Efficacy of speech pathology management for chronic cough: a randomised placebo controlled trial of treatment efficacy

A E Vertigan, D G Theodoros, P G Gibson, A L Winkworth

Background: Chronic cough that persists despite medical treatment may respond to speech pathology intervention, but the efficacy of such treatment has not been investigated in prospective randomised trials. The aim of this study was to determine the efficacy of a speech pathology intervention programme for chronic cough.

Methods: A single blind, randomised, placebo controlled trial was conducted in 87 patients with chronic cough that persisted despite medical treatment. Patients were randomly allocated to receive either a specifically designed speech pathology intervention or a placebo intervention. Participants in both groups attended four intervention sessions with a qualified speech pathologist.

Results: Participants in the treatment group had a significant reduction in cough (8.9 to 4.6, p < 0.001), breathing (7.9 to 4.7, p < 0.001), voice (7.3 to 4.6, p < 0.001) upper airway (8.9 to 5.9, p < 0.001) symptom scores and limitation (2.3 to 1.6, p < 0.001) ratings following intervention. There was also a significant reduction in breathing (6.8 to 5.6, p = 0.047), cough (7.6 to 6.3, p = 0.014), and limitation (2.3 to 2.0, p = 0.038) scores in the placebo group, but the degree of improvement was significantly less than in the treatment group (p < 0.01). Clinical judgement of outcome indicated successful ratings in 88% of participants in the treatment group compared with 14% in the placebo group (p < 0.001).

Conclusion: Speech pathology is an effective management intervention for chronic cough which may be a viable alternative for patients who do not respond to medical treatment.
group and 44 in the placebo group. The mean (SD) age of participants included in the study was 59.4 (13.6) years (range 23–84); 64 were women and 23 were men. The demographic data and history of co-morbid medical conditions of the study participants are summarised in table 1.

### Procedure

Participants completed a symptom frequency and severity rating before and after the intervention. Twenty three different cough, respiratory, voice, and upper airway symptoms were rated on a 5-point scale from 1 (never present or absent) to 5 (present all the time or most severe discomfort ever) based on symptoms over the preceding week. Five composite scores were calculated from the symptom rating data and included a total symptom score, breathing score, cough score, voice score and upper airway score. The limitation of symptoms on everyday activity was also rated on a 5-point scale ranging from 1 (not limited, have done all the activities that I want to) to 5 (severely limited).

Participants were then randomised by random number generation to receive either a treatment or placebo intervention. Once the participant consented to the study, a random number between 0.000 and 0.999 was computer generated and given to the treating speech pathologist. Participants with numbers between 0.000 and 0.499 received the placebo programme while those with numbers between 0.500 and 0.999 received the treatment programme. The treatment speech pathologist was not involved in the randomisation process; however, once the treatment group was allocated, the speech pathologist knew the participant’s group allocation. Group allocation was concealed from participants until the post-intervention symptom rating and clinical judgement of outcome had been recorded.

The intervention for both treatment and placebo groups was provided by qualified speech pathologists with experience in treating voice disorders. Participants in each group attended four individual 30 minute intervention sessions scheduled over a 2 month period. Following the post-intervention rating, the treating speech pathologist made a clinical judgement of each participant’s outcome as successful, unsuccessful, or partially successful. Clinical judgements were made with reference to participant’s informal reports of the effectiveness of the intervention and the speech pathologist’s judgement of the individual’s capacity to understand and implement the strategies.

Participants allocated to the treatment programme were offered the SPEICH-C in accordance with the standard clinical procedure at John Hunter Hospital. The SPEICH-C comprises four components including education about the nature of chronic cough, strategies to control the cough, psycho-educational counselling, and vocal hygiene education to reduce laryngeal irritation. Examples of these strategies are
The psycho-educational component addressed some differences between behavioural and medical treatment and aimed to facilitate acceptance of a behavioural approach.\(^9\) This component was designed to facilitate internalisation of control over their cough and view the cough as something individuals do in response to irritating stimuli rather than a phenomenon outside of their control. This approach is commonly used to establish internalised control in other clinical populations such as stuttering and Parkinson’s disease.\(^{20,21}\) Each component in the treatment programme was addressed at least once during the course of the intervention and was revisited during subsequent therapy sessions according to the needs of individual participants. The programme was tailored for each participant according to specific cough characteristics such as the pattern and degree of warning before the cough that had been identified during their case history.\(^4\) Home practice of these components was also recommended.

The placebo programme consisted of four components of healthy lifestyle education including relaxation, stress management, exercise, and diet. These components were provided during four individual sessions with the treating speech pathologist in which participants received information and home practice exercises relating to each of the components. Each component was covered at least once during the course of the placebo programme.

