Understanding patient-reported outcomes to inform development of an international core outcome set for vitiligo clinical trials

Section 1 – Project Details:

Maximum 800 words, using the following headings

Rationale:
An international core outcome set initiative is currently underway to establish an agreed set of outcomes for use in future vitiligo trials. The core outcome domains have already been agreed by international consensus (Eleftheriadou et al 2015), and validation studies of the most likely candidate outcome instruments are now required.

Our previous work has highlighted discrepancies between what is measured in published vitiligo trials and what patients actually value (Eleftheriadou et al 2012). In response, we developed the Vitiligo Noticeability Scale (VNS) (Tour et al 2014, Batchelor et al 2015). (http://www.nottingham.ac.uk/research/groups/cebd/projects/2vitiligo/vitiligo-outcome-measures.aspx ). This is the first ever patient-rated outcome measure of vitiligo treatment success. Development of the scale used a mixture of clinical images and others that had been developed using digital image software. Following the initial validation of this new scale, one of the recommendations for future work was to further validate the scale using a larger database of clinical images of vitiligo patches before and after treatment.

The NIHR-funded HI-Light Trial is one of the largest randomised controlled trials to have been conducted in patients with vitiligo (n=516) and includes both adults and children. This unique dataset has outcomes collected over a 9-month treatment period for all of the agreed domains for inclusion in the vitiligo core outcome set, and is the first to have captured VNS data. Availability of high-quality digital images taken during the trial means that this provides a unique resource to allow further validation of the core outcome instruments for vitiligo.

Aims and methodology:

Aims:
- To evaluate the validity and responsiveness of the Vitiligo Noticeability Scale (VNS) in assessing treatment response in vitiligo patients
- To evaluate the validity and responsiveness of quality of life measures used in the HI-Light trial
- To inform development of a core outcome set for vitiligo

Methodology:
This PhD will follow best practice guidance for the development of a core outcome set as recommended by the COMET initiative (www.comet-initiative.org), and for validating the outcome instruments using guidance from COSMIN (www.cosmin.nl).

Using data collected in the HI-Light trial, the PhD will involve:
- Systematically reviewing the existing evidence from validation studies of vitiligo quality of life scales
- Testing the reliability, validity, responsiveness and interpretability of the VNS
- Exploring the time interval between end of treatment and assessment of VNS to determine the optimum timing of assessment (allowing for residual hyperpigmentation around the treated patch of vitiligo to be resolved)
- Testing the validity and responsiveness of vitiligo quality of life scales (VitiQol, Skindex 16 and EQ-5D-3L and CHU-9D)
**Benefits and suitability as a PhD project:** This is an ideal opportunity to provide training into the development and validation of outcome measures for use in clinical trials, and to engage with international experts in the field to develop consensus over the core outcome set. This PhD fits with the strategic priorities and strengths of the Centre of Evidence Based Dermatology and aligns well with international efforts to reduce research waste by ensuring that clinical studies measure outcomes in a consistent way, so that results can be combined in meta-analysis and systematic reviews.

We currently have a similar PhD ongoing that was funded by the British Skin Foundation (Laura Howells), and the two projects would be complementary and supportive of each other.

**Key References:**


**Section 2 – Training Provision:**

Maximum of 250 words. *Please detail the training provision that will be made available to the student.*

This PhD would be based at the Centre of Evidence Based Dermatology, which includes a multi-disciplinary team of 20+ researchers, methodologists and clinicians interested in the treatment and prevention of skin disease. One of the key strategic priorities of the Centre is methodological advancements to support better trial design, and colleagues at the Centre have considerable experience of designing and testing outcome scales, as well as leading the development of core outcome sets (particularly through the HOME initiative for eczema [www.homeforeczema.org](http://www.homeforeczema.org) and CSG-COUSIN [www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zegv/cousin/about-csg-cousin](http://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zegv/cousin/about-csg-cousin)).

Our group has strong international links, and so an international visit can be arranged with another research centre depending on the interests of the candidate.

Our group has existing links with both COMET and COSMIN, which will facilitate specialist training and support in core outcome set development, and the student will be encouraged to attend relevant conferences, such as the COMET initiative conference and the Clinical Trials Methodology Conference.
In addition to the usual training course available through the Graduate School and the UoN more widely, the successful candidate will attend our 3-day “Getting to Grips with Evidence Based Dermatology” course and annual summer schools (various topics e.g. better paper writing, statistics and systematic reviewing).