

Use physical therapy to head off this deformity in infants. *J Fam Pract.* 2009;58(8);E1-E3 (online exclusive at jfonline.com)

Potential PURL Review Form: Randomized controlled trials

SECTION 1: IDENTIFYING INFORMATION FOR NOMINATED POTENTIAL PURL

1. Citation	van Vlimmeren LA, van der Graaf Y, Boere-Boonekamp MM, et al.. Effect of pediatric physical therapy on deformational plagiocephaly in children with positional preference: a randomized controlled trial. <i>Arch Pediatr Adolesc Med.</i> 2008;162:712-718.
2. Hypertext link to PDF of full article	http://www.ncbi.nlm.nih.gov/entrez/utils/fref.fcgi?PrId=3051&itool=AbstractPlus-def&uid=18678802&db=pubmed&url=http://archpedi.ama-assn.org/cgi/pmidlookup?view=long&pmid=18678802
3. First date published study available to readers	August 2008
4. PubMed ID	18678802
5. Nominated By	Michael Mendoza
6. Institutional Affiliation of Nominator	University of Chicago
7. Date Nominated	August 28, 2008
8. Identified Through	Other
9. PURLS Editor Reviewing Nominated Potential PURL	Bernard Ewigman
10. Nomination Decision Date	August 28, 2008
11. Potential PURL Review Form (PPRF) Type	RCT
12. Other comments, materials or discussion	
13. Assigned Potential PURL Reviewer	Lisa Vargish
14. Reviewer Affiliation	University of Chicago
15. Date Review Due	August 17, 2008
16. Abstract	<p>OBJECTIVE: To study the effect of pediatric physical therapy on positional preference and deformational plagiocephaly.</p> <p>DESIGN: Randomized controlled trial.</p> <p>SETTING: Bernhoven Hospital, Veghel, the Netherlands.</p> <p>PARTICIPANTS: Of 380 infants referred to the examiners at age 7 weeks, 68 (17.9%) met criteria for positional preference, and 65 (17.1%) were enrolled and followed-up at ages 6 and 12 months.</p> <p>INTERVENTION: Infants with positional preference were randomly assigned to receive either physical therapy (n=33) or usual care (n=32).</p> <p>MAIN OUTCOME MEASURES: The primary outcome was severe deformational plagiocephaly assessed by plagiocephalometry. The secondary outcomes were positional preference, motor development, and cervical passive range of motion.</p> <p>RESULTS: Both groups were comparable at baseline. In the intervention group, the risk for severe deformational plagiocephaly was reduced by 46% at age 6 months (relative risk [RR], 0.54; 95% confidence interval [CI] 0.30-0.98) and 57% at age 12 months (0.43; 0.22-0.85). The numbers of infants with positional preference needed to treat were 3.85 and 3.13 at ages 6 and 12 months, respectively. No infant demonstrated positional preference at follow-up. Motor development was not significantly different between the intervention and usual care groups. Cervical passive range of motion was within the normal range at baseline and at follow-up. When infants were aged 6 months, parents in the intervention group demonstrated significantly more symmetry and less left orientation in nursing, positioning, and handling.</p> <p>CONCLUSION: A 4-month standardized pediatric physical therapy program to treat positional preference significantly reduced the prevalence of severe deformational plagiocephaly compared with usual care.</p> <p>CLINICAL TRIAL REGISTRATION: isrctn.org Identifier: ISRCTN84132771.</p>
17. Pending PURL Review Date	October 8, 2008

