

SYSTEMATIC REVIEW

Patient reported outcome measures (PROMS) for body image in dermatology: A systematic review

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Email: johannes.kristensen@dadlnet.dk**Abstract**

Introduction: It is widely acknowledged that negative body image perception is linked to anxiety, depression, and body dysmorphic disorder. However, there is no gold standard, body image related patient reported outcome measure in use, specific for dermatologic disease, despite evidence to suggest a high prevalence of mental health problems relating to body image in this group of patients.

Aim: The aim of this study was to perform a review of body image Patient Reported Outcome Measures (PROMs) used in dermatology and to evaluate their effectiveness.

Methods: Searches were performed in the major databases. Two investigators independently performed full text evaluation by applying an established checklist to evaluate the conceptual model, content validity, reliability, construct validity, scoring and interpretability and respondent burden.

Results: Six different PROMs were identified of which only one was fully validated. There was a significant lack of patient involvement in the development of PROMs in this context.

Conclusions: We therefore encourage further research in this field to improve the quality of evidence to better understand the relationship between mental health and dermatologic disease.

Body image is a multidimensional construct that can be defined as the subjective emotions surrounding the degree of satisfaction an individual has with their appearance.¹ An individual's level of concern regarding their body image can be quantified on the Body Image Concern (BIC) scale and has been shown to strongly correlate with quality-of-life scores.^{2,3} Furthermore, high BIC scores have been linked to psychological disorders including Body Dysmorphic Disorder (BDD).⁴ BDD which was previously classified as a somatoform disorder, has now been defined within obsessive-compulsive disorders in Diagnostic and Statistical Manual of Mental Disorders (DSM-5). A relationship to

major depression, Obsessive Compulsive Disorder (OCD) and Social Phobia has been demonstrated.⁵ The prevalence of BDD in patients with dermatological conditions is reported as ranging between 4.9% and 36% compared with just 1.8–2.3% of the general population.⁶ In addition, a negative body image has been linked to anxiety and depression in dermatology patients.⁷

To date, no study has assessed which body image scoring tool is most reliable and fit for purpose and currently there are a variety of tools being adopted in the study of this topic which has resulted in a significant heterogeneity in data interpretation.

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We set out to evaluate which body image Patient Reported Outcome Measure (PROM), relating to dermatological disease, reported within the published literature over the last 10 years, have undergone a validation process, as well as a critical appraisal.

This paper will highlight the current strengths, weaknesses and shortcomings in PROMs used to measure body image in dermatology patients which may inform future study design and clinical mental health evaluation of this high-risk group.

1 | METHODS

The methods for this systematic review were developed according to the recommendations from the Preferred Reporting Items for Systematic Reviews and Meta Analyses Protocol (PRISMA-P) statement.⁸ The protocol for the study has been registered in The International Register of Systematic Reviews (PROSPERO): CRD 42021240444.

We planned to search several databases. We concentrated on generic (or if possible) specific instruments measuring body image in dermatologic diseases. The second aim was to perform a quality appraisal of all the discovered instruments. To avoid a subjective and to obtain an objective evaluation we chose to use the COSMIN approach (The Consensus based Standards for the selection of health Measurement Instruments)⁹ as modified by Francis.¹⁰ The modified version reduces the number of items from 119 to 17.

In study part one, a systematic literature search was performed in PubMed, **EMBASE**, **Scopus**, **PSYCH Info** and **Cochrane Library databases using Medical Subject Headings (Mesh)** 'body image', combined with 'skin diseases', 'dermatology patients', 'PROMS', 'surveys' and 'questionnaires'. We chose studies that had been published between 2010 and present and stratified the results according to the PRISMA flow chart (Figure 1). Only PROMs published more than once in the literature were included in this study.

In Study part two, a second search was performed for each PROM to identify articles pertaining to evaluation of the measure. Articles with paediatric data were not evaluated. We performed hand searches as well in a few published surveys of generic instrument concentrating on other subjects, as no previous review of body image in dermatology was found except for a book chapter.¹¹

Evaluation of **psychometric properties** provide a level of evidence that an instrument is fit for the purpose.

Reliability assesses the extent to which a PROM tool yields consistent and reproducible results. The most important test for reliability is (1) test-retest

What is already known about this topic?

