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Efficacy Of Speech Pathology Management For Chronic Cough: A Randomised Placebo Controlled Trial Of Treatment Efficacy

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ABSTRACT

Background: Chronic Cough (CC) that persists despite medical treatment may respond to speech pathology intervention, however, 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 program for CC.
Methods: The design was a single-blind, randomised, placebo controlled trial of speech pathology intervention. Eighty seven patients with CC that persisted despite medical treatment were randomly allocated to receive either a specifically designed speech pathology intervention for their CC or a placebo intervention. Participants in both groups attended four intervention sessions with a qualified speech pathologist.
Results: Participants in the treatment group demonstrated a significant reduction in cough (8.9 to 4.6, $p < .001$), breathing (7.9 to 4.7, $p < .001$), voice (7.3 to 4.6, $p < .001$) upper airway (8.9 to 5.9, $p < .001$) symptom scores and limitation (2.3 to 1.6, $p < .001$) ratings following intervention. There was also a significant reduction in breathing (6.8 to 5.6, $p = .047$), cough (7.6 to 6.3, $p = .014$) and limitation (2.3 to 2.0, $p = .038$) scores in the placebo group however the degree of improvement in the treatment group was significantly greater than in the placebo group ($p < .01$). Clinical judgement of outcome indicated successful ratings in 88% of participants in the treatment group compared with 14% on the placebo group, $p < .001$.
Conclusion: This result demonstrated the efficacy of speech pathology management for CC and suggests that such intervention could be a viable alternative for patients who have not responded to medical intervention.

Key words: efficacy, chronic cough, speech pathology

INTRODUCTION

Chronic Cough (CC) is a common problem that has an impact on resource utilisation and quality of life. CC can persist despite medical treatment based on the anatomic diagnostic protocol, in 12 to 42% of cases of CC.[1-5] There is emerging evidence for the efficacy of behavioural approaches for the treatment for CC arising from speech pathology intervention,[6-10] however the role of these treatments is not universally understood in the either the medical or speech pathology communities. The efficacy of speech pathology management has yet to be evaluated before such intervention can be recognised as a viable treatment option and incorporated into protocols for the management of CC.

While CC is considered an entity within respiratory medicine, chronic coughing and throat clearing might be conceptualised differently in the fields of otolaryngology and speech pathology. In some voice disorders, coughing and throat clearing are considered to be phonotraumatic or vocally abusive behaviours that have contributed to, exacerbated or perpetuated the voice disorder. These behaviours may be considered habitual and targeted in treatment programs for voice disorders. Vocal hygiene education for hyperfunctional voice disorders includes strategies to reduce coughing and throat clearing in individuals with voice disorders and has been found to improve voice quality.[11, 12] However these treatment programs have not been systematically applied to persons with CC.

Although preliminary research into behavioural management for CC indicates that this form of intervention might be a feasible treatment option, the efficacy of these treatment approaches has not been systematically investigated making it difficult to draw firm conclusions about their potential benefits. There are limitations to reports of speech pathology management for CC including small subject numbers, lack of comparison groups, limited standardised prospective and objective measures for voice and the lack of prospective and randomised trials.[8] Few studies of speech pathology management for CC have explored treatment description and efficacy in detail.

The aim of the current study was to determine the efficacy of a speech pathology management program for CC through a prospective randomised trial of behavioural intervention. It was hypothesised that persons with CC will demonstrate greater improvement in clinical outcome and symptom ratings following speech pathology intervention compared to placebo intervention. In order to test this hypothesis, this study proposed to determine (a) whether individuals with CC who receive direct speech pathology intervention demonstrated a significant improvement in symptom ratings and clinical outcome and (b) whether the extent of change in symptom ratings is significantly different between individuals who receive active treatment versus a placebo intervention.

METHODOLOGY

This study involved a single blind, randomised, placebo controlled trial to examine the efficacy of speech pathology treatment for CC. Participants were randomised to receive either Speech Pathology Evaluation and Intervention for CHronic Cough (SPEICH-C) (treatment) or to receive an equivalent course of healthy lifestyle education (placebo). Symptom profiles were compared before and after intervention for the treatment and placebo groups along with clinical judgements of the outcome of intervention. This study was approved by the Hunter Area Research Ethics

Committee and the University of Queensland Medical Research Ethics Committee. All participants provided informed and written consent for this study.

