



DIGITAL THERAPEUTIC FOR CHRONIC COUGH

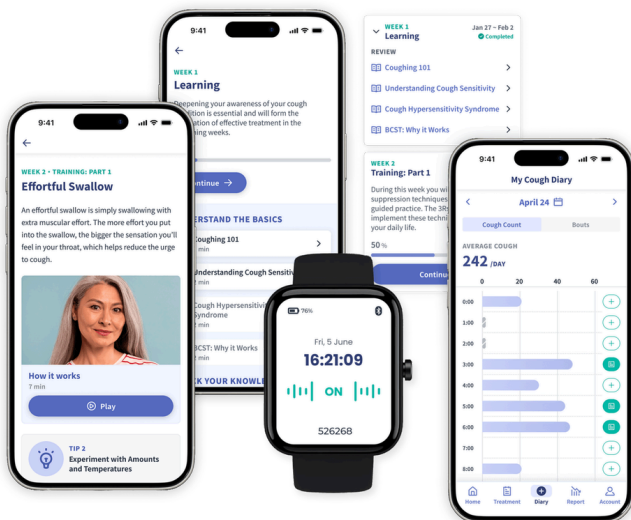
The World's **First DTx** for Chronic Cough

Bringing proven behavioral therapy to the millions who need it.

Regulated SAMD

Prescription DTx for the Japanese Market

Being developed as a prescription-only regulated Software as a Medical Device (SaMD) in partnership with KYORIN Pharmaceutical Co Ltd, for the Japanese market.



GLOBAL · CONSUMER

CoughPro Consumer Wellness App

Globally available app featuring AI-powered cough monitoring and Cough Management, giving individuals tools to better understand their cough.



THE PROBLEM

Burden & Unmet Need

Why Chronic Cough Demands a New Approach

~7M

RCC/UCC patients
in the United States

~200M globally

<200

Behavioral therapy
providers in the US

Despite guideline recommendation

0

Approved antitussive
drugs for RCC/UCC

No pharmacological standard of care

UNMET NEEDS

Millions of patients, no viable treatment

Behavioral therapy for RCC/UCC is recommended in clinical guidelines as a first-line approach. Yet fewer than 200 specialists in the US provide it, leaving millions without approved drugs or access to effective care.

BCST Proven To Work

>15 studies across 4 RCTs, 11+ cohorts,
4 languages — ~500 unique patients

+4-7.5

Mean LCQ improvement
(MCID = 1.3-2.0)

41%

Cough count reduction
in largest RCT

0

Adverse events
excellent safety profile



Cough Hypersensitivity Syndrome

Heightened cough
reflex & reduced ability
to suppress the urge to
cough



BCST Intervention

Behavioral cough suppression therapy

- Trains patients to recognize urge to cough
- Teaches specific suppression techniques



Improved Cough Control

RCC patients regain
control over cough
hypersensitivity with
reduced urge to
cough

THE SOLUTION

Hyfe's AI-powered DTx for chronic cough

WHAT IT IS?

Digitally Delivered BCST

- Digitally delivered behavioral cough suppression therapy (BCST)
- Designed for high engagement to promote strong adherence
- Continuous, privacy preserving passive monitoring
- Biofeedback loop enabling tailored personalization

HOW IT WORKS?

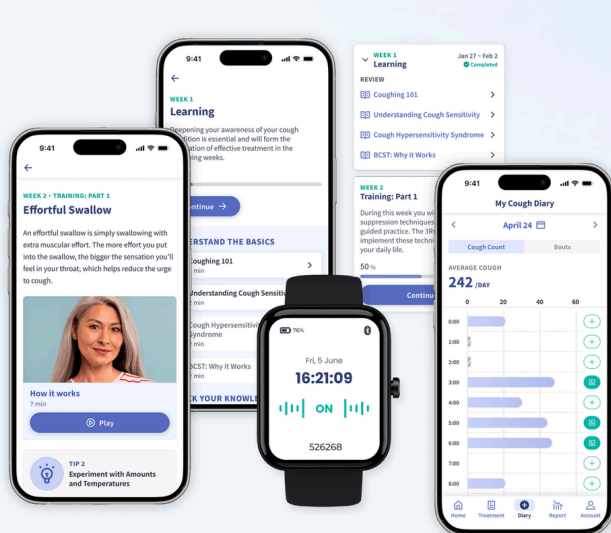
AI-Powered & Adaptive

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

VALIDATED

Clinically & Commercially Proven

- 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



Regulated DTx in partnership with KYORIN Pharmaceutical for the Japanese market

Globally available CoughPro with Cough Management: a consumer wellness app



DIGITAL THERAPEUTIC OPPORTUNITY

Why now?

