Complementary and alternative therapies for autism:
Separating fact from fiction

Andrew Whitehouse
What is CAM?

- a large and diverse set of systems of diagnosis, treatment, and prevention based on philosophies and techniques other than those used in conventional Western medicine, often derived from traditions of medical practice used in other (non-Western) cultures.

**Complementary**: used with conventional medicine

**Alternative**: used in place of conventional medicine
How do you view CAM?
CAM

• Australia

Australian Bureau of Statistics
CAM

- Australia

![Bar chart showing CAM usage in Australia over time]

Australian Bureau of Statistics
• Autism
  – Up to 95% of children and adults on the spectrum have tried some form of CAM in the hope of reducing ASD behaviours (Wong & Smith, 2006, *JADD*).

  • Compared to 35% of children not on spectrum (MacLennan et al., 2006, *MJA*).
### Table 3: Use of therapies and parent perception of efficacy

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Used therapy</th>
<th>Therapy helpful</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Count (%)</td>
</tr>
<tr>
<td>Conventional Therapies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Educational techniques</td>
<td>112</td>
<td>105 (94%)</td>
</tr>
<tr>
<td>Sensory therapies</td>
<td>112</td>
<td>99 (89%)</td>
</tr>
<tr>
<td>Prescription drugs</td>
<td>112</td>
<td>79 (71%)</td>
</tr>
<tr>
<td>Biologically Based Therapies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified diet</td>
<td>112</td>
<td>60 (54%)</td>
</tr>
<tr>
<td>Vitamins/minerals</td>
<td>112</td>
<td>43 (38%)</td>
</tr>
<tr>
<td>Food supplements</td>
<td>112</td>
<td>33 (30%)</td>
</tr>
<tr>
<td>Herbal remedies</td>
<td>112</td>
<td>26 (23%)</td>
</tr>
<tr>
<td>Secretin</td>
<td>112</td>
<td>12 (11%)</td>
</tr>
<tr>
<td>Mind-Body Interventions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prayer/shaman</td>
<td>112</td>
<td>16 (14%)</td>
</tr>
<tr>
<td>Biofeedback</td>
<td>112</td>
<td>8 (7%)</td>
</tr>
<tr>
<td>Meditation/relaxation response</td>
<td>112</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Guided imagery/hypnosis</td>
<td>112</td>
<td>9 (8%)</td>
</tr>
<tr>
<td>Manipulation and Body Based Methods</td>
<td></td>
<td></td>
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<tr>
<td>Massage/bodywork</td>
<td>112</td>
<td>12 (11%)</td>
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<tr>
<td>Craniosacral therapy</td>
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<td></td>
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<tr>
<td>Special exercises</td>
<td>112</td>
<td>11 (10%)</td>
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<tr>
<td>Auditory integration</td>
<td>112</td>
<td>8 (7%)</td>
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<tr>
<td>Vagus nerve stimulation</td>
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<td>2 (2%)</td>
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<tr>
<td>Energy Therapies</td>
<td></td>
<td></td>
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<tr>
<td>Healer/healing touch</td>
<td>112</td>
<td>9 (8%)</td>
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<tr>
<td>Alternative Medical Systems</td>
<td></td>
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<tr>
<td>Acupuncture/acupressure</td>
<td>112</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Anthroposophic medicine</td>
<td>112</td>
<td>0 (0%)</td>
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CAM

• Autism

  – Up to 95% of children and adults on the spectrum have tried some form of CAM in the hope of reducing ASD behaviours (Wong & Smith, 2006, JADD)

  • Compared to 35% of children not on spectrum (MacLennan et al., 2006, MJA)

• Why so high?

  • Unsurprising

  • Secondary ‘symptoms’ (aren’t often addressed in conventional therapy)

  • Gain some control over intervention
• Why am I interested?
  – controversial
• Because usage is so high
Which interventions?