Participants

Potential participants assessed for eligibility in this study included 120 persons with CC that had persisted despite medical treatment according to the anatomic diagnostic protocol. These participants had been referred to the speech pathology department at John Hunter Hospital, New South Wales, Australia, from April 2003 until October 2004 for behavioural management of their CC. CC was defined as the presence of chronic coughing that persisted for two months following medical treatment based on the approach recommended by Irwin et al.,[13] including treatment for asthma, postnasal drip syndrome (PNDS), gastroesophageal reflux (GER) and withdrawal of angiotensin converting enzyme (ACE) inhibitors (if used). The severity of the cough was sufficient for participants to seek medical attention by both general practitioner and respiratory physician. Participants had undergone respiratory case history, hypertonic saline challenge, and induced sputum analysis prior to inclusion in the study. Significant symptoms identified during the case history were subsequently investigated and treated. Exclusion criteria included recent upper respiratory tract infection, untreated allergy, PNDS, asthma, GER, eosinophilic bronchitis, lung pathology, abnormality on chest X-Ray, Chronic Obstructive Pulmonary Disease and neurological voice disorder. Inclusion criteria included a minimum age of 18 years and ability to travel to John Hunter Hospital.

A flowchart of participants in the study according to the CONSORT statement [14] is described in figure 1. Six of the 120 potential participants did not meet the inclusion criteria and were excluded from the study. A further 17 potential participants declined consent to participate in the study. Of the remaining 97 participants, 47 were randomly allocated to the treatment group and 50 to the placebo group. One participant in the treatment group and four in the placebo group did not commence their respective intervention programs due to unexpected family responsibilities and spontaneous resolution of symptoms before treatment commenced. Three participants in the treatment group and two in the placebo group discontinued intervention through failure to contact or attend appointments. Thus 43 participants were included in the treatment group and 44 in the placebo group. The mean age of participants included in the study was 59.4 years (SD = 13.6, R = 23 – 84). Sixty four participants were female and 23 were male. Participant demographics and history of comorbid medical conditions are summarised in table 1.

Table 1
Participant demographics and co-morbid medical conditions that had been treated prior to inclusion in the study.

History		
Age (years)	M (SD)	59.4 (13.6)
Gender	Male/Female	64/23
Asthma [a]	N (%)	18 (20.7)
Reflux [b]	N (%)	41 (47)
ACE inhibitors	N (%)	10 (11.5)
Allergies	N (%)	52 (59.8)
Post nasal drip syndrome [c]	N (%)	44 (50.6)
Smoking	N (%)	2 (2.3)
FEV1 (%predicted)	M (SD)	95 (20)
FVC (%predicted)	M (SD)	100 (21)
FEV1/FVC	M (SD)	78 (8)
AHR [d]	N (%)	8 (9)

[a] previous asthma treatment included previous asthma treatment included inhaled corticosteroid and long-acting brionchodilator; [b] previous reflux treatment proton pump inhibitors; [c] previous PNDS treatment included topical nasal steroids and ingested antihistamines; [d] AHR = airway hyperresponsiveness to hypertonic (4.5%) saline

Procedure

Participants completed a symptom frequency and severity rating prior to and following intervention.[15] Twenty three different cough, respiratory, voice and upper airway symptoms were rated on a five-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.[15] The limitation of symptoms on everyday activity was also rated on a five-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 program while those with numbers between 0.500 and 0.999 received the treatment program. The treating 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 treating voice disorders. Participants in each group attended four individual thirty-minute intervention sessions scheduled over a two-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 intervention

and the speech pathologist's judgement of the individual's capacity to understand and implement the strategies.

Participants allocated to the treatment program were offered the SPEICH-C in accordance with the standard clinical procedure at John Hunter Hospital.[9] The SPEICH-C comprised four components including education about the nature of CC, strategies to control the cough, psycho-educational counselling and vocal hygiene education to reduce laryngeal irritation. Examples of these strategies are outlined in table 2. These techniques were designed to improve the efficiency of voicing by reducing the load on the larynx while promoting adequate breath support and oral resonance. The education component emphasised the futility and negative side effects of repeated coughing, the benefits of cough suppression and capacity of individuals to develop voluntary control over cough.[16] The cough suppression component required participants to anticipate when a cough was about to occur and then implement a strategy to suppress or replace the cough.[7] [9][10] [17-20] The vocal hygiene component included strategies to reduce laryngeal irritation and maximise hydration in order to reduce stimulation of cough receptors. Relaxed throat breathing exercises were also provided for those participants with inspiratory dyspnoea. 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.[21, 22] Each component in the treatment program was addressed at least once during the course of intervention and was revised during subsequent therapy sessions according to individual participant's needs. The program 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.[15] Home practice of these components was also recommended.

