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### **Validation and application of a core set of patient-relevant outcome domains to assess the effectiveness of a multimodal pain therapy (VAPAIN; supported by BMBF)**

#### **1. Aim of the study**

Aim of the study is an interdisciplinary consensus recommendation to domains and relevant measuring instruments for assessing the outcome of multimodal pain therapy. The focus lays on comments to validity, reliability and sensitivity in assessing effectiveness of multimodal therapy of chronic pain.

#### **2. Background: Why do we need an international Delphi consensus study?**

Measuring the effectiveness of multimodal pain therapy is one of the most fundamental challenges communicating clinically relevant information.

The assessment of the effectiveness of multimodal pain therapy in clinical trials and in routine care is rather heterogeneous at present. This leads to the situation, that studies and treatments cannot be reliably compared according to the principles of evidence based medicine. This constitutes an important barrier in clinical decision making. While recent initiatives, such as IMMPACT, focused on clinical trials only, the main focus of this consensus study is daily record keeping for documentation of routine care (e.g. development of a core set) and quality assurance.

#### **3. Work plan**

The study is divided into two parts:

PART 1 focus on a final and consensus definition of a core set of patient-relevant outcome measures for the investigation of the effectiveness of multimodal pain therapy. In the center of Part 1 is a multiperspective Delphi consensus study involving scientists and clinicians with different backgrounds (medical, physiotherapeutic,



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methodological and psychotherapeutic) and patients as well. The aim of this subpart is to define a core set of patient-relevant outcome domains for multimodal pain therapy. The required information will be raised via systematic literature review on the validity of instruments to measure these core outcome domains. Additionally there will be conducted secondary analyses on an existing data set of patients of a comprehensive pain center to estimate quality criteria of demanded instruments.

PART 2: According to the final recommendation of the Delphi-Consensus a multicenter prospective cohort study will investigate the effectiveness of multimodal pain therapy and determinants of treatment response. Qualitative interviewing about acceptance of questionnaire and satisfaction will be conducted additionally. The validation of the core set will be estimated for further recommendations.