

# BMJ Open Stigmatisation and body image impairment in dermatological patients: protocol for an observational multicentre study in 16 European countries

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## ABSTRACT

**Introduction** Patients with common skin diseases may have substantial psychosocial comorbidity and reduced quality of life. This study aims at exploring further the psychosocial burden of skin diseases by assessing stigmatisation and body image problems in a large sample of patients with skin disease across Europe.

**Methods and analysis** The study is an observational cross-sectional multicentre study across 16 European countries comparing stigmatisation and body image in patients with skin disease compared with controls. Consecutive patients will be recruited in outpatient clinics and will complete validated questionnaires prior to clinical examination by a dermatologist at each recruitment site. In addition to sociodemographic background information, the outcomes will be: mood disorders assessed by short versions of the Patient Health Questionnaire and the General Anxiety Disorder Assessment; general health assessed by the EuroQol-Visual Analogue Scale; stigmatisation experience assessed by the Perceived Stigmatisation Questionnaire; stress assessed by the Perceived Stress Scale and body image assessed by the Dymorphic Concern Questionnaire. The main criteria for eligibility are to be 18 years old or more. The analysis will include comparison between patients and controls for the main outcomes using t-tests, analyses of covariance and multivariate logistic regression models adjusting for potential confounding factors.

**Ethics and dissemination** The study protocol is approved by the University of Giessen and by the local Ethical Committee in each recruitment centre. Informed consent will be given by each participant. The results of the study will be disseminated by publications in international peer-reviewed journals and presented at international conferences and general public conferences. Results will influence support intervention and management of patients with skin disease across Europe.

**Trial registration number** DRKS00012745; Pre-results.

## INTRODUCTION

The psychological impact of skin diseases is an issue of increasing concern worldwide.<sup>1–3</sup> Skin diseases are the fourth leading cause of

## Strengths and limitations of this study

- The large size of this multicentre study is a strength.
- The multicentre study conducted in 16 countries across Europe will enable to explore cultural and gender aspects of stigmatisation and body dysmorphic concern in patients with skin disease.
- The inclusion of a control group will enable to compare with a reference population.
- The design of the study is cross-sectional, therefore, it will not be possible to establish the direct causation of any possible association.
- No aspects of dermatological treatments were included in this study.

non-fatal disease in the recent Global Burden of Disease Study 2010.<sup>3</sup> Most skin conditions are non-fatal and chronic. Globally, the most prevalent conditions are skin infections, acne, pruritus and eczema.<sup>3 4</sup> The psychosocial impact of common skin disease is expected to be large worldwide but little research or exploration in this area has been undertaken. Our group has recently demonstrated, in far reaching publications, the psychosocial burden of skin conditions in 13 European countries by documenting the psychological comorbidity and the impairment on sexual life, attachment style and general quality of life in common skin diseases.<sup>5–9</sup>

We believe that there is a requirement to further explore in different parts of the world aspects of the psychosocial burden of skin disease. This, we believe, will achieve greater knowledge and understanding of the aspects of living with skin disease over time and enable healthcare professionals to target appropriate intervention programmes.

## Stigmatisation

Patients with chronic skin disease can display a fear of negative evaluation and perceived

stigmatisation. Patients with visible skin lesions are reported to be more likely to have fear of social rejection together with fear of negative evaluation by others either within their peer group or from others. The perceived stigmatisation is best described as experiences of social disapproval, discrediting or devaluation based on an attribute or physical mark.<sup>10</sup> Patients with chronic skin diseases regularly report experiences of perceived stigmatisation, for example, others staring at them, receiving negative comments or avoiding physical contact.<sup>11–13</sup>

Culture, societal and other social influences appear to play a role in this stress experience, based on common misconceptions, for example, that skin diseases are contagious or a consequence of poor hygiene.<sup>14</sup> It is known that perceived stigmatisation experiences are common among patients with chronic diseases.<sup>11–13</sup> In addition, perceived stigmatisation is higher when physical and psychological well-being and functioning in daily life is reduced, for example, in patients with chronic skin diseases, such as atopic dermatitis and psoriasis.<sup>13 15–17</sup> When considering interindividual differences, research in psoriasis patients indicated that younger patients, those who have no partner, those with a lower educational level as well as patients who may experience higher levels of social inhibition and negative affectivity might be more affected by this experience of perceived stigmatisation.<sup>15</sup>

Finally, stigmatisation may also affect other areas of functioning other than only the self-reported well-being of the patients. For example, a stigmatisation-related implicit bias regarding the disgust reactions of others has recently been shown in patients with chronic skin conditions of psoriasis.<sup>18</sup> A more systematic research of stigmatisation among patient groups can produce an important insight into the possible social and cultural difference of stigmatisation experience in patients with skin diseases. This will enable healthcare professionals to finally develop screening and intervention procedures to better support patients in coping with these stigmatisation experiences.