Table 2

Examples of strategies in the treatment program

Component	Example
Education	No physiological benefit from cough; capacity for voluntary cough control
Strategies to reduce cough	Identify warning signs for cough and replace with modified swallow technique, pursed lip breathing exercise, or relaxed throat breath
Reduce laryngeal irritation	Increase hydration, decrease exposure to irritating stimuli
Psycho-educational counselling	Internalising locus of control; acceptance that treatment is hard work; setting realistic goals

The placebo program 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 whereby 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 program.

Data Analysis

Pre-intervention breathing, cough, voice, upper airway, limitation and total symptom scores were compared between treatment and placebo groups using a Mann Whitney U test. The Wilcoxon signed ranks test was then used to compare pre and post-intervention scores in each of the treatment and placebo groups. The degree of change in symptom scores following intervention was compared between the 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 post-intervention analysis. The measure of clinical judgement of treatment outcome was compared between treatment and placebo groups using the Chi Square test.

RESULTS

There was an equivalent distribution of participants into treatment and placebo groups according to gender and age. The treatment group contained 8 males and 35 females, while the placebo group contained 15 males and 29 females. The mean age for participants in the treatment group was 57.5 years (SD = 13.8) and in the placebo group 61.3 years (SD = 13.2). There was no significant difference in age distribution between groups in terms of age (p = .187), gender (p = .102), reflux (p = .911), ACE inhibitor use (p = .526), allergies (p = .837), asthma (p = .187), PNDS (p = .914) or smoking (p = .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 than the placebo group for all symptom scores analysed by intention to treat (see table 4). Participants in the treatment group had a significant reduction in all symptom scores post-intervention (see 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 from pre to post-intervention in both 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.

Table 3

Comparison of pre-intervention symptom scores for participants in the treatment and placebo groups using a Mann-Whitney U test (U)

Score	Treatment M (SD) N = 43	Placebo M (SD) N = 44	p
Total symptom	32.9 (16.0)	30.4 (12.9)	.634
Breathing	7.5 (4.1)	6.9 (4.1)	.591
Cough	8.6 (3.0)	7.7 (3.4)	.119
Voice	7.0 (5.8)	7.8 (4.7)	.892
Upper airway	8.5 (6.4)	7.8 (5.1)	.878
Limitation	2.3 (1.1)	2.3 (1.1)	.715

Table 4

Comparison of pre and post-intervention symptom scores and degree of change for participants in the treatment and placebo groups

Score	Group	Pre	Post	Diff	95% CI		
		M (SD)	M (SD)	M (SD)	Low	Upp	p
Total	Treatment[a]	35.4 (16.0)	22.7 (18.0)	12.7 (12.7)	9.0	16.1	< .001*
	Placebo[a]	29.9 (13.5)	28.8 (16.5)	2.9 (12.5)	-.7	6.5	.170
	Diff [b]			8.5 (13.9)	4.7	14.9	< .001*
Breathing	Treatment[a]	7.9 (4.1)	5.0 (4.2)	2.9 (3.6)	1.8	3.9	< .001*
	Placebo[a]	6.6 (4.7)	5.5 (3.5)	1.1 (3.4)	0.1	2.0	.004*
	Diff [b]			2.2 (3.7)	0.4	3.2	< .001*
Cough	Treatment[a]	8.8 (2.8)	4.9 (3.0)	3.9 (3.2)	3.0	4.9	< .001*
	Placebo[a]	7.5 (3.6)	6.3 (3.5)	1.2 (3.4)	0.3	2.2	<.001*
	Diff [b]			2.8 (3.6)	1.3	4.0	.003*
Voice	Treatment[a]	7.2 (6.0)	4.7 (5.2)	2.5 (4.3)	1.2	3.7	< .001*
	Placebo[a]	6.5 (4.6)	6.2 (5.0)	.3 (4.1)	-0.9	1.5	.959
	Diff [b]			1.5 (4.5)	0.5	3.9	.005*
Upp airway	Treatment[a]	9.2 (6.6)	6.5 (6.3)	2.7 (4.7)	1.4	4.1	< .001*
	Placebo[a]	7.4 (4.9)	7.4 (5.5)	.1 (4.1)	-1.1	1.2	.946
	Diff [b]			1.5 (4.8)	0.9	4.4	.002*
Limitation	Treatment[a]	2.3 (1.2)	1.6 (1.0)	0.7 (1.1)	0.4	1.0	< .001*
	Placebo[a]	2.2 (1.1)	2.0 (1.0)	0.3 (0.9)	0.0	0.6	.038*
	Diff [b]			0.5 (1.0)	0.0	0.8	.011*