- A Review or Systematic Review has not been published previously.

What does this study add?

- This study lists the patient reported outcome measures (PROMs) used in dermatology to measure body image. This is important as a deranged body image can lead to Body Dysmorphic Disorder. Not all PROMs are validated properly and patient participation during construction was not always the case. This could be unethical and should be corrected in future work on these PROMs.

measures. (2) Internal consistency (or reliability) is often measured using Cronbach's alfa. As this measure is influenced by the number of items, users of this test have to be aware of questionnaires with redundant questions. Alfa should be not lower than 70 and not higher than 90.¹²

Validity describes the extent to which an instrument measures what it purports to measure. This is specific to the population and setting. (1) Construct validity signifies that the items provide distinctive clinical information. This is often explored using factor analysis and correlation coefficients. 'Face validity' is often used instead. (2) Criterion validity: This can be described as (a) predictive validity which means ability to predict response to treatment and clinical outcome and (b) concurrent validity where the correlation with another previously validated instrument is explored.

Sensitivity means that the items should be able to discriminate between different groups of patients, between patients and controls, it should be able to give meaningful results in clinical trials, be able to measure wanted or unwanted effects, measure active versus placebo. Sensitivity is crucial when treatment effects are small.

Sensibility (or clinical utility). The instrument should be easy to use, be short, use the right wording, be calibrated, and facilitate patient-clinician interaction.

As previously mentioned, we adopted a modified COSMIN approach.^{9,10}

As the COSMIN approach was found to be too complex to use without modifications. Instead, the simplified version incorporates the critical features highlighted in COSMIN and other relevant literature^{13,14} and hence will enable even unexperienced researchers to appraise a wide variety of PROMs.¹⁰

The quality of the individual papers can be judged indirectly from the scoring list (Table 2).