### Body image disorders

Dissatisfaction with the body or the skin is common. Most people are not fully satisfied with their body appearance or their skin but accept and live with the realisation that their body is imperfect. The influence of culture and ethnicity might be important aspects of body satisfaction.

For some, the degree of dissatisfaction is so high that it culminates in a preoccupation with a perceived defect of their body which interferes dramatically with their daily life and routine. This is known as body dysmorphic disorder (BDD). BDD is a recognised psychiatric condition and categorised as part of the obsessive–compulsive and related disorders in the latest edition of the Diagnostic and Statistical Manual of Mental Disorders.<sup>19</sup> The condition occurs in around 2% in the general population in the developed world and recent data suggest that this occurrence could be increasing.<sup>19–22</sup> The prevalence is varying in different patient settings and, among dermatological patients, the prevalence is estimated to be at least 11%.<sup>21 23</sup>

BDD is a distressing condition which can be connected to any part of the body and often linked to shame. Depression, social anxiety and suicidal ideation are frequently comorbidities. In addition, there is a higher rate of suicide among patients with BDD.<sup>24 25</sup>

Persons with BDD frequently consult a dermatologist but are rarely seen by a psychiatrist or mental health specialist. Patients with BDD are often dissatisfied with their treatment and ‘doctor shop’. They are convinced that their problem is physical and not mental. Also, patients with BDD consume substantial resources in healthcare systems and are challenging to help.<sup>19</sup> Therefore, it is important for the clinicians to understand when the patient is suffering from the condition in order to provide adequate treatment and also to be able to distinguish the BDD condition from the more trivial condition of dissatisfaction with body.

### The psychosocial burden of skin disease

The primary objective of the present study is to describe the psychosocial burden of skin diseases by assessing the experience of stigmatisation of patients with common skin disease and by estimating the prevalence of body image disorder in patients with skin disease. The secondary objective is to compare this burden in different countries across Europe.

## METHODS AND ANALYSIS

### Setting

The study is an observational cross-sectional multicentre study across 16 European countries comparing stigmatisation and body image in patients with skin disease compared with controls. Patients will be recruited from public general dermatological outpatient clinics at each participating centre. The study will be organised following the time table (table 1) and conducted by members of the European Society for Dermatology and Psychiatry. The dermatological departments of the following institutions have signed an agreement to participate: University of Graz (Austria), University of Copenhagen, Roskilde Hospital (Denmark), Brest University (France), Justus Liebig University, Giessen (Germany), Muenster University (Germany), University of Szeged (Hungary), Istituto Dermatologico dell’Immacolata, Rome (Italy), Skopje University (Macedonia), University of Leiden, Radboud University of Nijmegen, University of Amsterdam (Netherlands), University of Stavanger, Innlandet Hospital Trust (Norway), Wroclaw University, University of Rzeszow (Poland), University of Coimbra (Portugal), First Moscow State Medical University, Moscow Scientifica and Practical Centre for Dermatology and Cosmetology (Russia), Alcaniz Hospital, Alcaniz, Department of dermatology, Zaragoza, Hospital of Barbastro, Huesca, Aragon (Spain), Skåne University Hospital, Malmö, Lund University (Sweden), Sisli Etfal Hospital, Istanbul (Turkey), Barts Health National Health Service Trust London, Sheffield University, Cardiff University (UK).