- behavioural
- biological
- complementary
- educational
- other
Why am I interested?
- controversial

Because usage is so high
- Want to provide a clearer road map for families
- Want to decrease time and money waste
- Want to reduce emotional distress (fear and guilt)

If it works:
- Great! Let’s tell people about this

If it doesn’t work:
- Great! Let’s tell people about this!
CAM

• How do we assess interventions?
  – Historically
    • Anecdotal reports
    • Case studies
    • Uncontrolled studies
    • Good, but…
  – Sufficient evidence:
    • Randomized-controlled trials
Randomized controlled trial

Assessed for eligibility → Baseline assessment

Test group → Control group
CAM

• How do we assess interventions?
  – Randomized-controlled trials
    • **Single Blind**: patients don’t know what Tx they are receiving
    • **Double blind**: Experimenters and patients don’t know what Tx patients are receiving
Interventions

• Autism Clinical Trials (ACT)

ACT FOR AUTISM
Tonight...

1. Mind-body medicine
   - Music therapy
   - Yoga therapy

2. Biologically-based
   - Melatonin
   - Chelation
   - Secretin
   - Hyperbaric O$_2$ chamber
   - Vitamin B$_6$, Magnesium

3. Manipulative and body-based practices
   - Massage-therapeutic touch
Evaluation

• How do I evaluate therapies?

1. What is it?
2. What’s the rationale?
3. Safety?
4. Effective?
   – Are there studies?
   – Do studies report positive effects?
   – Quality of studies?
## Report card

### Summary

<table>
<thead>
<tr>
<th></th>
<th>⭐⭐⭐⭐⭐</th>
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<th>✗</th>
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<tbody>
<tr>
<td>Rationale plausible?</td>
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### Recommendation

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Rationale plausible?  
Safe?  
Are there studies?  
Studies report positive effect?  
Quality of studies  

Safe?

Unsafe
Mind-body medicine
Music therapy

• What is it?
  – Free and structured improvisation, songs and listening to music
  – Frequently applied to initiate communication

• Rationale:
  – early communicative exchanges are almost musical in nature, and vice versa
### Music therapy

- **Review (Gold, Wigram, & Elefant, 2006)**

#### Comparison 1. Music therapy vs. “placebo” therapy

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
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</thead>
<tbody>
<tr>
<td>1 Communicative skills: gestural</td>
<td>2</td>
<td></td>
<td>SMD (Fixed, 95% CI)</td>
<td>0.50 [0.22, 0.79]</td>
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<tr>
<td>2 Communicative skills: verbal</td>
<td>2</td>
<td></td>
<td>SMD (Fixed, 95% CI)</td>
<td>0.36 [0.15, 0.57]</td>
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<tr>
<td>3 Behavioural problems (end of therapy)</td>
<td>1</td>
<td></td>
<td>SMD (Fixed, 95% CI)</td>
<td>-0.14 [-0.42, 0.14]</td>
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<tr>
<td>4 Behavioural problems (using all measurements from 2nd day on)</td>
<td>1</td>
<td></td>
<td>SMD (Fixed, 95% CI)</td>
<td>-0.24 [-0.45, -0.03]</td>
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</table>

Music therapy

- More recent study (Kim et al., 2008, )

<p>| | |</p>
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<tr>
<td>Participant age</td>
<td>3 – 5 years of age (10 children)</td>
</tr>
<tr>
<td>ASD severity</td>
<td>Half nonverbal, other using language to varying degree</td>
</tr>
</tbody>
</table>
| **Therapy**              | **Content:** Improvising with musical instruments
                                    **Frequency:** 12 X 30 min sessions (weekly)                                             |
| ‘Placebo’                | **Content:** Improvising with non-musical toys
                                   **Frequency:** 12 X 30 min sessions (weekly)                                             |
| Target behaviours        | Eye contact and turn taking                                                                    |
Music therapy

- More recent study (Kim et al., 2008)

Participants

- 5 children

Outcomes:

- ↑ eye contact
- ↑ turn taking

Problems with study:
- Small number
- Not ‘blind’
- Investigators CoI

Therapy

- Music therapy
- Play therapy

Outcome

- Much less improvement

# Report card - Music therapy

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Yoga therapy

• What is it?
  – Physiological and psychological processes that change physiological parameters through respiratory manipulation (breathing technique), postures (asanas), and cognitive controls (relaxation and meditation).

