



INHALE is a unique way of delivering nicotine into the body FAST; just as fast as a cigarette but without the dangerous chemicals

INHALE is a safe new rapid-acting nicotine inhaler that we are testing to see just how effective it is. We would like it if you could help test it with us.

*What is in it for you to join our study?*

- The chance to kick your habit once and for all, FREE OF CHARGE
- Six months supply of INHALE canisters
- Five months supply of nicotine patches
- Six one-on-one sessions with an expert quit coach

*What's in it for us?*

- The opportunity for us to test the effectiveness of INHALE
- To pick your brains about your smoking history so we can learn from you
- Seeing people quit smoking

*How does the study work?*

- This study is for 7 months and everything is FREE including parking if you need it.
- The INHALE canister looks just like an asthma inhaler. You can use it as often as you like for 6 months and nicotine patches daily for 5 months.
- You don't have to quit immediately. You get to reduce your smoking during the first four weeks of the study while using INHALE and the patches. That gives you time to get used to using INHALE and the patches, and get skilled at using INHALE instead of smoking, before you stop smoking completely.
- We don't expect you to do this alone. You get six, one-on-one, in-depth supportive sessions with a smoking cessation coach, two of which are face-to-face and four via the telephones. The first visit is when you start the study, and the second at 2 months after the first visit. We also call you 1 week after your first visit, at 1 day after your target quit date, and at 3 and 6 months after your quit date to see how you are doing, and how much INHALE is helping you.

*Who can take part in this study?*

Smokers aged between 18 and 70 and who smoke 9 or more cigarettes per day.

*Who cannot take part in this study?*

- People with asthma who have used an asthma preventer in the past 12 months such as Beclomethasone (Becotide, Beclazone, Respocort, Beclacort), Flixotide, sodium cromoglycate (Intal, Vicron), budesonide (Pulmicort).
- People who are allergic to nicotine patches.
- People with a serious medical conditions including uncontrolled high blood pressure, something wrong with their heart or blood vessels that occurred or got worse in the past 3 months (fast or irregular heart rhythm, angina, chest pain, had a heart attack or stroke).
- People who have ever had a serious stomach ulcer, or heartburn, kidney disease, liver disease, over-active thyroid, phaeochromocytoma (tumour of the adrenal gland), or unstable diabetes.
- People who have had worsened asthma and/or used an Asthma preventer (steroid) in the past year (such as, prednisone, prednisolone, beclomethasone (*Qvar*, brown inhaler); budesonide (*Pulmicort*, brown inhaler); fluticasone (*Flixotide*, orange inhaler); ciclesonide (*Alvesco*, rust-coloured inhaler) Seretide (Purple inhaler), Symbicort (red and white inhaler)
- Pregnant or breast-feeding women and women who are not using contraception (if appropriate).
- People taking certain types of medication such as theophylline (Nueline, Theo-Dur), propranolol, labetalol, verapamil, insulin, imipramine (Tofranil), pentazocline (Fortral), entazocline, clozapine (Clozaril), oxazepam, ropinirole (Requip, Ropark, Adartel), olanzapine (Zyprexa), clomipramine (Anafranil, Clopress), fluvoxamine (Luvox).

*What's next?*

Please answer our online questionnaire to find out if the INHALE trial would be useful for you. The information you provide is absolutely confidential.

Thank you for your interest in helping us find out how effective INHALE is. We appreciate you answering these questions. A researcher will contact you very soon.

Many thanks, The INHALE Team