**Table 1** Study dates

Action	Study dates	Involved colleagues
Ethical committee	March–June 2017	Working group
Submission study proposal	Dec 2016–August 2017	Working group
Invitation centres	October–January 2017	
Translation questionnaires	March–September 2017	All
Study agreement	May–June 2017	All
Data collection	September 2017–September 2018	All
Data cleaning	September 2018–December 2018	Giessen
Data analysis	January 2019–April 2019	Jörg Kupfer and Florence Dalgard
First article	May–November 2019	All
Following articles	January 2020–January 2022	All

### Procedure

Recruitment of cases will take place at the general dermatological outpatient clinic at each centre in each participating country in the same way as described in the previous study.<sup>5</sup> From the previous study, we expect that the most common skin diseases will be: psoriasis, non-melanoma skin cancers, infections of the skin, non-classified eczema and acne. Consecutive patients will be invited to participate in the study on one or more random days until the required number of 250 respondents is reached. All patients will be fully briefed by a research assistant and will be accepted onto the study by signing a written consent form. Each patient will be examined by a dermatologist who will record the diagnosis; and, if required any secondary diagnosis will be recorded. The recruitment of 125 controls at each centre will be completed by announcement among the staff in the hospital institution.

### Inclusion and exclusion criteria

Eligible patients and controls must be 18 years old or more and able to read and write the language of the questionnaire. Exclusions include patients unable to read the questionnaires in available languages, and, for controls, people with a skin condition under treatment.

### Assignment

All consecutive patients on specific days in the general dermatology clinics will be approached. Randomisation is therefore unnecessary for this study design. The drop-out rate will be recorded (noting age and gender) and reasons why they do not wish to participate.

### Outcome measures

#### Clinical assessment of patients

The dermatologist making the diagnosis will objectively evaluate and record International Classification of Disease 10<sup>th</sup> revision (ICD-10) diagnose for each condition. The severity will be assessed as ‘mild’, ‘moderate’ or ‘severe’. The presence of other conditions including the following treated comorbidities will be recorded: cardiovascular disease, chronic respiratory disease, diabetes and rheumatological disease. Clinicians will also be required to answer questions on whether signs of depression, anxiety and feelings of dysmorphic concern are present in the patient.

#### Self-reported measures

A background questionnaire (online supplementary appendix) will be filled in by patients and controls and provide information on sociodemographics including income, education, employment and disease characteristics such as duration and localisation of skin disease. Data on comorbidities, weight and height, presence of pruritus and its characteristics will also be recorded. Data on suicidal ideation will be collected in the same way as the previous study<sup>5</sup> with the item ‘Did you ever have suicidal ideation?’ Patients only will give information on severity of their skin condition, age of onset and localisation of the skin disease.

#### Scales

Wherever possible, we have chosen validated scales that were adapted and translated to most European languages to minimise the back-translation workload. Those scales that were not previously translated were back translated following instructions for cultural adaptation for the Dermatology Life Quality Index <http://sites.cardiff.ac.uk/dermatology/quality-of-life/dermatology-quality-of-life-index-dlqi/>.

#### Mood disorders are to be assessed by

The Patient Health Questionnaire-2: a validated questionnaire with two items assessing depression. The General Anxiety Disorder Assessment-2: a validated instrument with two items assessing anxiety. The two scales have solid psychometric properties and are used in different patient populations.<sup>26</sup> They are translated and culturally adapted to many languages (<http://www.phqscreener.com/>). Both short versions have a range from 0 to 6 and have a cut-off value  $\geq 3$  with sensitivity and specificity values about 0.85 and Cronbach’s alpha about 0.83.

#### Quality of life is to be assessed by

Self-reported Health State: EuroQol-five dimension-Visual Analogue Scale (VAS): a standardised generic instrument assessing general health state<sup>9</sup> with a VAS assessing the health state, from ‘0’ to ‘100’ (worst to best imaginable health state). This scale is used in different medical conditions and because of existing population norms is prized by health economists.<sup>27</sup> Recently its utility in

dermatology was demonstrated in a multicentre study among dermatological patients across Europe.<sup>6</sup>

#### Stigmatisation is to be assessed by

Perceived Stigmatisation Questionnaire: a generic instrument with 21 items assessing perceived stigmatisation and social experience in people with visible difference. The good reliability and validity of the scale have been demonstrated among patients with scars.<sup>28</sup>

#### Stress is to be assessed by

Perceived Stress Scale<sup>29 30</sup>: a 10-item questionnaire assessing perceived stress with solid psychometric properties widely used in different settings, translated and cultural adapted to many languages.<sup>29 31</sup>

