



Assessing the Patient's Perspective in End-stage Kidney Disease – A Domain-Guided Approach Applied in the CONVINCE Trial

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Aim

To apply psychometrically advanced instruments, in combination with new tools to assess most relevant proximal and distal health outcomes of patients with end-stage kidney disease.

Background

Patient-Reported Outcomes (PRO) are an important aspect in clinical trials. In order to compare own results to results of previous studies, common legacy measures are used. However, this bears the risk of neglecting newly developed and psychometrically advanced measures. Further, relevant aspects could be omitted due to the fixed combination of health information developed for a particular treatment situation.

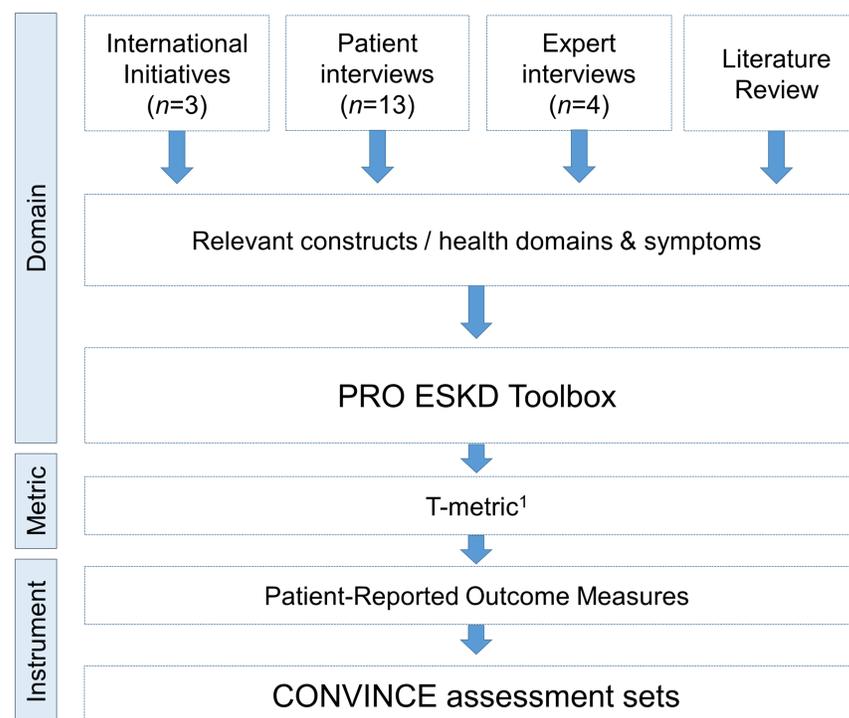
For the CONVINCE trial we decided on a domain-guided approach, where we first defined *what* health aspects to measure, before we decide on *how* to measure these health aspects.

CONVINCE Trial Info Box

The CONVINCE Study is a international, multicentre, prospective, randomized controlled trial comparing high-dose haemodiafiltration versus conventional high-flux haemodialysis. For more information:

www.ucl.ac.uk/convince-hemodiafiltration-dialysis-study/

Methods



Results

We identified 11 health domains and 41 disease-specific symptoms/problems as relevant for ESKD patients. To balance the comprehensiveness of assessments and respondent burden, we decided to follow up with 9 domains and 20 symptoms/problems according to the objectives of the trial. For the more proximal outcomes, i.e. recovery time and recovery time pattern, no instrument has been available, and thus needs to be developed by the CONVINCE consortium applying established state-of-the-art methods. For generic outcomes, e.g. fatigue, physical function, we decided to apply psychometrically advanced tools from the PROMIS® initiative.

Table 1:

CONVINCE Domains	SONG ²	ICHOM ³	PROMIS
Symptoms	X		
Fatigue	X	X	X
Social activity / social roles	X		X
Physical Function	X	X	X
Depression	X		X
Anxiety	X		X
Pain	X	X	X
Sleep	X		X
Cognitive Function	X		X
General Health / Health Perception		X	

Conclusion

A domain-based ESKD PRO-Toolbox allows flexible application of assessments sets in the prospective CONVINCE trial to assess relevant proximal and distal outcomes in patients with End-Stage Kidney Disease (ESKD).

References:

1: HealthMeasures. Presenting PROMIS Results: Use T-scores [cited October 7, 2019] Available from: <http://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administer-measures/presenting-results>

2: SONG Initiative: The SONG Handbook. Version 1.0. Sydney, Australia, 2017

3: International Consortium for Health Outcomes Measurements (ICHOM): Chronic Kidney Disease Data Collection Reference Guide. 2017