# Treatment of hyperhidrosis: assessment of clinical and cost-effectiveness and recommendations for further research

This project was undertaken by researchers at the Centre for Reviews and Dissemination, University of York and the Institute of Health and Society, Newcastle University, in collaboration with consultant dermatologists and a consultant vascular surgeon. Comments and advice were also provided by a specialist nurse and patients suffering from hyperhidrosis. The project was commissioned by the National Institute for Health Research, Health Technology Assessment Programme.

## Background

Hyperhidrosis is uncontrollable excessive sweating, which occurs at rest, regardless of temperature. It can have a major impact on quality of life. Despite existing research, it is unclear which treatments are the best and as a consequence there is substantial variation in the availability of treatments in the NHS.

### **Objectives**

The aim of this project was to summarise the evidence on the clinical effectiveness and costeffectiveness of treatments for primary hyperhidrosis, and to assess whether it is worth conducting further research.

### Methods

We systematically reviewed studies of the clinical effectiveness of treatments for hyperhidrosis of the hands, feet and armpits. We specifically looked at treatments available for prescription and minor surgical treatments. We did not review studies of endoscopic thoracic sympathectomy (ETS), which is a surgical procedure not recommended by many practitioners, but, when used, is an end of line treatment. We performed a comprehensive search for studies of medical and minor surgical treatments for primary hyperhidrosis. The results were summarised in tables and in text. Some studies evaluating botulinum toxin (BTX) injections for armpit hyperhidrosis could also be pooled together to estimate average effects.

We analysed the cost-effectiveness of treatment sequences and the value of conducting further research for hyperhidrosis of the armpit. There was insufficient evidence to conduct analyses for any other body site. The treatment sequences comprised combinations of the following treatments: topical aluminium chloride, iontophoresis, medication, BTX, curettage and ETS. Quality adjusted life years (QALYs) and costs were calculated for 64 different treatment sequences. The economic analysis modelled treatment received by patients from the age of 18 through to age 65. We consulted patients and clinical experts about our analysis and findings.

We also conducted a review to identify the quality of life tools most commonly used in hyperhidrosis research.

#### Results

We found 50 studies for our systematic review of clinical effectiveness. Most studies were small and of poor quality. We identified studies on the following treatments: iontophoresis, BTX, anticholinergic medications, curettage and newer energy based technologies that damage the sweat gland, such as laser or microwave. There was moderate quality evidence that BTX reduces symptoms of armpit hyperhidrosis in the short and medium term (up to 16 weeks), compared with placebo; combining the results from several studies we found that BTX was more than 3 times as effective as placebo. There was weak but consistent evidence of some benefit from using iontophoresis for hyperhidrosis of the hands. Evidence for other interventions was of low or very low quality.

There are ongoing studies of the new energy based technologies: microwave, laser, fractionated microneedle radiofrequency and ultrasound. If the results of this ongoing research are promising then trials comparing these with BTX, and with curettage, for armpit hyperhidrosis may be warranted.

There are ongoing/recently completed trials of new oral and topical anticholinergic medication formulations; therefore at this stage it is unlikely to be worthwhile undertaking further research of the anticholinergic medications currently available. There is little value in undertaking further studies of BTX versus placebo for hyperhidrosis of the armpit or iontophoresis versus placebo for hyperhidrosis of these treatments is already available.

Results of the economic model indicated that treatments tried in the following order: iontophoresis, BTX, medication, curettage, ETS, was the most cost-effective sequence of treatments for patients with armpit hyperhidrosis (with an 80% probability of being best). This sequence had an incremental cost-effectiveness ratio of £9,304 per QALY, which is within the range where treatments are considered to be cost-effective for the NHS. The evidence for these treatments is limited and a high level of uncertainty is present. Conducting further research to reduce some of the uncertainty around the results of the model may be useful. For example, we found that further research on the effectiveness and safety of medication compared with placebo may be worthwhile. This may be partially addressed when trials of new medications are published. However, it was not certain that these trials, or other further research on this comparison, would change the first and second best positions of iontophoresis and BTX.

Twenty two individual quality of life tools were identified in studies of hyperhidrosis; many studies used two or more tools for measuring quality of life. The Dermatology Life Quality Index (DLQI), the Hyperhidrosis Disease Severity Scale (HDSS), and the Hyperhidrosis Quality of Life

Questionnaire (HQLQ) were used more often than any other tool. The Hyperhidrosis Quality of Life index (HidroQoL<sup>©</sup>) is the most recent tool to be designed and validated for measuring quality of life in patients with hyperhidrosis.

Patients and clinicians attending an end-of-project workshop were unsurprised by the positive findings regarding BTX for armpit hyperhidrosis. They were satisfied with the sequence of treatments for armpit hyperhidrosis identified as being cost-effective. All patient advisors considered that the HidroQoL<sup>©</sup> was superior to other tools commonly used in hyperhidrosis research for assessing quality of life. Combining the evidence and patient advisor input, we concluded that further research on the clinical and cost-effectiveness of BTX (with anaesthetic) compared with iontophoresis for hyperhidrosis of the hand would be useful.

## Conclusions

- The evidence for the effectiveness of treatments for primary hyperhidrosis is limited overall and few firm conclusions can be drawn. However, there is moderate quality evidence to support the use of BTX injections for armpit hyperhidrosis.
- The cost-effectiveness analysis for armpit hyperhidrosis found that the treatment sequence iontophoresis, BTX, medication, curettage, ETS was the most cost-effective for the NHS.
- Combining the evidence and patient advisor input, we concluded that further research on the clinical and cost-effectiveness of BTX (with anaesthetic) compared with iontophoresis for hyperhidrosis of the hand would be useful.
- Future studies of the effectiveness of treatments for hyperhidrosis would benefit from including a hyperhidrosis-specific quality of life tool, such as the HidroQoL© tool, favoured by our patient advisors.