SECTION 2: CRITICAL APPRAISAL OF VALIDITY

1. Number of patients starting each arm of the study? 33 intervention, 32 control
2. Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.)? Inclusion: by 7 weeks, infants had to have positional preference
Exclusion: congenital muscular torticollis, dysmorphisms, and syndromes
3. Intervention(s) being investigated? Physical therapy (PT) versus usual care (pamphlet and typical health education)
PT consisted of 8 sessions between 7 weeks and 6 months, or until preferential positioning stopped in sleep or wakefulness; 2-5 sessions at infant's home, parents educated in how to hold, feed, play with infant in prone position, etc
4. Comparison treatment(s), placebo, or nothing? PT versus usual care (see PT description above)
5. Length of follow up? Note specified end points e.g. death, cure, etc. PT stopped at 6 months, but infants followed to 12 months
6. What outcome measures are used? List all that assess effectiveness. Primary: severe deformational plagiocephaly
Secondary: positional preference, motor development, cervical passive range of motion
7. What is the effect of the intervention(s)? Include absolute risk, relative risk, NNT, CI, *P*-values, etc. Deformational plagiocephaly reduced by 46% at 6 months (RR: 0.54, 95% CI: 0.30-0.98) and 57% at 12 months (RR: 0.43, 95% CI 0.22-0.85), number needed to treat [NNT] 3.85 at 6 months and 3.13 at 12 months. Motor development showed no difference, no child had a positional preference at 12 months, and cervical passive range of motion was within normal limits at baseline and follow-up. When infants were 6 months old, parents in intervention group were more symmetric in how they approached their child than parents of infants in the control group.
8. Study addresses an appropriate and clearly focused question - **select one**
 Well covered
 Adequately addressed
 Poorly addressed
 Not applicable
9. Random allocation to comparison groups - **select one** Well covered
10. Concealed allocation to comparison groups - **select one** Well covered
11. Subjects and investigators kept "blind" to comparison group allocation - **select one** Adequately addressed
Comments: single-blinded, but did well at keeping everyone else blinded.
12. Comparison groups are similar at the start of the trial - **select one** Well covered
13. Were there any differences between the groups/arms of the study other than the intervention under investigation? If yes, please indicate whether the differences are a potential source of bias. - **select one** Well covered
14. Were all relevant outcomes measured in a standardized, valid, and reliable way? - **select one** Well covered

15. Are patient-oriented outcomes included? If yes, what are they?	Yes, motor development and passive range of motion, as well as head shape.
16. What percent dropped out, and were lost to follow up? Could this bias the results? How?	No one was lost to follow-up, some dropped out or were not compliant, but there were only 2.
17. Was there an intention-to-treat analysis? If not, could this bias the results? How?	Yes
18. If a multi-site study, are results comparable for all sites?	N/A
19. Is the funding for the trial a potential source of bias? If yes, what measures were taken to insure scientific integrity?	No
20. To which patients might the findings apply? Include patients in the study and other patients to whom the findings may be generalized.	All infants with plagiocephaly
21. In what care settings might the findings apply, or not apply?	Primary care
22. To which clinicians or policy makers might the findings be relevant?	Pediatrics and family medicine

SECTION 3: REVIEW OF SECONDARY LITERATURE

1. DynaMed excerpts	Nothing found
2. DynaMed citation/access date	September 15, 2008
3. Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences)	
4. UpToDate excerpts	Indicates that PT could be tried, but is not specific about what that entails; discusses surgery; helmets are mentioned as well. Overall coverage is in reference to plagiocephaly, not deformational plagiocephaly.
5. UpToDate citation/access date	September 15, 2008
6. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences)	
7. PEPID PCP excerpts	Nothing found
8. PEPID citation/access data	September 15, 2008
9. PEPID content updating	1. Do you recommend that PEPID get updated on this topic? Yes, there is important evidence or recommendations that are missing

If yes, which PEPID Topic, Title(s):
There is nothing on deformational plagiocephaly

2. Is there an EBM Inquiry (HelpDesk Answers and Clinical Inquiries) as indicated by the EB icon (E) that should be updated on the basis of the review?
Again, there is nothing on deformational plagiocephaly in PEPID at all.

