Digital Therapeutic For Refractory And Unexplained Chronic Cough: A Proof Of Concept Study

Laurie Slovarp[1] , Jane Salois[1], Reid Moorsmith[1], Mindaugas Galvosas[1], Stephanie Swift[1], Amy Talbot[1], Caledonia Gerner[1], Peter M. Small[1, 2]

1. Research & Development Department, Hyfe Inc., Wilmington, DE, United States; 2. University of Washington, Department of Global Health, Seattle, WA, United States

Background and Purpose

Despite recent advances, there are no FDA-approved drugs for refractory/unexplained chronic cough (RCC/UCC). Numerous studies have demonstrated efficacy of cough suppression treatment (CST) by specialty-trained speech-language pathologists (SLPs). While recommended in consensus statements, there is a significant shortage of specialized SLPs to treat the estimated 5-7 million cases of RCC/UCC in the US. We have integrated essential components of CST within the CoughPro cough monitoring application with the purpose of testing proof of concept for a CST digital therapeutic.

Methods

Adults with RCC enrolled prospectively for this single-cohort 4-week intervention study (NCT07070895). Participants accessed CST components through an extension of the CoughPro app. CST material was delivered via text, audio, and video and consisted of education on cough hypersensitivity syndrome and instruction in cough suppression techniques. Cough rate and cough bout rate were measured for 7 days prior to treatment and continuously throughout the 4-week treatment period. The Leicester Cough Questionnaire (LCQ) was measured at baseline and end of treatment.

WHAT IS IT?

- Digitally delivered cough suppression treatment (CST)
- Designed for high engagement to promote strong adherence
- Continuous, passive cough monitoring provides biofeedback to self-assess progress

HOW DOES IT WORK?

- AI passively monitors cough frequency and patterns
- App delivers proven techniques to suppress cough
- Real-time efficacy tracking and biofeedback enables personalization and promotes adherence

CLINICALLY & COMMERCIALLY VALIDATED

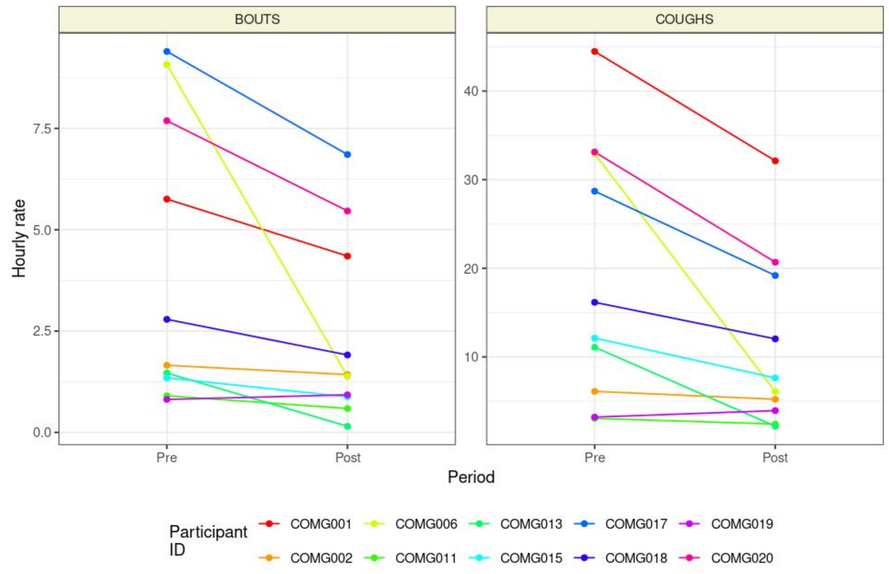
- BCST has demonstrated up to 88% effectiveness in reducing cough frequency
- Safe, easy, and with zero side effects
- In development as a prescription-only regulated SaMD for the Japanese market

Results

10 subjects completed the study. Baseline cough rate: 3.1 to 44.7 coughs per hour (mean = 19.1); bout rate varied: 0.8 to 9.4 bouts/hour (mean = 4.1).

By week 4 of the intervention, the mean hourly cough rate had fallen to 11.1 (**41.8% reduction**); mean hourly bout rate had fallen to 2.4 (**41.5% reduction**).

Cough rate reduction was slightly higher in those with a starting cough rate of >10 coughs/hr (n=7) with a **reduction of 43.9% and 44.2% in coughs and bouts,** respectively.



80% (8/10) of subjects achieved a clinically meaningful improvement in the LCQ (i.e., change score >2 points).

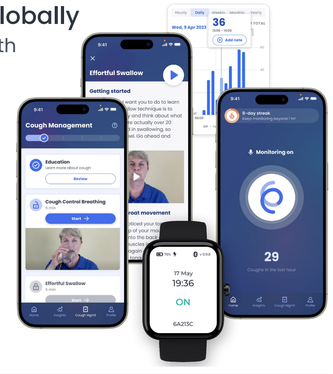
Results indicated a statistically significant improvement in cough-related quality of life at study end (median = 14.33) compared to baseline (median = 11.42), Z = -2.50, p = .009, with a large effect size (r = 0.79).

Conclusions

This study provides strong proof-of-concept evidence for feasibility and efficacy of a digitally delivered cough suppression treatment program and, when combined with objective cough monitoring, may provide motivation, adherence, and relief for RCC patients, as well as improved accessibility to this efficacious zero-side-effect treatment. These results warrant further development and evaluation of digitally delivered CST program in a controlled clinical trial.

CoughPro available globally

Consumer Wellness App with Cough Management



Clinical Implications

Delivery of cough suppression treatment via a digital therapeutic has the potential to dramatically increase accessibility and reduce healthcare burden related to RCC/UCC.

Contact:
Laurie Slovarp, Ph.D, CCC-SLP
laurie@coughcoach.com

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Disclosures: LS and JS are scientific advisors to Hyfe Inc. RM, MG, SS, AT, CG and PMS are employees and own equity in Hyfe Inc.