• Rationale:
  – No rationale put forward

• Studies
  – No studies published in reputable journals
## Report card – Yoga therapy

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Biologically-based practices
Secretin

• **What is it?**
  – Hormone that controls secretions into the duodenum
  – Most often used to treat peptic ulcers
  – Perhaps the most thoroughly studied biological treatment for ASD (~700 children with ASD in well-designed RCTs).

• **Rationale:**
  – Gut problems (‘leaky gut’)

Secretin

• Gut problems...
Secretin

• What is it?
  – Hormone that controls secretions into the duodenum
  – Most often used to treat peptic ulcers
  – Perhaps the most thoroughly studied biological treatment for ASD (~700 children with ASD in well-designed RCTs).

• Rationale:
  – Gut problems (‘leaky gut’)
  – Secretin aids proper digestion of food
    • supposedly prevents harmful chemicals in undigested food reaching the brain
  • BUT the evidence for a ‘leaky gut’ is inconclusive
# Secretin

- **A study example** (Dunn-Geier et al., 2000)

<table>
<thead>
<tr>
<th>Participant age</th>
<th>2 – 7 years of age (88 males, 7 females)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASD severity</td>
<td>Range</td>
</tr>
</tbody>
</table>
| **Therapy**      | **Content:** Porcine secretin (intravenous)  
                  **Frequency:** single dose (reassessed 3 weeks later) |
| ‘Placebo’        | **Content:** Saline (intravenous)  
                  **Frequency:** single dose (reassessed 3 weeks later) |
| **Target behaviours** | Preschool Language Scale (primary outcome measure), CARS, Autism Behavior Checklist, GI symptoms |

Secretin

- **Study** (Dunn-Geier et al., 2000)

  Participants
  - 47 children
  - 48 children

  Therapy
  - Secretin
  - Placebo

  Outcome

Secretin


<table>
<thead>
<tr>
<th>Measure</th>
<th>Secretin (n=47)</th>
<th>Placebo (n=48)</th>
<th>Mean difference (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Baseline Mean (SD)</td>
<td>Change Mean (SEM)</td>
<td>n</td>
</tr>
<tr>
<td>Childhood Autism Rating Scale</td>
<td>47</td>
<td>38.5 (4.5)</td>
<td>−1.2 (0.3)</td>
<td>47</td>
</tr>
<tr>
<td>Preschool Language Scale, total</td>
<td>41</td>
<td>25.2 (11.8)</td>
<td>2.4 (0.8)</td>
<td>44</td>
</tr>
<tr>
<td>Auditory comprehension</td>
<td>44</td>
<td>12.2 (7.5)</td>
<td>1.5 (0.6)</td>
<td>45</td>
</tr>
<tr>
<td>Expressive communication</td>
<td>42</td>
<td>12.9 (4.8)</td>
<td>0.6 (0.4)</td>
<td>44</td>
</tr>
<tr>
<td>Autism Behavior Checklist, total</td>
<td>45</td>
<td>79.0 (31.6)</td>
<td>−13.1 (2.6)</td>
<td>48</td>
</tr>
<tr>
<td>Sensory</td>
<td>43</td>
<td>3.3 (7.4)</td>
<td>−4.8 (0.8)</td>
<td>45</td>
</tr>
<tr>
<td>Social relatedness</td>
<td>44</td>
<td>0.1 (8.3)</td>
<td>−0.9 (1.0)</td>
<td>47</td>
</tr>
<tr>
<td>Body and object use</td>
<td>45</td>
<td>7.5 (9.4)</td>
<td>−6.0 (0.9)</td>
<td>48</td>
</tr>
<tr>
<td>Language</td>
<td>42</td>
<td>5.3 (7.6)</td>
<td>−0.9 (0.6)</td>
<td>42</td>
</tr>
<tr>
<td>Socialization</td>
<td>42</td>
<td>14.7 (5.9)</td>
<td>−2.5 (0.6)</td>
<td>45</td>
</tr>
<tr>
<td>Number of gastrointestinal problems</td>
<td>47</td>
<td>1.0 (1.1)</td>
<td>0.0 (0.2)</td>
<td>48</td>
</tr>
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</table>

In the Preschool Language Scale, a high score is indicative of high-level functioning, whereas the reverse is true in the Autism Behaviour Checklist. SEM, standard error of the mean.