### RESULTS

There was an equivalent distribution of participants into the treatment and placebo groups according to sex and age (eight men and 35 women in the treatment group, and 15 men and 29 women in the placebo group). The mean (SD) age of participants in the treatment group was 57.5 (13.8) years compared with 61.3 (13.2) years in the placebo group. There was no significant difference in age distribution between the two groups (Mann-Whitney U test, p = 0.170). The sex distribution was also not significantly different between the treatment and placebo groups (chi-square test, p = 0.715). The mean (SD) pre-intervention symptom scores for participants in the treatment and placebo groups are shown in Table 3. The degree of change in symptom scores following intervention was compared between treatment and placebo groups using a Mann-Whitney U test. Symptom scores were analysed by intention to treat with the pre-intervention data carried forward for placebo groups using the \(\chi^2\) test.

### Table 3 Comparison of mean (SD) pre-intervention symptom scores for participants in the treatment and placebo groups (Mann-Whitney U test)

<table>
<thead>
<tr>
<th>Score</th>
<th>Treatment (N = 43)</th>
<th>Placebo (N = 44)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total symptom</td>
<td>32.9 (16.0)</td>
<td>30.4 (12.9)</td>
<td>0.634</td>
</tr>
<tr>
<td>Breathing</td>
<td>7.5 (4.1)</td>
<td>6.9 (4.1)</td>
<td>0.591</td>
</tr>
<tr>
<td>Cough</td>
<td>8.6 (3.0)</td>
<td>7.7 (3.4)</td>
<td>0.119</td>
</tr>
<tr>
<td>Voice</td>
<td>7.0 (5.8)</td>
<td>7.8 (4.7)</td>
<td>0.892</td>
</tr>
<tr>
<td>Upper airway</td>
<td>8.5 (6.4)</td>
<td>7.8 (5.1)</td>
<td>0.878</td>
</tr>
<tr>
<td>Limitation</td>
<td>2.3 (1.1)</td>
<td>2.3 (1.1)</td>
<td>0.715</td>
</tr>
</tbody>
</table>

### Table 4 Comparison of mean (SD) pre- and post-intervention symptom scores and degree of change for participants in the treatment and placebo groups

<table>
<thead>
<tr>
<th>Score</th>
<th>Group</th>
<th>Pre</th>
<th>Post</th>
<th>Difference</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total symptom</td>
<td>Treatment†</td>
<td>35.4</td>
<td>22.7</td>
<td>12.7</td>
<td>9.0 to 16.1</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Placebo†</td>
<td>29.9</td>
<td>28.8</td>
<td>2.9</td>
<td>0.7 to 6.5</td>
<td>0.170</td>
</tr>
<tr>
<td></td>
<td>Difference‡</td>
<td>5.5</td>
<td>2.9</td>
<td>2.6</td>
<td>3.3 to 1.2</td>
<td>0.004*</td>
</tr>
<tr>
<td>Breathing</td>
<td>Treatment†</td>
<td>7.9</td>
<td>5.0</td>
<td>2.9</td>
<td>3.0 to 3.9</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Placebo†</td>
<td>6.6</td>
<td>5.5</td>
<td>1.1</td>
<td>0.1 to 2.0</td>
<td>0.004*</td>
</tr>
<tr>
<td></td>
<td>Difference‡</td>
<td>1.3</td>
<td>2.2</td>
<td>1.0</td>
<td>2.3 to 1.0</td>
<td>0.170</td>
</tr>
<tr>
<td>Cough</td>
<td>Treatment†</td>
<td>8.8</td>
<td>4.9</td>
<td>3.9</td>
<td>3.0 to 4.9</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Placebo†</td>
<td>7.3</td>
<td>6.3</td>
<td>1.2</td>
<td>3.0 to 2.2</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Difference‡</td>
<td>1.5</td>
<td>2.2</td>
<td>0.7</td>
<td>3.0 to 1.5</td>
<td>0.959</td>
</tr>
<tr>
<td>Voice</td>
<td>Treatment†</td>
<td>7.2</td>
<td>4.7</td>
<td>2.5</td>
<td>1.2 to 3.7</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Placebo†</td>
<td>6.5</td>
<td>6.2</td>
<td>0.3</td>
<td>0.9 to 1.5</td>
<td>0.959</td>
</tr>
<tr>
<td></td>
<td>Difference‡</td>
<td>0.7</td>
<td>1.8</td>
<td>1.1</td>
<td>3.0 to 1.5</td>
<td>0.170</td>
</tr>
<tr>
<td>Upper airway</td>
<td>Treatment†</td>
<td>9.2</td>
<td>6.5</td>
<td>2.7</td>
<td>1.4 to 4.1</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Placebo†</td>
<td>7.4</td>
<td>7.4</td>
<td>0.0</td>
<td>1.1 to 1.2</td>
<td>0.946</td>
</tr>
<tr>
<td></td>
<td>Difference‡</td>
<td>1.8</td>
<td>0.1</td>
<td>1.7</td>
<td>3.0 to 1.5</td>
<td>0.170</td>
</tr>
<tr>
<td>Limitation</td>
<td>Treatment†</td>
<td>2.3</td>
<td>1.6</td>
<td>0.7</td>
<td>0.4 to 1.0</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Placebo†</td>
<td>2.2</td>
<td>2.0</td>
<td>0.3</td>
<td>0.0 to 0.6</td>
<td>0.038*</td>
</tr>
<tr>
<td></td>
<td>Difference‡</td>
<td>0.1</td>
<td>0.0</td>
<td>0.1</td>
<td>0.0 to 0.8</td>
<td>0.011*</td>
</tr>
</tbody>
</table>