10. Other excerpts
(USPSTF; other
guidelines; etc.)

American Academy of Pediatrics (AAP), September 16, 2008

11. Citations for other
excerpts

Persing J, James H, Swanson J, et al. American Academy of Pediatrics Committee on Practice and Ambulatory Medicine, Section on Plastic Surgery and Section on Neurological Surgery. Prevention and management of positional skull deformities in infants. *Pediatrics*. 2003;112(1):199-202.

12. Bottom line
recommendation or
summary of evidence
from Other Sources (1-2
sentences)

BOTTOM LINE: AAP recommends that primary care doctors should do counseling to prevent it and that this can be managed by teaching exercise to parents. However, Persing et al do not specifically discuss a formal PT program. PT is discussed only after mentioning several other specialists. In contrast, this potential PURL article suggests that PT should be done early on, not as an afterthought or after all other specialists are consulted.

Persing et al also address referrals to neurosurgeons, pediatric surgical specialists, and/or helmet use. The article does mention referral to craniofacial specialists, but this needs to happen early so that something can be done sooner rather than later.

SECTION 4: CONCLUSIONS

1. **Validity:** How well does the study minimize sources of internal bias and maximize internal validity? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly) 1

2. If 4.1 was coded as 4, 5, 6, or 7 please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?

3. **Relevance:** Are the results of this study generalizable to and relevant to the health care needs of patients cared for by "full scope" family physicians? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly) 1

4. If 4.3 was coded as 4, 5, 6, or 7, please provide an explanation.

5. **Practice-changing potential:** If the findings of the study are both valid and relevant, does the practice that would be based on these findings represent a change from current practice? Give one number on a scale of 1 to 7 (1=definitely a change from current practice; 4=uncertain; 7=definitely not a change from current practice) 1

6. If 4.5 was coded as 1, 2, 3, or 4 please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit.

7. Applicability to a Family Medical Care Setting: 1

Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, educating or counseling a patient; or creating a system for implementing an intervention? Give one number on a scale of 1 to 7 (1=definitely could be done in a medical care setting; 4=uncertain; 7=definitely could not be done in a medical care setting)

8. If you coded 4.7 as a 4, 5, 6 or 7 please explain. .

9. Immediacy of Implementation: Are there major barriers to immediate implementation? 1

Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug or other essentials available on the market? Give one number on a scale of 1 to 7 (1=definitely could be immediately applied; 4=uncertain; 7=definitely could not be immediately applied)

10. If you coded 4.9 as 4, 5, 6, or 7 please explain why.

11. Clinical meaningful outcomes or patient-oriented outcomes: Are the 1

outcomes measured in the study clinically meaningful or patient oriented? Give one number on a scale of 1 to 7 (1=definitely clinically meaningful or patient oriented; 4=uncertain; 7=definitely not clinically meaningful or patient oriented)

12. If you coded 4.11 as a 4, 5, 6, or 7 please explain why.

13. In your opinion, is this a Pending PURL? 2

Give one number on a scale of 1 to 7 (1=definitely a Pending PURL; 4=uncertain; 7=definitely not a Pending PURL)

Criteria for a Pending PURL:

- Valid: Strong internal scientific validity; the findings appears to be true.
- Relevant: Relevant to the practice of family medicine
- Practice changing: There is a specific identifiable new practice recommendation that is applicable to what family physicians do in medical care settings and seems different

than current practice.

- Applicability in medical setting:
- Immediacy of implementation

14. Comments on your response in 4.13

If primary care physicians do not realize that PT needs to be done immediately, then this is a PURL.

SECTION 5: EDITORIAL DECISIONS

1. FPIN PURLs editorial decision
(select one)

Pending PURL—Forward to JFP Editor

2. Follow-up issues for Pending PURL
Reviewer

Review SERMO poll

3. FPIN PURLS Editor making decision

Bernard Ewigman

4. Date of decision

October 8, 2008

5. Brief summary of decision

A much more common problem since "Back to Sleep" campaign. Good study with good results. Suspect most family physicians are not aware of the value of physical therapy.