- Proven mechanism – neuroplastic retraining of cough reflex
- Compelling effect size – equal or superior to top antitussive molecules in development, potential for “software + pill”
- No safety liabilities
- Telehealth validation – 88% responder rate in video-BCST cohort
- Pathways to reimbursement are increasing worldwide

THE SOLUTION

Proven BCST effect: 3 RCTs and multiple studies

ERJ OPEN RESEARCH

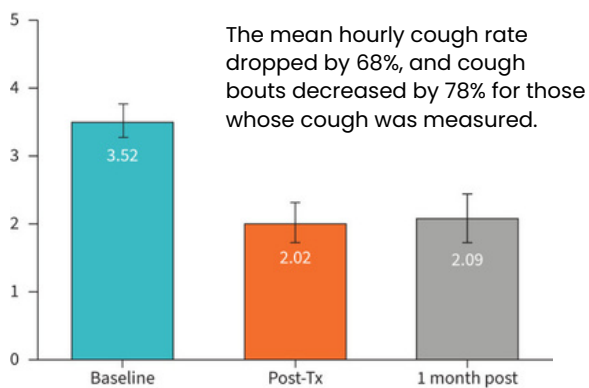
Telehealth Cohort · Slovarp et al.

98% of patients

Among 47 RCC patients who completed group telehealth BCST, 98% exceeded the LCQ's minimal clinically important difference, with a mean improvement of 7.04 points sustained at 1 month post-treatment ($p < 0.001$).

Telehealth group behavioural cough-suppression therapy for refractory chronic cough using a rolling enrolment model

Laurie J Slovarp¹, Jane R Salois¹, Kinsey Roberts¹, Emily Ehli¹, Mackenzie Majors¹, Mackenzie Rosenleaf¹



RCT

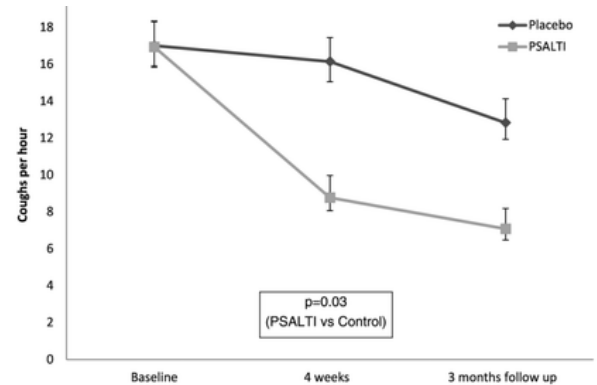
Multicentre · Chamberlain Mitchell et al.

41% reduction

Among 75 RCT participants, objective cough frequency decreased by 41% (95% CI 36% to 95%) in cough suppression group (PSALTI) relative to control ($p = 0.030$).

Physiotherapy, and speech and language therapy intervention for patients with refractory chronic cough: a multicentre randomised control trial

Sarah A F Chamberlain Mitchell^{1, 2}, Rachel Garrod³, Lynne Clark⁴, Abdel Douiri^{5, 6}, Sean M Parker⁷, Jenny Ellis⁷, Stephen J Fowler⁸, Siobhan Ludlow⁹, James H Hull¹⁰, Kian Fan Chung¹⁰, Kai K Lee¹, H Bellas¹¹, Anand Pandyan², Surinder S Birring¹



A meta-analysis (Dec 2024) of 12 BCST studies found BCST significantly improved all cough PROs and objective cough frequency.

Yi B, et al. Efficacy of behavioral cough suppression therapy for refractory chronic cough or unexplained chronic cough: a meta-analysis of randomized controlled trials. *Ther Adv Respir Dis.* 2024

FUTURE POTENTIAL: COMBINATION THERAPY FOR COUGH

Software-enhanced drug therapy in action

Limited options
Limited efficacy
Adverse effects

Drug

Drug + DTx
Combination
Therapy

BCST

Limited access
Variable quality
High Friction

✓ Highly effective ✓ Convenient & accessible ✓ Personalized & customized

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