

## **The Hand Eczema Core Outcome Set (HECOS) Initiative**

Dear Colleague,

We invite you to join the HECOS initiative. This document provides you with all crucial information. It addresses clinical hand eczema experts, researchers, journal editors, and other stakeholders including patients with a background in clinical research. For patients and other people who are interested in joining the initiative but do not have a scientific background, plain language invitations in several languages are available at <http://cs-cousin.org/hecos>.

### **What is a core outcome set (COS)?**

A COS is a standard that defines the minimum of what should be measured in studies (e.g. hand eczema severity) and which instruments should be applied to measure them (e.g. the Hand Eczema Severity Index HECSI). Beyond the core outcomes, researchers are free to measure further outcomes that are relevant for their research questions.

### **Why do we need a COS?**

Clinical trials of hand eczema currently apply a variety of outcomes to measure the effects of interventions. It is therefore hard to compare the results of individual studies in reviews and meta-analyses. This considerably impairs the quality of the evidence. Consequently, recommendations for clinical practice are weaker than they could be. The HECOS initiative addresses this shortfall and seeks to develop two sets of core outcomes that should be measured and reported in all future clinical trials of hand eczema: One set addresses the evaluation of therapeutic interventions; the other set addresses the evaluation of preventive interventions.

### **Who decides which outcomes should be measured?**

A COS misses its point if it is not endorsed by the scientific community or if it is not meaningful for patients. HECOS is therefore going to be a worldwide initiative of researchers, physicians, patients, journal editors, and other stakeholders. Candidate outcomes are identified by systematic reviews of previous trials and existing measurement instruments. Decisions will then be made by an integrative panel of stakeholder. For this purpose, HECOS is organizing a consensus study consisting of online as well as face-to-face surveys.

### **Which quality standards does HECOS apply?**

HECOS is part of the Cochrane Skin Core Outcome Set Initiative (CS-COUSIN, <http://cs-cousin.org>). CS-COUSIN provides structured guidance and advice for the development of COS in dermatology. Being part of CS-COUSIN means that relevant up-to-date guidelines are applied in any step of HECOS. In particular, these guidelines are:

- COMET handbook
- Core Outcome Set-Standards for Development: The COS-STAD recommendations
- Core Outcome Set-Standardised Protocol Items: The COS-STAP Statement
- Core Outcome Set-Standards for Reporting: The COS-STAR Statement
- COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures

## Who can join HECOS?

Anybody with an interest in a COS for hand eczema is invited to join HECOS. There are, however, two pragmatic limitations: We include only adults (18 years of age or more) because data protection requirements for younger persons are more restrictive. Also, participants need to be able to communicate well in English. This limitation does not apply for members who participate only in the online consensus panel because we will provide the survey documents in a variety of languages.

## How can I join HECOS?

There are three options to contribute to HECOS. If you wish to join one or several parts of the initiative, please complete and sign the form (available at <http://cs-cousin.de/hecos>) and send it to [Henriette.Roensch@tu-dresden.de](mailto:Henriette.Roensch@tu-dresden.de).

### **A) Two consensus panels (therapeutic interventions/preventive interventions)**

By joining a HECOS consensus panel you can make sure that your vote towards a hand eczema COS matters. Consensus will be achieved by online surveys and facultative face-to-face meetings. The results of face-to-face meetings will be confirmed by an online survey involving the whole panel.

### **B) Initiative**

HECOS is performing several projects to achieve its aim:

- interviews with hand eczema patients
- interviews with persons who are at risk of developing hand eczema
- interviews with hand eczema experts
- organizing online Delphi consensus surveys
- organizing face-to-face consensus meetings
- systematic literature review of outcome measurement instruments
- validation studies of outcome measurement instruments if needed

The projects will be performed by several project groups. For the most part, they are conducted separately for developing a COS for therapeutic interventions and for preventive interventions, respectively. Initiative members also contribute by inviting further potential participants, by translating project documents, by providing feedback to the steering committee, and by publishing their project's results.

### **C) Steering committee**

A steering committee is currently being formed. The main tasks of the steering committee are to coordinate the initiative and to ensure methodological integrity. The individual tasks will be performed by small working groups. If you want to take part in deciding how consensus is achieved in HECOS, you are welcome to join the steering committee. The same steering committee is responsible for the COS development for therapeutic as well as preventive interventions.

***Your contribution to enhance hand eczema research by joining HECOS is highly appreciated.***

***<http://cs-cousin.org/hecos>***

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