†Calculated using Wilcoxon signed rank test.  
‡Calculated using Mann-Whitney U test.
groups in terms of age (p = 0.187), sex (p = 0.102), reflux
(p = 0.911), ACE inhibitor use (p = 0.526), allergies
(p = 0.837), asthma (p = 0.187), PNDS (p = 0.914), or smoking
(p = 0.148).

Symptom scores
There was no significant difference in any pre-intervention
symptom score between the treatment and placebo groups
(table 3). The magnitude of improvement was significantly
greater in the treatment group than in the placebo group for
all symptom scores analysed by intention to treat (table 4).
Participants in the treatment group had a significant
reduction in all symptom scores after the intervention
(table 4). In the placebo group there was a significant
difference between pre and post-intervention breathing and
cough scores but no significant improvement in total
symptom, voice, or upper airway scores. Although there
was a significant improvement in limitation scores after the
intervention in both the treatment and placebo groups, the
degree of improvement was significantly greater in the
treatment group. Outcomes for treatment and placebo group
are summarised in table 5.

Clinical outcome
The clinical outcome for each participant was rated as
successful, unsuccessful, or partially successful (table 6).
Most of the participants in the treatment group were rated as
having a successful outcome, while most in the placebo
group were rated as having an unsuccessful outcome. The treatment
group had a significantly higher incidence of participants
with a successful outcome than the placebo group. Three
participants in each group made positive progress but were
considered to require additional speech pathology treatment
at the conclusion of the programme to achieve satisfactory
resolution of symptoms. Comparison of outcomes based on
intention to treat was also statistically significant (p<0.001).

DISCUSSION
This study is the first randomised controlled trial of speech
pathology intervention for chronic cough and is the largest
investigation of speech pathology management for chronic
cough reported in the literature.

The symptom data suggested that speech pathology was
effective in reducing symptoms in chronic cough and that the
treatment was more effective than a placebo intervention.
The lack of a significant difference in pre-intervention
symptom scores between the treatment and placebo groups
indicated that improvements observed in the treatment group
were due to the intervention rather than inherent pre-
intervention differences between groups. Both the treatment
and placebo groups showed a significant reduction in
limitation scores following the respective interventions, but
the degree of improvement was significantly greater in the
treatment group. It might be supposed that the reduction in
symptoms and the positive attention provided during the
treatment programme. The placebo effect could be relevant in
both treatment and placebo groups; however, the degree of
attention received during the intervention programme was
consistent between the two groups.

The results of the clinical judgement were consistent with
the symptom ratings and indicated that most of the
participants in the treatment group had a successful out-
come. The use of clinical judgement as an outcome measure
is similar to the judgements made in everyday clinical
practice and those described in previous reports.7 10 However,
for research purposes, unblinded clinical judgements from
the participant’s treating speech pathologist are likely to be
affected by bias and are therefore less robust than
formal symptom ratings. The interpretation of the outcome of
clinical judgements in this study should therefore be made
with reference to the methodological shortcoming of this
procedure.

Because of the single blinded design of this study and the
nature of the intervention programmes, it was not possible to
blind the treating speech pathologist to the type of interven-
tion. The possibility that unconscious bias could have been
conveyed to the participants during the course of intervention
cannot therefore be discounted. Double blinding is not
possible in studies of behavioural intervention. Despite this
limitation, the participants remained blinded until after
completion of the post-intervention symptom ratings.