Note. [a] calculated using a Wilcoxon Signed Ranks Test; [b] calculated using a Mann Whitney U test; Diff = difference; Low = lower; Upp = upper

Table 5

Summary of outcomes for the treatment and placebo groups

Score	Treatment	Placebo	Treatment versus placebo
Total	√	X	√√
Breathing	√	√	√√
Cough	√	√	√√
Voice	√	X	√√
Upper Airway	√	X	√√
Limitation	√	√	√√

Note. √ = significant improvement from pre to post-intervention; X = no significant improvement from pre to post-intervention; √√ = improvement significantly greater in treatment than placebo groups

Clinical Outcome

The clinical outcome for each participant was rated as *successful*, *unsuccessful* or *partially successful* (table 6). The majority of participants in the treatment group were rated as having a successful outcome whereas the majority of participants in the placebo group were rated as having an unsuccessful outcome. The treatment group had a significantly higher incidence of successful outcome than the placebo group. Three participants in each group made positive progress however were considered to require additional speech pathology intervention at the conclusion of the program in order to achieve satisfactory resolution of symptoms. Comparison of outcome based on intention to treat was also statistically significant ($p < .001$).

Table 6
Comparison of clinical judgement of the outcome of intervention between the treatment and placebo groups using a Chi Squared test (X2)

Outcome	Treatment N = 43	Placebo N = 44	p
Successful	38	6	< .001
Unsuccessful	2	35	
Partially successful	3	3	

DISCUSSION

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

The symptom data suggested that speech pathology intervention was effective in reducing symptoms in CC and that the treatment was more effective than a placebo intervention. The lack of 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 treatment and placebo groups demonstrated a significant reduction in limitation scores following respective interventions, however the degree of improvement was significantly greater in the treatment group. It might be supposed that the reduction in limitation scores was affected by both the improvement in symptoms the positive attention provided during the treatment program. The placebo effect could be relevant in both treatment and placebo groups however the degree of attention received during the intervention program was consistent between the two groups.

Results of the clinical judgement were consistent with the symptom ratings and indicated that the majority of participants in the treatment group demonstrated a successful outcome. 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.

Due to the single blinded design of this study and the nature of the intervention programs, it was not possible to blind the treating speech pathologist to the type of intervention. Therefore the possibility that unconscious bias could have been conveyed to the participants during the course of intervention cannot 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 utilised in the placebo program were unrelated to the cough. The lifestyle education program 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 program also comprised real life education rather than nonsensical or foil activities. Although the placebo program was not specific for the CC, 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 program.

The two-month duration of follow-up chosen in the current study reflected current practice, however long-term follow up as recommended by McGarvey [23] was lacking in the current protocol. Long term follow up is lacking in many studies of the medical management of the condition. For example a systematic review of randomised trials for Omeprazole in the treatment of CC found limited follow-up beyond the study period in the majority of studies.[24] Future studies of speech pathology intervention in CC are needed to investigate the duration of the beneficial effect.

This study provides preliminary support for the effectiveness of speech pathology management for CC that persists despite medical treatment. Speech pathology intervention for CC is multifactorial. This study demonstrates the effectiveness of the SPEICH-C however further studies are needed to determine which specific components are the most beneficial. This study raises the possibility that protocols for the management of CC according to the anatomic diagnostic protocol could be expanded to include speech pathology treatment. Behavioural control of CC is a management option with the potential to provide many savings in terms of health care resources including expensive medications and diagnostic investigations that may continue in a potentially fruitless search for an organic cause.[25]

Although speech pathology treatment appears to be successful in improving symptoms in persons with CC, the mechanism behind symptom improvement is yet to be determined. The education and reassurance given in the treatment program 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 CC. [26-28] Smith et al. compared cough sensitivity and ratings of the urge to cough amongst healthy volunteers assigned to a psychological exercise group, a cough suppression group whereby they were advised to *try not to cough* or a no intervention control group.[29] 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 speech pathology intervention directed at cough suppression could increase the threshold for cough and reduce cough sensitivity in persons with CC. However, further studies of cough sensitivity in persons with CC would be needed to confirm this proposition.

Several studies have found a beneficial effect on the larynx of adequate hydration including attenuating or delaying elevation of phonatory threshold pressure, which is the minimum amount of pressure needed to set the vocal folds into vibration and reduced risk of laryngeal injury.[30, 31] Increasing hydration in the treatment group may have reduced 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.

CONCLUSION

Clinical judgement and symptom ratings supported the hypothesis that speech pathology treatment is an effective behavioural intervention for CC. It would appear that speech pathology intervention 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 CC.

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