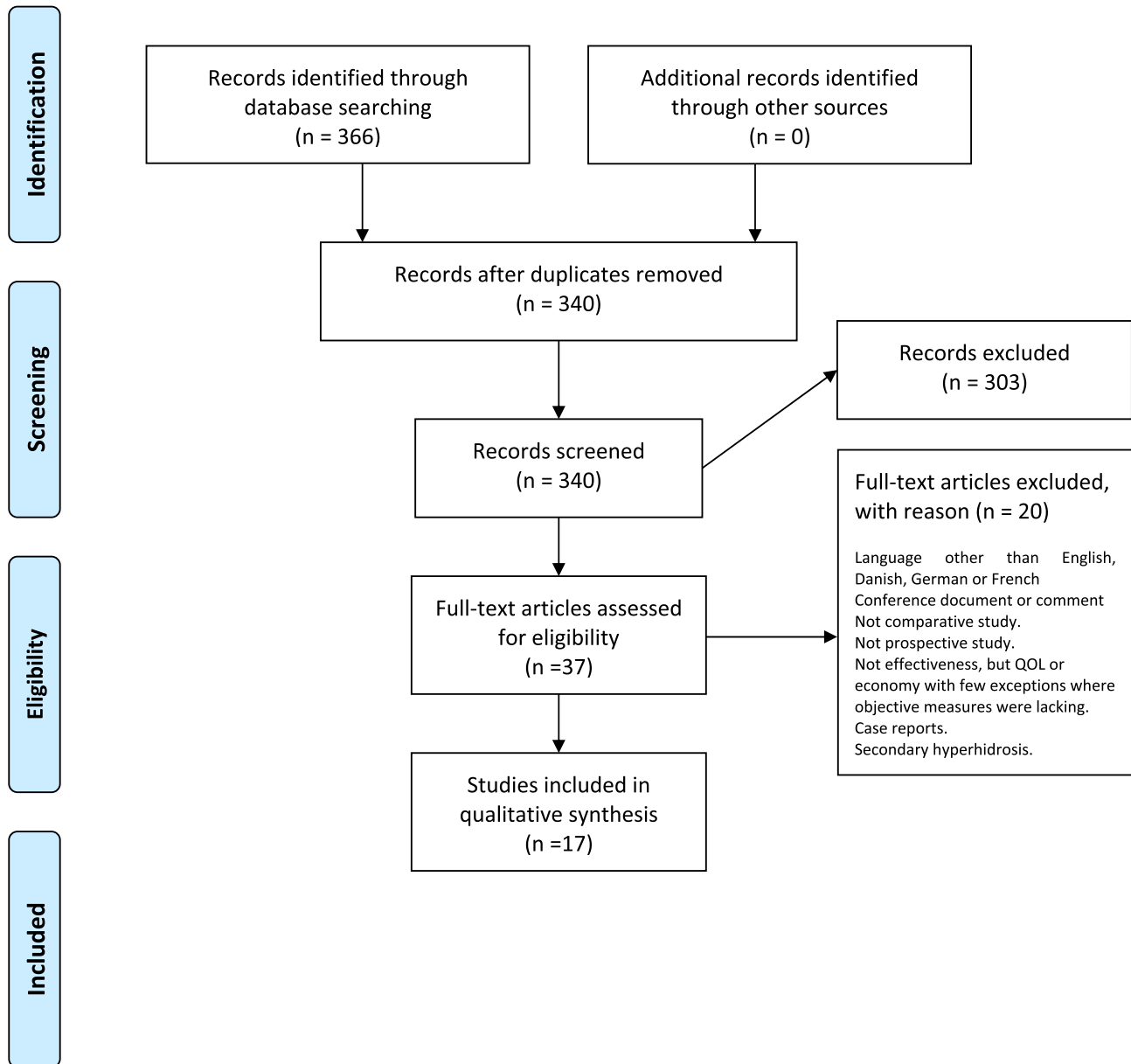


FIGURE 1 Flow chart of systematic literature search

2 | RESULTS

Table 1 shows the items in the short form PROM appraisal.¹⁰

The literature search is summarized in the PRISMA diagram (Figure 1).

We found six PROMS published in 17 papers and validated in 10 papers. One PROM was specific to dermatology, while the other five were generic.

The main properties of each PROM were extracted, and the results are presented in the text.

Their psychometric properties are presented in Table 2. From this table it is possible to deduct the quality of the papers produced with each individual PROM.

The main properties and uses of each PROM will be presented in the following.

The Cutaneous Body Image Scale (CBIS) is a 7-item (10 point) Likert scale from 0 'not at all' to 9 'very markedly'. 'I like the overall appearance of my skin'. The CBIS has been used and validated in multiple skin diseases by the construction team¹⁵; it has been used in patients with psoriasis, atopic dermatitis, and acne.^{16,17}

The Japanese version of CBIS has been used in dermatitis, acne, alopecia, psoriasis, and skin tumours.¹⁸

The Body Image Quality of Life Inventory (BIQLI)^{19–21} is a 19 item 7-point Likert scale from -3 very negative to +3 very positive: 'How confident I feel in my

TABLE 1 Simplified approach

| |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Conceptual model</p> <ol style="list-style-type: none"> 1. Has the PRO construct to be measured been specifically defined? 2. Has the intended respondent population been described? 3. Does the conceptual model address whether a single scale or multiple subscales are expected? |
| <p>Content validity</p> <ol style="list-style-type: none"> 4. Is the evidence that members of the respondent population were involved in the development of the PRO measure? 5. Is there evidence that content experts were involved in the development of the PRO measure? 6. Is there a description of the methodology by which items/questions were derived? |
| <p>Reliability</p> <ol style="list-style-type: none"> 7. Is there evidence that the reliability of the PRO measure was tested (e.g.: test-retest, internal consistency)? 8. Are reported indices of reliability adequate? |
| <p>Construct validity</p> <ol style="list-style-type: none"> 9. Is there reported mathematical justification that a single scale or multiple subscales exist in the PRO measure (e.g.: factor analysis, item response theory). 10. Is the PRO measure intended to measure change over time? If yes, is there evidence of both test-retest reliability and responsiveness change? Otherwise there may be an explicit statement that this PRO measure, is not intended to measure change over time. 11. Are there findings supporting expected correlations with existing PRO measures or other clinical data? 12. Are there findings supporting expected differences in scores between known groups |
| <p>Scoring and interpretation</p> <ol style="list-style-type: none"> 13. Is there documentation how to score the PRO measure? 14. Has a plan for managing and/or interpreting missing responses been described? 15. Is there information on how to interpret the PRO measure scores? |
| <p>Respondent burden and presentation</p> <ol style="list-style-type: none"> 16. Is time to complete reported and reasonable? If not, are number of questions appropriate for the intended application 17. Is the entire PRO measure available for public viewing? |

everyday life'. The BIQLI has been used in cutaneous lupus erythematosus²² in facial palsy before and after botulinum toxin injection²³ before and after injectable procedures for facial ageing.²⁴

