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### **Q.RARE.LI - Improving health-related quality of life in patients with rare autoimmune liver diseases by structured peer-delivered support: a transnational effectiveness-implementation hybrid trial**

#### **Background/aims:**

The proposed project addresses the unmet psychosocial support needs of patients. We will assess the effectiveness of a peer-delivered psychosocial support intervention (that was developed in Hamburg, Germany by Bernd Löwe and Natalie Uhlenbusch) in routine care and prepare the implementation in different health systems for patients with rare autoimmune liver diseases.

#### **Study design:**

Effectiveness-implementation hybrid trial. Effectiveness: RCT comparing structured peer-delivered support plus care-as-usual (CAU) with CAU alone. Implementation: Quantitative survey and qualitative focus groups to assess acceptability and feasibility in routine care.

#### **PROMS:**

SF-12 (QoL, primary outcome), PHQ9 (depression severity), PHQ15 (somatic symptom severity), GAD7 (anxiety severity), HeiQ (self-management abilities), ICQ (illness-related cognitions), Brief IPQ (illness perceptions), SWE (self-efficacy), TEX-Q (treatment-related expectations), F-SozU (social support), SSD12 (somatic symptom disorder B-criteria).

#### **Target population:**

Include N=240 and analyse N=200 patients with rare autoimmune liver diseases (PSC, PBC, AIH).

#### **Languages:**

All questionnaires are either already available or will be professionally translated into the following languages: English, German, Polish, Dutch, Hungarian

#### **Countries:**

University Medical Center Hamburg-Eppendorf (Germany), University Health Network & University of Toronto (Canada), Ghent University Hospital (Belgium), Medical University of Warsaw (Poland), University of Debrecen (Hungary)

#### **Inclusion and exclusion criteria:**

Effectiveness focus: Inclusion criteria: autoimmune rare liver disease (AIH, PSC, PBC), subjective psychosocial support need, ≥18 years, written informed consent. Exclusion criteria: life-threatening health-status, acute suicidality, ongoing psychotherapy, severe cognitive, auditory or visual impairment, inability to complete assessments. Implementation focus: Inclusion criteria: Patients: see above. Stakeholders: involvement in delivery/implementation of the intervention i.e. healthcare providers, patient representatives, health insurers; written informed consent. Exclusion criteria: involvement in outcome assessment or data analysis.

#### **Study period:**

June 2022 – May 2025

#### **Contact details:**

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