SafetyNET Patient Information Sheet - Pediatric

Title of Study: Improving the Assessment of Safety in Pediatric Chiropractic Manual Therapy

Investigators:
Dr. Katherine Pohlman (780-342-8447)
Dr. Sunita Vohra (780-342-8592)
Dr. Linda Carroll (780-492-9767)

Why is your child being asked to take part in this research study?
Your child is being asked to take part in this research study being done with the University of Alberta because your chiropractor is a research participant in this study. The purpose of the study is to collect information related to children patient’s experience of chiropractic manual therapy, including safety information. Your participation is voluntary and completion / return of the form means you agree to be part of this study.

What is the reason for doing the study?
The study is being done to support patient safety which will allow doctors of chiropractic to identify concerns and find ways to reduce them.

What will I be asked to do?
If you agree to take part on behalf of your child, we will ask you to complete 2 forms about your child’s visit with your chiropractor today. The forms will only take a few minutes to fill out. The PRE form will be completed before your child sees the chiropractor. The POST form will ask you to comment on any effects / problems / symptoms your child may have experienced during or after his / her treatment. This form can be completed and returned at any time, using the pre-addressed and postage paid envelope; however, we are most interested in your feedback one week after your child’s visit, but prior to your child’s next visit with this chiropractor.

What are the risks and discomforts?
There are no known risks associated with participating in this study.
What are the benefits to me?
You and your child are not expected to get any benefit from being in this research study. The benefits of taking part are to help increase our knowledge about the potential effects and safety of chiropractic manual therapy.

Do I have to take part in the study?
Being in this study is your choice. If you decide your child should be in the study, you can change your mind and stop being in the study at any time, and it will not affect you or your child’s treatment. No one, including the researcher, will know whether or not you have participated.

Will my information be kept private?
During the study, if you choose to complete the forms on behalf of your child, we will collect data about the care he or she received from your chiropractor. We will do everything we can to make sure that this data is kept private. No data relating to this study includes your child’s name. Sometimes, by law, we may have to release our data and the information you provided, so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your child’s information is kept private. Furthermore, your chiropractor identified by a code, rather than by name, and this identifying code will be destroyed 90 days after their participation in the study. After that time, we will not have any record of who took part in the study. Thus, we will not be able to connect your chiropractor to any of your child’s visit after this time.

What if I have questions?
If you have concerns about this research now or later, please contact the study coordinator, Dr. Katie Pohlman at 780-342-8447. If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office has no affiliation with the study investigators.
Thank you for your support.
Your feedback is extremely valuable.

Completing this form means you agree to be part of this study. Please give to your chiropractor before your visit starts.

1. This form is being completed for this child by: ☐ Mother ☐ Father ☐ Other, specify: _______________________

2. Please mark the reason(s) for your child’s appointment today:
   - Preventative / Wellness / No Symptoms
   - Headache
   - Neck pain
   - Mid-back pain
   - Low-back pain
   - Arm / Shoulder / Knee / Leg Pain
   - ADD / ADHD
   - Autism
   - Breastfeeding Difficulties
   - Cold
   - Colic
   - Digestive Issues
   - Plagiocephaly
   - Torticollis
   - Other, specify: ____________________________

3. How long has your child had this condition? ________ week(s) ☐ >1 year ☐ N/A

4. How many treatments has your child had for this condition? ________ treatments ☐ N/A
   Over what period of time? ________ week(s) ☐ >1 year ☐ N/A

5. In the past 7 days, how would you rate your child’s pain on average?
   0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐
   No pain ☐ Worst imaginable pain

6. Please indicate any medications that your child is taking: ☐ None
   - Acetaminophen / Ibuprofen
   - Cetirizine (Zyrtec/Reactine)
   - Diflucan
   - Gaviscon
   - Omeprazole (Prilosec, Losec)
   - Ranitidine (Zantac)
   - Other: ______________________

7. Please indicate any vitamins or natural health products that your child is taking: ☐ None
   - Omega-3
   - Probiotics
   - Vitamin D
   - Other: ______________________

8. Does your child have a history of any of the following? ☐ None
   - Bleeding disorder
   - Cancer
   - Diabetes
   - Other: ______________________