The BIQLI has been adapted to Danish.²⁵ The Danish version has been used in Hidradenitis Suppurativa.²⁶

The Body Image scale (BIS)^{27,28} was developed for use in cancer patients. It is a 10 item Likert scale from score 0 'not at all' to score 3 'very much'. The BIS has been used in Cutaneous lupus erythematosus and in skin tumours.²⁹

The Portuguese version of BIS has been used in skin tumours and breast cancer.^{30–32}

The Appearance Schema's Inventory Revised (ASI-R) is a 20 item, 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). It contains two subscales. (1) Self-evaluative salience and (2) Motivational salience.³³ The questionnaire has been used in psoriasis^{34,35} and in pemphigus.³⁶

The Body Image State Scale (BISS) is a Likert scale with six nine-point items.³⁷ Low scores reflect more negative body image. This questionnaire has been used in hyperhidrosis.³⁸

The Spanish version of BISS was thoroughly validated in diverse groups and compared to other questionnaires.³⁹

The Body-Self Relations Questionnaire (BSRQ) contains 10 subscales and consists of 69 Likert type items with five grades from 1 'never' to 5 'very often'. The questionnaire is available in a shorter version containing only five subscales with 35 items.⁴⁰ This questionnaire has been used in psoriasis.⁴¹

3 | DISCUSSION

The aim of this systematic review was to identify and evaluate the Body Image PROMS used in studies involving dermatologic conditions. In general, there is a paucity of studies investigating body image in dermatology and hence scarcer those fully evaluating the use of PROMs in this domain. A total of five PROMs were reported more than once within a 10-year period. One instrument used only once was chosen as it was previously validated.

However, there were few descriptions of item development, and in three cases factor analysis was not performed.

An evaluation of expected differences between known groups was not undertaken in four proms. There was a lack of sensibility in everyday practical use of the PROMs regarding patient involvement in

TABLE 2 Level of evidence per measurement property and PRO

| | CBIS ^a | CBIS ^a Japanese | BIQLI ^a | BIQLI ^a Danish | BIS ^a | BIS ^a Portuguese | ASI- R ^a | BISS ^a | BISS ^a Spanish | MBSRQ ^a |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------------|--------------------|------------------------------|------------------|--------------------------------|------------------------|-------------------|------------------------------|--------------------|
| Measurement property | | | | | | | | | | |
| Conceptual Model | | | | | | | | | | |
| Has the PRO construct to be measured been specifically defined? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Has the intended respondent population been described? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Does the conceptual model address whether a single scale or multiple subscales are expected? | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 |
| Content validity | | | | | | | | | | |
| Is there evidence that content experts were involved in the development of the PRO measures? | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 1 | 0 |
| Is the evidence that members of the respondent population were involved in the development of the PRO measures? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Is there a description of the methodology by which items/questions were derived? | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| Reliability | | | | | | | | | | |
| Is there evidence that the reliability of the PRO measure was tested (e.g.: test-retest, internal consistency)? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Are reported indices of reliability adequate? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Construct validity | | | | | | | | | | |
| Is there reported mathematical justification that a single scale or multiple subscales exist in the PRO measure (e.g.: factor analysis, item response theory (IRT))? | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 |
| Is the PRO measure intended to measure change over time? If yes, is there evidence of both test-retest reliability and responsiveness change? Otherwise, there may be an explicit statement that this PRO measure, is not intended to measure change over time. | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Are there findings supporting expected correlations with existing PRO measures or other clinical data? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Are there findings supporting expected differences in scores between known groups? | 0 | 0 | 1 | 0 | 1 | 1 | 1 | 1 | 0 | 1 |

(Continues)