The activities used in the placebo programme were unrelated
to the cough. The lifestyle education programme was chosen
for its similarity to the direct SPEICH-C whereby behaviour
change was targeted over a number of sessions through
education and specific activities. The placebo programme
also comprised real life education rather than nonsensical or foil
activities. Although the placebo programme was not specific for
chronic cough, it is possible that the placebo activities such as
stress management and progressive relaxation had a more
direct influence on voice and cough symptoms than was
previously anticipated. Comparison of treatment and placebo
responses with a non-intervention control group might provide
further information on the impact of the activities used in the
placebo programme.

The 2 month duration of follow up chosen in the current
study reflected current practice, but long term follow up as
recommended by McGarvey10 was lacking in the current
protocol. Long term follow up is lacking in many studies of

<table>
<thead>
<tr>
<th>Table 5</th>
<th>Summary of outcomes for the treatment and placebo groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>Treatment</td>
</tr>
<tr>
<td>----------</td>
<td>-----------</td>
</tr>
<tr>
<td>Total</td>
<td>x</td>
</tr>
<tr>
<td>Breathing</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td></td>
</tr>
<tr>
<td>Voice</td>
<td></td>
</tr>
<tr>
<td>Upper airway</td>
<td></td>
</tr>
<tr>
<td>Limitation</td>
<td></td>
</tr>
</tbody>
</table>

(\h: significant improvement from pre- to post-intervention; x: no significant improvement from pre- to post-intervention; /: improvement significantly greater in treatment group than in placebo group.)

<table>
<thead>
<tr>
<th>Table 6</th>
<th>Comparison of clinical judgement of outcome of the intervention between treatment and placebo groups ((\chi^2) test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome</td>
<td>Treatment (N = 43)</td>
</tr>
<tr>
<td>----------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Successful</td>
<td>38</td>
</tr>
<tr>
<td>Unsuccessful</td>
<td>2</td>
</tr>
<tr>
<td>Partially successful</td>
<td>3</td>
</tr>
</tbody>
</table>
the medical management of chronic cough. For example, a systematic review of randomised trials of omeprazole in the treatment of chronic cough found limited follow up beyond the study period in the majority of studies.21 Further studies of speech pathology interventions in chronic cough are needed to investigate the duration of the beneficial effect.

This study provides preliminary support for the effectiveness of speech pathology management for chronic cough that persists despite medical treatment. Speech pathology intervention for chronic cough is multifactorial. This study demonstrates the effectiveness of the SPEICh-C, but further studies are needed to determine which specific components are most beneficial. It is possible that protocols for the management of chronic cough according to the anatomical diagnostic protocol could be expanded to include treatment with speech pathology. Behavioural control of chronic cough is a management option with the potential to provide many savings in terms of healthcare resources including expensive medications and diagnostic investigations that may continue in a potentially fruitless search for an organic cause.24

Although speech pathology treatment appears to be successful in improving symptoms in persons with chronic cough, the mechanism behind the symptom improvement is yet to be determined. The education and reassurance given in the treatment programme may have resulted in a more rapid subjective improvement. Nevertheless, it is possible that processes such as muscle tension and cough reflex sensitivity could play an important role in chronic cough.25–27 Smith et al compared cough sensitivity and ratings of the urge to cough among healthy volunteers assigned to a psychological exercise group, a cough suppression group who were advised to try not to cough, or a no intervention control group.28 The cough threshold was significantly reduced in the psychological exercise and cough suppression groups, but there was no significant difference in ratings of the urge to cough between the groups. The authors concluded that psychological factors could influence cough reflex sensitivity and that reducing concern and active suppression of the cough could raise the cough threshold. Extrapolating these results to the current study, it is possible that a speech pathology intervention directed at cough suppression could increase the threshold for cough and reduce cough sensitivity in persons with chronic cough. However, further studies of cough sensitivity are needed to confirm this proposition.

Several studies have found a beneficial effect on the larynx of adequate hydration including attenuating or delaying an increase in the phonation threshold pressure, which is the minimum amount of pressure needed to set the vocal folds into vibration and reduced risk of laryngeal injury.29–30 Increasing hydration in the treatment group may have reduced the phonation threshold pressure and subsequent stimulation of the cough receptors.

Although the results of this study are favourable, they need to be replicated in order to achieve a higher level of evidence for the intervention, examine alternative treatment regimes, expand the range of outcome measures employed, and provide measures of long term follow up.

In conclusion, clinical judgement and symptom ratings support the hypothesis that speech pathology treatment is an effective behavioural intervention for chronic cough which could be considered a valid alternative for individuals whose cough persists despite medical intervention. Further investigations are required to understand the pathophysiological bases of the outcome of speech pathology intervention for chronic cough.

REFERENCES

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