9. Child is: ☐ Male ☐ Female ☐ Other: ______________________

10. Child’s date of birth? _____Month _____Day 20_____

11. Today’s fees covered by: ☐ N/A ☐ Self-pay ☐ Car Accident Coverage ☐ Other Insurance: ____________________________

Please continue with questions on the back.
### Post Symptoms

<table>
<thead>
<tr>
<th>Post Symptoms (check all that apply)</th>
<th>Pre-Existing:</th>
<th>If Yes: Better, Worse, or Unchanged?</th>
<th>Anticipated?</th>
<th>Overall Severity Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discomfort / Pain</td>
<td>Yes</td>
<td>B</td>
<td>Yes</td>
<td>Mild</td>
</tr>
<tr>
<td>Stiffness</td>
<td>Yes</td>
<td>B</td>
<td>Yes</td>
<td>Moderate</td>
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<tr>
<td>Weakness</td>
<td>Yes</td>
<td>B</td>
<td>Yes</td>
<td>Severe</td>
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<tr>
<td>Fatigue / Tiredness</td>
<td>Yes</td>
<td>B</td>
<td>No</td>
<td>Serious</td>
</tr>
<tr>
<td>Headache</td>
<td>Yes</td>
<td>B</td>
<td>No</td>
<td>Serious</td>
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<tr>
<td>Dizziness</td>
<td>Yes</td>
<td>B</td>
<td>No</td>
<td>Serious</td>
</tr>
<tr>
<td>Numbness / Tingling</td>
<td>Yes</td>
<td>B</td>
<td>No</td>
<td>Serious</td>
</tr>
<tr>
<td>Irritability / Crying</td>
<td>Yes</td>
<td>B</td>
<td>No</td>
<td>Serious</td>
</tr>
<tr>
<td>Other: ___________________________</td>
<td>Yes</td>
<td>B</td>
<td>No</td>
<td>Serious</td>
</tr>
</tbody>
</table>

Please put completed form in SafetyNET Box.
Thank you for your support.
Your feedback is extremely valuable.

- Completion and return of this form means you agree to be part of this study on behalf of this child. Please answer the questions based upon the appointment date identified below.
- You can complete this survey at any time; however, we are most interested in the feedback one week after your child's visit, but before his / her next visit.

1. Date of completion: _____ _____ / _____ _____ / 201____ (Month / Day / Year)

2. This form is being completed for this child by: ☐ Mother ☐ Father ☐ Other: ____________________________

   | Mark only one checkbox on each line | Very satisfied | Somewhat satisfied | Neither satisfied nor dissatisfied | Somewhat dissatisfied | Very dissatisfied |
---|-------------------------------------|---------------|------------------|-----------------------------------|----------------------|------------------|
3. How satisfied are you with the information you have been given from your child’s chiropractor? | ☐   | ☐   | ☐   | ☐   |
4. How satisfied are you with the treatment(s) that your child received? | ☐   | ☐   | ☐   | ☐   |
5. How satisfied are you with the overall care that your child received? | ☐   | ☐   | ☐   | ☐   |

6. In the past 7 days, how would you rate your child’s pain on average?

   0 1 2 3 4 5 6 7 8 9 10
   ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

   No pain   Worst imaginable pain

7. During the appointment with the chiropractor, did your child receive **manual therapy** (also called manipulation, mobilization or adjustment; defined as ‘A hands-on therapy to affect joints in the neck, back or limbs; sometimes hand-held mechanical devices are also used.’)?
   ☐ No
   ☐ Yes, please mark all areas where you received a manual therapy:
     - ☐ Neck
     - ☐ Back
     - ☐ Shoulder/Arms/Knee/Legs
     - ☐ Other: ____________________________

8. Since your child’s appointment with the chiropractor, what other treatments / therapies has your child had?
   ☐ None
   - ☐ Other **manual therapy** (also called manipulation, mobilization or adjustment; defined as ‘A hands-on therapy to affect joints in the neck, back or limbs; sometimes hand-held mechanical devices are also used.’)
     please specify: ____________________________
   - ☐ New medicine, please specify: ____________________________
   - ☐ New natural health products, please specify: ____________________________
   - ☐ Other, please specify: ____________________________

9. How would you describe the overall effect of your child’s visit with your chiropractor?
   ☐ Favorable ☐ Unfavorable ☐ None ☐ Unsure

Please complete page 2 (on reverse)
**FIRST:** Since the appointment did your child have any of the following? 
(check all that apply below)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
<th>Better</th>
<th>Worse</th>
<th>Unchanged</th>
<th>Not there</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discomfort/Pain</td>
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<tr>
<td>Stiffness</td>
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<td>Weakness</td>
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<td>Tiredness/Fatigue</td>
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<td>Headache</td>
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<tr>
<td>Problems Sleeping</td>
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<tr>
<td>Irritability/Crying</td>
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<tr>
<td>Other Condition</td>
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**SECOND:** For each item you checked ‘yes’ in the first column, please answer the questions below.