*a* Derived from the Gastrointestinal Symptoms Questionnaire, monitoring reflux, nausea, vomiting, abdominal pain, diarrhea, stool problems, and constipation.

*b* t-test for no treatment difference.
Secretin

• More recent study (Kim et al., 2008)

Participants

47 children

Secretin

Some improvements

48 children

Placebo

Some improvements

Problems with study:
• Very little wrong

Report card - Secretin

Summary

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Rationale plausibility?

Safe?

Are there RCTs?

Studies report positive effect?

Quality of studies
Chelation

• What is it?
  – Administration (orally, intravenously or intramuscularly) of chelating agents (chemical), which bind and remove heavy metals from the body.
  – Originally developed as treatments for lead toxicity

• Rationale:
  – Individuals with ASD have difficulty eliminating mercury and other heavy metals that can interfere with immune function and other biochemical systems
  – Very much unproven
Chelation

- **Safety**
  - Unsafe
    - Strip body of essential minerals
    - Can lead to hypocalcemia → death
    - 3 deaths between 2003 and 2005 (including one child with autism)
  - One trial started
    - Halted after results of rodent trial found lasting cognitive impairment

- **Currently, aggressively marketed**
  - Industrial products designed to separate metals in mining operations
  - Many not tested in humans (or animals!)
Report card – Chelation

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Melatonin

• What is it?
  – a hormone secreted by the pineal gland, is well established as a regulator of circadian rhythms

• Rationale:
  – Many individuals with ASD have:
    • Sleeping difficulties
    • Low melatonin levels
    • Abnormal melatonin synthesis (i.e., production)
Melatonin

- Over 10 well-conducted RCTs
- Meta analysis found:
  - Sleep duration:
    - 73 minutes (compared to baseline)
    - 44 minutes (compared to placebo)
  - Sleep onset latency:
    - 66 minutes (compared to baseline)
    - 39 minutes (compared to placebo)
  - Night time awakenings
    - No reduction
  - Effect on day-time behaviour

Melatonin

- Safety:
  - No serious adverse effects
  - Only a few minor side-effects (morning sleepiness, enuresis)
  - No reported effects on seizures
  - Inexpensive
    - But not on PBS

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Melatonin

• Availability:
  – For many years, unavailable in Australia
  – Now available with:
    • Prescription from doctor
    • (Homeopathic doses available at chemist)
  – Important: Please discuss with Pediatrician (or GP)
HBO$_2$ therapy

- **What is it?**
  - Medical use of oxygen at a level higher than atmospheric pressure.
  - Very popular (500 centres in US alone)
  - Generally safe, but can have adverse effects: reversible myopia, seizures, pulmonary complications
HBO$_2$ therapy

- Rationale:
  1. People with ASD have decreased blood flow to the brain;
  2. People with ASD have neuroinflammation;
  3. HBO$_2$ therapy increases the amount of oxygen delivered to the brain and decreases neuroinflammation

BUT…
- Very preliminary evidence for #1 and #2
- Yes for #3, but has only been observed in rodents
# HBO$_2$ therapy

- **Study** (Rossignol & Rossignol, 2009)

| Participants | **Age:** 2 – 7 years  
| Number: 56 children |
|---|---|
| ASD severity | Range |
| Therapy | **Content:** 24% Oxygen at 1.3 atmospheres  
**Frequency:** 40 X 1 hour sessions (over four-week period) |
| ‘Placebo’ | **Content:** 21% Oxygen at 1.0 atmospheres  
**Frequency:** 40 X 1 hour sessions (over four-week period) |
| Target behaviours | Clinical Global Impression scale (CGI), the Aberrant Behavior Checklist (ABC), and the Autism Treatment Evaluation Checklist (ATEC). |

HBO$_2$ therapy

- More recent study (Rossignol et al., 2009)

