

Lessons Learned from the Cranial Helmet Experience

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The Randomized Control Trial (RTC)

- April 30th 2014 – Became aware of the RCT on CRO's had been conducted in the Netherlands and was published in the BMJ. A review of the study would be published in the NYT on May 1st.
- RCT_ A study in which the participants are assigned *by chance* to two or more separate groups, where one group receives the investigation under investigation and the others receive no treatment, a placebo or a standard intervention. Neither the researchers or the participants can chose which group.
- A well conducted RCT is a reliable “test” or study design and can frequently provide the strongest support of a cause and effect relationship.

1st RCT: Helmet Therapy

- ✓ RCT Class I Evidence
- ✓ Topic: Called for, for many years
- ✓ Well-Respected Investigators
- ✓ Robust / Well Detailed Study Design
- ✓ Applied and Received Funding:
ZonMW – Netherlands Organization for Health Research
- ✓ Registered: Clinical_Trials.gov; ISRCTN
- ✓ Premier Medical Journal



The New York Times

The New York Times

Family NYT NEWS

Helmets Do Little to Help Moderate Infant Skull Flattening, Study Finds

By CATHERINE SAINT LOUIS

Embargoed and Published May 1, 2014



you See? like This?

Helmets do not prevent skull flatness in infants, study says

How effective are baby helmets?

Helmets do not prevent skull flatness in infants, study says

Save 50% on more sleep

Market Saturation of this Negative Message (Stakeholders)

Specialists (Craniofacial Surgeons, Pediatric Neurosurgeons)
Have taken the time to read the study.
View the results with skepticism.
Believe in Helmets (have seen the positive results).

Pediatricians
Were aware of study, but most have not read.
Have learned from newspaper or news coverage (Sensational Headlines)
Have had their families bring it to their attention.
Have reported that study has influenced their treatment decision.

Our Patients
Have gotten their information primarily through Headlines.
Have had friends/family contact them, about what they heard on the news/read.
Current Patients are more skeptical – because they are already seeing change.
New Patients come with a healthy dose of skepticism.

**Market Saturation of this Negative Message
(Reimbursement & Access)**

3rd Party Coverage
Impact!!!

Several State Medicaid Programs – Changed Policy or Using for Denial of Coverage
A few smaller Commercial Insurers – Changed Policy or Using for Denial of Coverage
Concern that at year end more may change

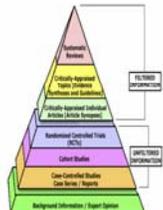
Concern over Limiting Access
Specialists familiar with helmets have expressed concern
Concern is not for majority who have mild – treat conservatively
Concern is limiting access for moderate-to-severe who,
a. Have not responded to conservative intervention
b. Are greater than 5-6 months
c. Where delay in treatment will impact effectiveness of helmet

**Placing the New York Times & BMJ
Articles in Context**

Higher Value on Research

Orthotics and Prosthetics

- We have mainly relied upon case control or cohort studies (with a higher risk of confounding or bias) and non analytical studies, e.g. case reports and case series **to form our scientific base.**
- Personal Clinical experience



“Of course helmets work”



The American Medical Association and Centers for Medicaid and Medicare define a reconstructive procedure as a process “performed to **improve function**, but may also be done to **approximate a normal appearance**”

References: Bialocerkowski et al 2005; Biggs 2003; Govaert et al 2008; Graham et al 2005; Lee et al 2008; Looman & Flannery 2012; Loose & Mason 2005; Laughlin et al 2011; Loose et al 2007; Littlefield & Kelly 2004; Persing et al 2003; Robinson & Proctor 2009; Rogers et al 2009; Stelwagen et al 2008; Teichgraber et al 2002; Thompson et al 2009

An RCT does not mean ‘Perfect’

Can Have the Same Limitations & Weaknesses of Any Study

- ✓ Study Design
- ✓ Inconsistent Cohort Populations
- ✓ Sample Size Issues
- ✓ Measurement Inaccuracies
- ✓ Investigator Bias
- ✓ Incorrect Statistical Analysis
-



Limitations: Study Population / Measurements

Exclusion of Infants with Torticollis – **WHY?**
Torticollis is #1 Risk Factor
85%-95% of Infants with Plagiocephaly

Excluded Very Severe Patients (29 of them)
They anticipated loss to follow up of these infants if they were randomized to the natural course arm.

Measurements (n=84)
29 Therapists – Obtained Initial Measurements
6 Therapists – Obtained Exit Measurements
Only the final six were blinded to treatment arm

Mixed Brachy, Plagio - (Averaging Error)



Limitations: Product / Treatment

Products / Treatment

- 2 Different Products
- 4 Different Institutions
- Did not report how many used which product
- Did not describe how infant model obtained (cast, 3D imaging, made-to-measure)
- Did not describe how product was manufactured (modification, design, materials)
- Did not describe treatment protocols / experience



Significant Fit / Compliance Issues

- 96% Skin Irritation
- 73% Ill-Fit
- 33% Pain
- 24% Acceptance

Objective – Study on Helmet Efficacy

- Did not appear that they understood helmets
- Did not appear to have relationship with providers

Limitations: Methods – (Sample Sizes – Do Not Add Up)

403 Eligible (2-4 months)

84 Eligible (21% participation)

21% participation rate, OK?

42 Helmet (21% participation)

42 Nothing (21% participation)

36 Helmet (9 never started)

30 Helmet (Do not explain -d)

19 Helmet (11 Discontinued Due to Side Effects, Door Results)

3 parents didn't want helmet; 3 doctor advised against; Can't lose any more

No explanation for loss of 6; Now below Statistical Significance Level; Fit Problems reported in 22/30 – 73%

11 drop out of treatment due to side effects and unhappiness with product/result; No specifics on when these dropped out, just before 12 months.

Cohort Groups Not Comparable; Helmet Group: More Brachycephalic & More Severe; 36 Required in each arm to achieve statistical significance

Figure 1 – 12 month and 24 month Follow Up

- At 12 months – followed up with 37 in treatment arm
- At 24 months – follow up with 39 in treatment arm

Current Thinking across the medical community

- Evidence from traditional RCTs must generally be supplemented by evidence from effectiveness studies to inform best clinical practice.
- Obtaining evidence that considers potential differences between the efficacy (i.e., can the treatment work under ideal circumstances?) and effectiveness (i.e., will the treatment work in real-world circumstances?) is essential.
- How can effectiveness studies help provide us with such evidence?