathy for certain conditions.

#### **5. Research design:**

An international surveillance study on the safety of osteopathic treatment in children (here report for the study in Scandinavia). A questionnaire was distributed through 30 participating osteopathic practices with the goal to reach out to 500 parents of children visiting an osteopath.

Research ethical approval was obtained in both Sweden (Central Ethical Review Board, Dnr Ö23-2014) and in Norway (Regional Committees For Medical and Health Research, Ref nr: 2014/2320).

#### **6. Project activities:**

##### 1. Safety Questionnaire

The questionnaire for surveillance of safety of osteopathic treatment was modified from the questionnaire as developed for a Dutch safety study on chiropractic practice (Rubinstein, 2008).

The questionnaire was translated into Swedish from Dutch by the research team and into Norwegian by a professional translator. In essence there were three different questionnaires; the *first* addressed the participating osteopaths and included information on gender, age, training and years of experience of the osteopath. The *second* questionnaire was directed towards parents and their children visiting a osteopath. This questionnaire was completed before the first visit to the osteopath. It included information on demographic characteristics of parents and children (education level of parents, age of child and complaints), other health professionals visited, medication use, apparent existing side effects, absence from school/day care, work absence due to illness of the child, treatment expectations and more. The parents (or older children) answered the *third* questionnaire circa one week after the first visit. It included information on treatment, severity of complaints before and after visit to osteopath, satisfaction with treatment, occurrence of side effects, onset of side effects, duration of side effects, impairment due to side effects and visits to other healthcare professionals.

All questionnaire data was collected through a web-based survey system, which was designed to work with both computers and smartphones.

##### 2. Recruitment of osteopaths

In Scandinavia (Sweden and Norway), osteopaths being members of the national organizations of proficiency was approached to participate in the study. In total 32 Osteopaths agreed to participate and recruit parents/children to the actual surveillance study. The

inclusion criteria's was that participating osteopaths should have at least five years of experience of working as an Osteopath and be member of a professional organisation.

### 3. Recruitment of parents and children for safety surveillance

The safety surveillance of osteopathic treatment was implemented through the participating osteopaths. Each osteopath consecutively approached parents of children (in Norway 0 - 18 years of age), or children >15 coming by themselves, that were scheduled for a visit. In Sweden, osteopaths are not allowed to treat children less than 8 years of age. Therefore, data was collected for children between 8-17 years of age. The goal was to include 500 parents in Scandinavia.

At arrival for the planned visit, parent and child was informed about the study by the Osteopath, they received an introduction letter with more lengthy information about study purpose, the procedure of responding to questionnaires, confidentiality as well that participation was voluntary. A signed copy of the informed consent was sent by regular mail to the researchers in a prepaid envelope.

The introduction letter/informed consent also contained instructions on how to respond to the web-based questionnaires, using a simple web-address. ([www.miun.se/voko](http://www.miun.se/voko))

### 4. Outcome measures and data analysis

For the evaluation of the safety of osteopathic treatment the following parameters was analyzed:

#### *Primary outcome measures*

- Side effects (adverse events) reported
- Frequency side effects.

#### *Secondary outcome measures*

- Descriptives on which complaints do children visit an osteopath.
- The general satisfaction of parents with respect to the osteopathic treatment of their children.

All data was processed and descriptive statistics was computed using SPSS statistics version 24.0. Due to the limited response rates no calculations on inferential statistics was possible. Since there were no existing studies providing reliable data on safety in osteopathic treatments in children we were unable to make a power calculation to determine sample size. The "chosen" number of participants (n=500) was thereby more decided upon how many we judged as reasonable to include.

## 7. Results

### *Recruitment of Osteopaths and study participants*

#### *The Osteopaths*

In total 32 osteopaths (12 from Norway and 20 from Sweden) approved to aid in recruitment of parents/children among their clients. The osteopaths were mainly men (n=20, 62.5%), a median age of 44 (Range 28-57 years), they had in median worked as osteopaths, as well with children for 8 years (Range 5-22 years). Ten (31.3%) of the osteopaths had undergone shorter courses with focus on children.

#### *Parents and children*

During the full study period (April 2015 - July 2016) circa 400 parents/children was invited for participation of which 73 responded on the first questionnaire, and 34 on the second. Reflecting a low response rate; 18% and 8.5% respectively.

Among the children 46 (63%) were boys and 25 (34%) were girls (missing data for two children). The median age of children were 11 years, ranging from 1 month to 17 years of age. In most (n=52, 71.2%) cases the mother was bringing the child for osteopathic treatment. Regarding education level of parents, 38 (52.1%) of the mothers and 19 (26%) of the fathers had had a degree on university level.

