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The evaluation of health-related quality of life issues experienced by patients with desmoid-type fibromatosis (The QUALIFIED STUDY)– a protocol for an international cohort study

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Background: Sporadic desmoid-type fibromatosis (DTF) is a rare soft tissue tumour with an unpredictable clinical course. Although histologically benign and incapable of metastasizing, the morbidity can be significant, resulting in a substantial symptom burden. Measuring the impact of DTF on the health-related quality of life (HRQoL) can be challenging due to the heterogeneous character of the disease. Therefore, HRQoL instruments assessing DTF-specific issues are needed. Previously, a DTF-specific questionnaire, the DTF-QoL, was designed based on the results of focus groups, patient interviews and ranking of issues by patients and health care professionals from the Netherlands and the United Kingdom. This paper describes the design of the QUALIFIED study (The evaluation of health-related quality of life issues experienced by patients with desmoid-type fibromatosis). The QUALIFIED study aims to (1) gain insight into DTF-specific HRQoL problems; (2) validate the DTF-specific HRQoL tool (the DTF-QoL); (3) identify subgroups at risk for impaired HRQoL.

Methods and analysis: The QUALIFIED study is an international, multicentre, cross-sectional, observational cohort study. Patients ≥ 18 years with pathologically proven, sporadic DTF from the Netherlands and United Kingdom (three centres in the Netherlands; one centre in the

United Kingdom) will be invited to complete a set of questionnaires specifically composed for this patient group. Questionnaires will be completed using PROFILES (Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship), a system to electronically capture questionnaire responses. Analyses will include content validation of the DTF-QoL and evaluating frequencies of HRQoL-problems using the DTF-QoL, EORTC QOL-C30 and EQ-5D-5L, among other questionnaires. Preliminary results are expected after April 2021 and will be presented at conferences.

Discussion: The QUALIFIED study will provide insight into HRQoL-problems experienced by patients with DTF. Awareness of these problems and the implementation of the DTF-QoL could help to improve overall patient experience, clinical care and HRQoL.

Trial registration: This study is registered on clinicaltrials.gov, number NCT04289077