Participants
- 30 children
- 26 children

Therapy
- HBO therapy
- Placebo

Outcome
- ‘Significant’ improvement in a number of behaviours
- No ‘significant’ improvement

Problems with study:
- Do not require HBO$_2$ therapy for 1.3 dose
- Flawed data analysis

• Aberrant Behaviour Checklist

<table>
<thead>
<tr>
<th>Before therapy</th>
<th>After therapy</th>
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<tbody>
<tr>
<td>Treatment</td>
<td>55.2 (28.7)</td>
</tr>
<tr>
<td></td>
<td>46.4 (24.7)</td>
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<tr>
<td>Δ = -8.8</td>
<td>= 1 point</td>
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<tr>
<td>Control</td>
<td>53.3 (24.0)</td>
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<tr>
<td></td>
<td>45.5 (17.3)</td>
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<tr>
<td>Δ = -7.8</td>
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</table>
HBO$_2$ therapy

- Undersea & Hyperbaric Medical Society (UHMS)
  - “At this time, the UHMS cannot recommend the routine treatment of ASD with HBO therapy outside appropriate comparative research protocols.”
  - http://www.uhms.org
### Summary

<table>
<thead>
<tr>
<th></th>
<th>Rationale plausibility?</th>
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<th>Are there RCTs?</th>
<th>Studies report positive effect?</th>
<th>Quality of studies</th>
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### Recommendation

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<th>Not effective</th>
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<tr>
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<td>Recommend</td>
<td>Tolerate. Encourage</td>
<td>Discourage</td>
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<tr>
<td></td>
<td></td>
<td>objective monitoring</td>
<td></td>
</tr>
<tr>
<td>Unsafe</td>
<td>Monitor closely or discourage</td>
<td>Discourage until further trials</td>
<td>Discourage</td>
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</tbody>
</table>
Vitamin B₆, Magnesium

• What is it?
  – B₆ (Pyridoxine) is an organic compound found in high doses in nuts and grains
  – Only small amount required

• Rationale:
  – Important in production of serotonin and dopamine, which are thought to be disrupted in ASD
Vitamin B$_6$, Magnesium

• History
  – 1950s and 1960s:
    • Rimland found some evidence of efficacy at very high doses (1000mg/day)
    • But these doses can’t be tolerated for extended periods
      – Can cause loss of sensation in legs and imbalance
  – 1990s and 2000s:
    • Lower doses (100-200mg/day)
    • Three RCTs conducted
    • All found no effect
Report card - Vitamin B₆, Magnesium

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Manipulative body practices
Massage and therapeutic touch

• What is it?
  – Manipulation of superficial and deeper layers of muscle and connective tissue through pressure and traction.

• Rationale
  – Reduce stress?
### Study (Escalona et al., 2001)

| Participant age | Age: 2 – 7 years  
Number: 20 children |
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>ASD severity</td>
<td>range</td>
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</table>
| **Therapy**     | **Content**: Massage therapy for 15 minutes just prior to bedtime  
**Frequency**: Every night for one month |
| **‘Placebo’**   | **Content**: Massage therapy for 15 minutes just prior to bedtime  
**Frequency**: Every night for one month |
| **Target behaviours** | Attention, classroom/playground behaviour, sleep |

**Massage therapy**

- **Study** (Escalona et al., 2001)

  - **Participants**: 10 children vs. 10 children
  - **Therapy**: Massage therapy vs. Dr Seuss read to them
  - **Outcome**: ↑ Sleep, ↑ Attention, ↓ Ster. Behav

  **Problems with study**:
  - Small number
  - Not ‘blind’
  - Related to ↑ sleep

Summary

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What we can all do
What we can all do

• CAM are widely used in ASD community
  • Some have good evidence (melatonin)
  • Some have no evidence (chelation, secretin)
  • For the majority, we just don’t know

• Much to do!
What we can all do

• It’s time to:
  – Test the claims of therapies
  – Develop new and innovative therapies
  – Determine with which individuals these may be effective
What we can all do

- Autism Clinical Trials (ACT)

ACT FOR AUTISM
Thank you

Email: awhitehouse@ichr.uwa.edu.au
Website: http://autism.childhealthresearch.org.au