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Thank you for participating in the SafetyNET study. Please seal in envelope provided and place in mail.
GENERAL ADVERSE EVENT NARRATIVE

1. Please describe what happened. (Include date of onset, manual therapy technique / location, treatment schedule, patient’s response, tests done to evaluate the symptoms, and all actions taken.)

2. How long after treatment did the adverse event occur?: ____________ Hours  OR  ____________ Days

3. In your opinion, what may have contributed to the adverse event?

__________________________________________________________________________________________________

__________________________________________________________________________________________________

__________________________________________________________________________________________________

PATIENT CHARACTERISTICS  Please describe what was known PRIOR TO treatment

4. Reason of patient visit: ________________________________________________________

5. What was patient’s specific diagnosis for treatment? (Include details such as acute / chronic / recurring, what symptoms they had, and what diagnostic tests were done prior to treatment.)

__________________________________________________________________________________________________

__________________________________________________________________________________________________

__________________________________________________________________________________________________

6. Has the patient experienced an adverse event to manual therapy in the past?
   ○ Yes  ○ No  ○ Unknown  ○ If yes, please specify ________________________________

Please continue with questions on the back.
**PATIENT CHARACTERISTICS con’t** — Please describe what was known PRIOR TO treatment

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7. Did the patient have any other diagnoses?  
   - [ ] Yes  
   - [ ] No  
   - [ ] Unknown  
   - If yes, please specify: ____________________________

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8. Were you aware if the patient had any of the following conditions prior to treatment?  
   - [ ] Acute infection  
   - [ ] Fracture  
   - [ ] Recent relevant trauma  
   - [ ] Bleeding tendency  
   - [ ] History of cancer  
   - [ ] Recent upper respiratory infection  
   - [ ] Connective tissue disorder  
   - [ ] History of stroke  
   - [ ] Vertigo  
   - [ ] Diabetes  
   - [ ] Prior spine surgeries  
   - [ ] Fever  
   - [ ] Radiculopathy  
   - [ ] Other: ____________________________

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9. Please check medication(s) or natural health product(s) the patient was taking prior to treatment.  
   **Prescription Medications**  
   - [ ] Don’t Know  
   - [ ] Acetaminophen / Ibuprofen  
   - [ ] Ceririzine (Zyrtec)  
   - [ ] Diflucan  
   - [ ] Gaviscon  
   - [ ] Omerprzole (Prolosec, Losec)  
   - [ ] Ranitidine (Zantac)  
   - [ ] Other, Specify: ____________________________
   
   **Natural Health Products**  
   - [ ] Don’t Know  
   - [ ] Omega 3 Fatty Acids  
   - [ ] Probiotics  
   - [ ] Vitamin D  
   - [ ] Other NHP, Specify: ____________________________

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**OUTCOME (from your perspective / awareness)**

**PATIENT IMPACT:**

10. What activities of daily living were affected?  
    ____________________________

11. Was self-care affected?  
    - [ ] Yes  
    - [ ] No  
    - [ ] Unknown

12. Was the patient hospitalized?  
    - [ ] Yes  
    - [ ] No  
    - [ ] Unknown

13. Describe any residual effect / permanent disability / death:  
    ____________________________

14. Did the adverse event require treatment?  
    - [ ] Yes  
    - [ ] No  
    - [ ] Unknown

15. Has the adverse event resolved?  
    - [ ] Yes  
    - [ ] No  
    - [ ] Unknown  
    If Yes, Date of Resolution (dd/mm/yyyy):  
    ___ ___ / ___ ___ / 201___

**PROVIDER IMPACT:**

16. Has this event caused you to make any changes to your practice?  
    - [ ] Yes  
    - [ ] No  
    If Yes, describe: ____________________________________________

17. Were there factors that could have minimized / prevented this event?  
    - [ ] Yes  
    - [ ] No  
    If Yes, describe: ____________________________________________