#### *Adverse events*

Among the 34 respondents who responded to questionnaire 2, adverse events was reported in **two** cases. In one infant of five months of age increased tiredness was reported and in another (14 years old) sleeping problems and increased tiredness was reported. The infant was treated for Colic, and the older child for headache.

#### *Contact reason*

The complaints underlying the visit to the osteopath reported by parents and children was classified into 18 different categories, where the majority (n=46, 65.8%) can be said to origin from musculoskeletal problems. For more information, see table 1. Prior to visiting an osteopath, most children (n=58, 79.5%) had visited general physicians (n=26, 35.6%), pediatricians (n=15, 20.5%), physiotherapists (n=16, 16.9%), child health nurses (n=21, 28.8%) or other therapists (n=15, 20.5%) for treatment and advice. A large proportion (n=27, 37%) had visited more than one of above-mentioned professions (missing data for seven children, 9.6%). Almost two thirds (n=47, 64.4%) of children had been on an earlier osteopathic treatment

A large proportion of the children had also suffered from their problem for more or equal to one year (n=31, 42.5%, data is missing for three children).

**Table 1. Categorized contact reasons**

<b>Complaint</b>	<b>Frequency</b>	<b>Percent</b>
Neck complaints	11	15,7
Back complaints	9	12,9
Gas-Colic-stomach complaints	9	12,9
Tib-fib-foot complaints	6	8,6
Worry-anxiety-restlessness	5	7,1
Health promotion	5	7,1
Preferential head turn	4	5,7
Lower back complaints	3	4,3
Femur-knee complaints	3	4,3
Headache	3	4,3
Bed wetting	3	4,3
Shoulder complaints	2	2,9
Inflammatory bowel disease	2	2,9
Arm-hand complaints	1	1,4
Hip-Pelvis complaints	1	1,4
Slow motoric development	1	1,4
Tempomandibular problems	1	1,4
Respiratory tract symptoms	1	1,4
	70*	100

\*contact reason missing in three cases

### *Expectations and general satisfaction of parents with respect to the osteopathic treatment of their children.*

#### Expectations

As measured with a visual analogue scale 0-10, parents expressed high expectations that the osteopathic treatment would be effective (Mean 8.0, SD 2.2).

#### Satisfaction

Data regarding satisfaction with treatment was collected a few days after the first treatment, and parents responding (n=38) express a high degree of satisfaction with treatment as measured with a visual analogue scale 0-10 with a mean value of 7.7 (SD 2.7).

## **8. Discussion**

The overall objective of this research project was to investigate the safety of osteopathic treatment in children of 17 years and younger. In the results section the objective and additional research questions has been partly investigated and illustrated. Partly, because as reported earlier, the research group has been unable to recruit participants according to study plan, in total 73 children instead of 500. Reasons for this low response rate are probably multifactorial based for example on: study design, delegating inclusion to osteopaths, having a web survey instead of paper-based, a lower frequency of children visiting osteopaths that predicted, lack of engagement among osteopaths and more.

Due to the low response rate, the results need to be interpreted with caution. From the data that we have there are indications that osteopathic treatment of children is safe: in two out

of 73 children (2.7%) minor adverse events occurred. In line with the standard of Council for International Organizations of Medical Sciences (1999), where adverse event occurring in 1-10% of treatments it is viewed as “**common**”. This preliminary conclusion is also well in line with previously published reviews on safety of manual therapies in children (Dobson et al 2012; Todd et al 2015), although they state that reporting of safety in included studies were inadequate.

Children in this present study mostly came to osteopaths with musculoskeletal complaints (65.8%), but also to some extent to psychosomatic/stress related problems, as well as more general and health promotive treatments. This is also well in line with the findings from Marchand (2012) where 59% of patients had musculoskeletal complaints.

Parents have high expectations of osteopathic treatments and are highly satisfied with its effects.

With hindsight on the lessons learned from pursuing this project we can conclude that a future project on the same topic needs to be made on a more strict basis where the researchers keeps personal contact with participants if possible, collect data directly by telephone, or on-site interviewing. A possible alternative could also be to equip all participating therapists with a tablet in the office where participants directly can respond on questionnaires on-site. In comments received from participating osteopaths, we have learned that they are really working on a tight schedule and thereby have little or no time to motivate, guide and support study participants to fill in questionnaire. We have noticed two osteopaths (one in Sweden and one in Norway) who were able to put extra time for explanation, and they had much higher response rates among their clients. But doing research with even more strict “control” also requires more resources to have researchers or research assistants to spend more time to work proactively in recruitment and data collection.

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