#### BDD is to be assessed by

Dysmorphic Concern Questionnaire: a 7-item scale assessing body image concern that has the advantage that it can be used among patients and controls as well. It has been shown to be a sensitive and specific screening instrument for BDD.<sup>32</sup>

#### Proposed analysis

Before the data collection starts, a back-translation process of the questionnaires will be done by each centre in the languages for whom the translation is not available. The back translations will be forwarded to the Statistical Centre (Institute of Medical Psychology, University of Giessen, Germany) to enable a standardised checking procedure for the identical sets of questionnaires. After collection, the data will be checked and entered in an SPSS or Excel database at each site. The final corrected data will be sent to the statistical centre. Data will be merged into a single file and rechecked and cleaned. SPSS V.24 software will be used to analyse the data. All diagnoses will be categorised in groups adapted from a previous study.<sup>5 33</sup> The largest groups of skin diseases like psoriasis, acne and atopic dermatitis will be defined. To characterise the study population, we will report numbers and percentages for categorical variables, and mean values with SD for continuous variables.

To compare patients and controls for perceived stigmatisation, t-tests and analyses of covariance (ANCOVAs) will be calculated adjusting for the following potential confounding factors: sociodemographic variables, anxiety, depression, overall health state and perceived stress. To compare the risk for BDDs between the patients and controls, we will use the  $X^2$  test for dichotomous variables. Multivariate logistic regression models will be tested to study the associations between the main outcome variable 'risk for BDDs' and groups (patients/controls). As a first step we will calculate the crude ORs and in the second adjusted OR simultaneously controlling for potential confounding factors (same as for ANCOVAs). The OR will be calculated from the estimated regression coefficients B from the logistic regressions.

#### Patient and public involvement

In a pilot study, the research questions were discussed with patients and their point of views about stigmatisation were taken into the study design. The Norwegian patient society 'the Psoriasis and Eczema Forbundet' (PEF) was involved in a discussion of the study design and fully accepted the proposals of the study group. The society was not involved in the recruitment of the study. We plan to send our results to our patient society, PEF, as well to other patient organisation in the countries who are participating in the study.

The study is not a randomised controlled trial and the questionnaires are routine assessments which normally do not impact subjects apart from the time commitment. We plan to acknowledge the PEF in future publications.

#### Ethics and dissemination

The study will be conducted in accordance with the Declaration of Helsinki. A study agreement has been signed by all participating colleagues in the study. All eligible patients and controls will be informed verbally and in writing of the purpose of the study, the expected duration and procedure, the right to decline to participate and to withdraw from the research, without any consequences, at any given time once participation has commenced. The results will be disseminated by publication in international peer-reviewed journals and presentations at national and international meetings.

With this innovative study, we will expand the knowledge of the psychosocial burden of common skin diseases in patients from different countries in and outside Europe, and specifically address the burden of stigmatisation of patients with dermatological disorders.

The large scale of this study is a strength, giving a good power to our results, and the study group has a successful provenance in managing this kind of work. Nevertheless, we expect some limitations, for example, the distribution of patients might be different from one centre to another, even though we have aimed to standardise the setting by recruiting from general outpatient clinics. The recruitment of controls might be challenging in some centres but we expect to manage this by recruiting local research assistant who will be supported by the study team.

The results will expand our knowledge on the psychosocial burden of skin disease both at a population and at an individual level. We expect that the findings will have an impact on the clinical management of patients with skin disease, enabling dermatologists to understand uncovered needs of their patients to better plan appropriate healthcare.

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**Contributors** JK and FJD contributed substantially to the idea and design of the study protocol, reviewed critically the protocol and the study procedures. AB, AWE, UG, LL, FS, SS, LT-A and NV have contributed fully to the conception and design of the work, the drafting of the manuscript and revised critically important intellectual content. All coauthors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy and integrity of any part of the work are appropriately investigated and resolved. All authors have given final approval of the version to be published.

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**Competing interests** The authors are all members of the EADV Taskforce for psychodermatology.

**Patient consent** Not required.

**Ethics approval** Study procedures for the whole study have been approved by the Ethical Committee at Giessen University (Protocol number 87/17) and at each centre of recruitment.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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