TABLE 2 (Continued)

| | CBIS ^a | CBIS ^a Japanese | BIQLI ^a | BIQLI ^a Danish | BIS ^a | BIS ^a Portuguese | ASI- R ^a | BISS ^a | BISS ^a Spanish | MBSRQ ^a |
|------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------------|--------------------|------------------------------|------------------|--------------------------------|------------------------|-------------------|------------------------------|--------------------|
| Scoring and Interpretation | | | | | | | | | | |
| Is there documentation how to score the PRO measure? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Has a plan for managing and/or interpreting missing responses been described? | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 |
| Is there information on how to interpret the PRO measure scores? | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Respondent burden and presentation | | | | | | | | | | |
| Is time to complete reported and reasonable? If not, are number of questions appropriate for the intended application? | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 1 |
| Is there a description of the literacy level of the PRO measure? | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| Is the entire PRO measure available for public viewing? | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

^aPROM's used; #score-0/1-criterion not met/ criterion met.

study design. A plan for missing scores were found only in two cases. Time to complete was not stated in any but had to be derived from the number of items. The literacy level of the PROM was only measured in three cases. Only one PROM (The BIS) ticked all the boxes in Table 2.

One of the main limitations in this study was the use of the COSMIN checklist. Several reviews have used the Cosmin approach^{42,43} others have not.^{44,45} It remains the gold standard in the assessment of PROMs.⁹ It was devised between 2006 and 2010 and consists of 119 items over 10 categories which may limit its usefulness. We therefore used the simplified approach devised by Francis.¹⁰ It should be noted that the relative importance of a specific measurement property may vary substantially with the purpose and context of the PROMs use. It was decided not to use a total score as this would imply that each item should be weighted equally.¹⁰ It is not recommended to use The Cosmin checklist in evaluation of PROMS developed using Modern Test Theory (MTT), but only those developed using classical test theory (CTT). MTT incorporates Item response modelling, which includes a Rasch analysis. CTT is based on simple mathematics, primarily averages, proportions, and correlations. Hence COSMIN is a major limitation to further progress in the field.⁴⁶ Psychometric criteria (COSMIN) are often inadequate in the setting of clinical assessment because of their quest for homogeneity of components and lack of attention to clinical utility and sensitivity in the real-world environment.^{47,48}

This study has highlighted that patient involvement in development of PROMs should be encouraged. Use of PROMs without patient input is increasingly being viewed as unwise and perhaps unethical.⁴⁶ Also, health outcome measures require new, better-quality PROMs, that aim to produce theory-based item calibration, approaching the standards of measurements found in physical science.⁴⁶ Item calibration is part of the larger topic of item response theory (IRT). The goal of item calibration is to develop a pool or bank of items which are on the same scale.

In conclusion, this study has demonstrated the limitations in data interpretation of studies investigating the effect of body image perception in dermatologic disease and calls for further research in the field. This will rely on the development of high-quality validated PROMs with patient involvement which can extend to specific psychological conditions such as Body Dysmorphic Disorder. Ultimately further research will equip clinicians with a better understanding of the relationship in the context of dermatologic disease and enable timely treatment and support for this high-risk group of patients.

AUTHOR CONTRIBUTIONS

Johannes Kjeldstrup Kristensen: Conceptualization (lead); Data curation (lead); Formal analysis (lead); Funding acquisition (equal); Investigation (lead); Methodology (lead); Project administration (lead); Resources (equal); Software (equal); Supervision (lead); Validation (lead); Visualization (lead); Writing – original draft (lead);

Writing – review & editing (equal). **Corina Nielsen:** Conceptualization (equal); Data curation (equal); Formal analysis (equal); Funding acquisition (equal); Investigation (equal); Methodology (equal); Project administration (supporting); Resources (supporting); Software (supporting); Supervision (supporting); Validation (supporting); Visualization (equal); Writing – original draft (supporting); Writing – review & editing (supporting). **Nora Haloob:** Conceptualization (supporting); Data curation (supporting); Formal analysis (supporting); Investigation (supporting); Methodology (equal); Project administration (equal); Resources (equal); Software (equal); Supervision (equal); Validation (supporting); Visualization (equal); Writing – original draft (supporting); Writing – review & editing (equal).

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CONFLICT OF INTEREST

None to declare.

DATA AVAILABILITY STATEMENT

Data available openly.

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