A Randomised Controlled Trial on the utility of a personalised Bronchiectasis Action Management Plan for children with bronchiectasis: A pilot

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What is bronchiectasis?

• Chronic progressive disease of the airways causing abnormal dilatation of the bronchi leading to poor clearance and pooling of mucus

• Symptoms often date back to early childhood
  ❖ Persistent or recurrent wet/productive cough
  ❖ Repeated acute lower respiratory infection (ALRI)

• Rare in developed countries, but high in Indigenous and low-middle income Countries

• Known to cause premature death in the 3rd - 4th decade of life among Indigenous adults

Burden of disease

Very little data

New Zealand
Incidence in Maori and Pacific Islander children
160 per 100,000
(1 in 625 < 15yrs)

Alaska natives
11 to 20 per 1,000 persons
(1 in 63 children)
Burden of disease cont...

- 147 per 100,000 Indigenous children <15 years in Central Australia (1 in 68 children)
- CF (Australia)

[Image of an iceberg]
Top End (NT) data

Number children:  n=304

Age (mths):  2.4 (1.6-3.9 IQR)

Males:  n=169 (56%)

Indigenous:  n=266 (88%)

BE:  n=270 (91%)

Suppurative:  n=188 (63%)
Does early diagnosis matter?

- Non treatment leads to early mortality
  - Indigenous data from Central Australia

- Delayed diagnosis
  - Poorer lung function
  - Reduced quality of life (QoL)
  - Chronic cough/systemic inflammation
    - Independent risk factors for non-smoking COPD, cardio-vascular disease

Management of bronchiectasis

Aim to optimise

• General well being

• Symptom control

• Preserve lung function

• QoL

• Reduce frequency of exacerbations
Management cont...

- Personalised asthma action plan improves clinical outcomes
  - QoL
  - Reduce acute doctor visits/hospitalisations

- Is a bronchiectasis action management plan (BAMP) beneficial??
BAMP

My child’s Bronchiectasis Action Management Plan (BAMP)

How will I know if my child becomes unwell?

- Cough becomes worse
- Spit/sputum is getting darker in colour from clear to yellow or dark green
- Child is feeling more short wind and breathing gets harder
- Child is feeling hot/cold
- Child is feeling more tired
- Child is eating or drinking less

My child has bronchiectasis in their:

- Left upper lobe
- Right upper lobe
- Right middle lobe
- Left lower lobe
- Right lower lobe

HRCT date: ___/___/___

Last sputum/BAL results: ___________________ / / ___

My bronchiectasis is caused by: ___________________

My yearly flu vaccination is due: ___/___/___

When I am well

- No cough
- No wheeze
- No sputum
- No shortness of breath

I AM able to:

- Eat and drink well
- Take part in physical activity

My Treatment Plan:

Antibiotics:

I need to take:

Puffers:

Physio:

Where I am well

- Cough increases
- Sputum increases
- Potential wheeze
- Shortness of breath
- Fever

I have REDUCED:

- Physical activity
- Appetite

Where I am severe

- Worsening wet cough
- Increased sputum (yellow/green)
- Fever
- Increase work of breathing
- Increased tiredness

I AM unable to:

- Take part in normal activity
- Eat and drink well

I need to see a Paediatrician or admitted to hospital for IV antibiotics:

Antibiotics:

I have:

Puffers:

Physio:

Other:
Aims

Primary question
Does routine use of a personalised written BAMP (compared to standard care) improve clinical outcomes [parent cough-specific quality of life (PC-QoL) and reduces non-scheduled doctor visits]? 

Hypothesis
Routine use of a personalised written BAMP (compared to standard care) improves clinical outcomes
Secondary aims

Determine if routine use of a personalised BAMP

i. Reduces rates of exacerbations over 12 months

ii. Improves the early uptake of yearly influenza vaccine (by 30\textsuperscript{th} May each year)
### Eligibility

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Aged &lt;19 years</td>
<td>Cystic Fibrosis</td>
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<tr>
<td>Diagnosis of bronchiectasis</td>
<td>Existing BAMP</td>
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<td>&gt;2 non-scheduled Dr visits/exacerbations in last 18 months</td>
<td>Inability to follow-up children</td>
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Methods

Children with bronchiectasis screened in respiratory clinics

Consent for study

Agreed

Refused

Routine care

Baseline data, medical history, clinical examination, PC-QoL questionnaire

Randomised to intervention for 12 months (n=198)

Interventional group (n=99)
Randomised to receive BAMP + Dr letter

Control group (n=99)
Randomised to usual care + Dr letter

Monthly phone calls until 12 months

PC-QoL questionnaire at 4, 8 and 12 months

End of study
Outcomes and analysis

ITT analysis

Primary outcome
• Difference between groups at 4-months in PC-QoL and acute Dr visits for bronchiectasis

Secondary outcomes
• PC-QoL at 8 and 12 months
• Bronchiectasis exacerbation rate by 12 months
• Influenza vaccination by 30th May each year
Progress to date

Dec. 2017
HOT NORTH pilot funding received

Jan-Mar. 2018
Protocol/form development/ethics submission

Apr-May. 2018
Trial registered with ANZCTR
Ethics approval
2018 plan

Database

Recruitment

Funding applications
Thank you

Investigator team
Professor Anne Chang
Professor Peter Morris
Mrs Kobi Schutz (PhD student)