Study protocol: Questionnaire on Experiences with Vitiligo Treatment

Background

Vitiligo is a common autoimmune disorder characterised by depigmented macules which has a significant impact on patients' quality of life. Treatment options vary based on individual factors and goals, making shared decision-making (SDM) crucial for aligning treatment with patient preferences. This study aims to investigate how patients experience shared decision-making in choosing their vitiligo treatment and which unmet needs they encounter in the treatment of vitiligo.

Objectives

Primary objectives:

- To assess the extent to which patients have experienced shared decision making when making a treatment decision in vitiligo.

Secondary objectives:

- To investigate the relationship between demographic factors and the experienced shared decision making and unmet needs.
- To assess patient's decisional conflict and their demand for shared decision making
- To identify the unmet needs patients experience in the current vitiligo treatment.

Methods

Study design

This multinational, cross-sectional exploratory survey study will be conducted across three countries in the Amsterdam UMC, National University Singapore, Cairo University and Ain Shams University. The survey will be carried out using the free online survey tool 'LimeSurvey'.

Study population

The desired sample size is between 100-150 patients per country. Patients that can be included have a physician-based diagnosis of non-segmental vitiligo, are 18 years or above and had a treatment visit at the dermatology department in the past 2 years.

Intervention

The patients will be asked to fill out a questionnaire that will take about 10 minutes to complete. The questionnaire was developed with input of 3 patients of the Dutch national vitiligo patient association. It was also tested on 3 vitiligo patients who visited the dermatology department in Amsterdam UMC and was adjusted based on their feedback. The survey contains questions about demographic variables (such as educational level, ethnicity, etc.) and unmet needs during treatment of vitiligo. Besides this, three validated questionnaires will be used: the 9-item Shared Decision-Making Questionnaire (SDM-Q-9), the Control Preference Scale (CPS) and the Decisional Conflict Scale (DCS) for assessing the need for and extent of shared decision-making. The survey was translated to English and Arabic for the participating hospitals in Singapore and Egypt by a certified translation agency. The English survey and the Arabic survey will be reviewed in LimeSurvey by two doctors who are (near)-native speakers of these languages before sending the survey out to the patients.

Data collection and statistical analysis

Patients will receive an email with the link to the survey on LimeSurvey. The data from Egypt and Singapore will be completely anonymous, and the survey is hosted on a secure platform of the Amsterdam University Medical Centre. Participants will give consent for the use of anonymous data for scientific research. The study protocol has been submitted to the Ethical Committee of the AUMC and the study was exempted from full ethical approval as the burden of this study for participants is minimal (METC 2024.0692). Statistical analyses will be mainly descriptive in nature, aimed at summarising the experiences of vitiligo patients. The effect of demographic and clinical variables on the outcomes will also be analysed. Statistical analyses will be conducted for differences between the Netherlands, Egypt and Singapore and the secondary objective.