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Development and preliminary validation of the Adolescent Psoriasis Quality of Life instrument: a disease-specific measure of quality of life in adolescents with psoriasis

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Summary

Background No age-appropriate and disease-specific instrument currently exists to measure health-related quality of life in adolescents with psoriasis (patients aged 12–17 years).

Objectives To develop and provide preliminary validation of the Adolescent Psoriasis Quality of Life instrument.

Methods Qualitative interviews with adolescents with psoriasis, parents of adolescents with psoriasis, and healthcare professionals informed the development of an initial item pool for the instrument, which was subsequently refined through cognitive interviews. Finally, data from an independent sample of adolescents with psoriasis (n = 50) were used for item reduction, scale construction and initial validation, using a combination of techniques from classical test theory and Rasch modelling.

Results Rich qualitative data concerning health-related quality of life in adolescents with psoriasis (from 18 adolescents, 14 parents and four healthcare professionals), combined with cognitive interview testing (n = 12), resulted in a 41-item draft version. Item reduction led to the final version, a 17-item instrument consisting of two subscales showing good fit to their respective Rasch models: psychosocial impact (12 items) and the impact of physical symptoms and treatment (five items). All a priori stated hypotheses regarding construct validity were supported. Both subscales and the total scale showed acceptable test–retest reliabilities (intraclass correlations 0·97, 0·89 and 0·96) and internal consistencies (Cronbach's α 0·94, 0·81 and 0·95).

Conclusions The preliminary form of the Adolescent Psoriasis Quality of Life instrument shows promising psychometric properties. It can be used in daily clinical practice and research to support a patient-centred approach and inform treatment planning.

What's already known about this topic?

- Health-related quality of life (HRQoL) instruments should be targeted towards narrowly defined age groups, as life contexts of children, adolescents and adults may differ substantially.
- Dermatology-specific instruments have been used to measure HRQoL in adolescents with psoriasis, but it is not known whether these instruments accurately capture all relevant HRQoL aspects in adolescent psoriasis.
- Age-appropriate and psoriasis-specific instruments may be more sensitive for HRQoL issues experienced by this unique group.

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What does this study add?

- The Adolescent Psoriasis Quality of Life instrument represents the first age-appropriate and disease-specific instrument for measuring HRQoL in adolescents (12–17 years old) with psoriasis.
- It is intended for use in daily clinical practice to support dermatologists and other healthcare professionals in providing optimal care for adolescents with psoriasis.

Health-related quality of life (HRQoL) reflects patients' physical, psychological and social function and wellbeing as it relates to medical diseases and their treatments.[1] Its content may vary across the lifespan as life contexts of children, adolescents and adults differ substantially,[2,3] and evidence shows that the better targeted an HRQoL instrument is towards a certain patient group, the higher its sensitivity in detecting relevant issues.[4]

Psoriasis treatment aims at minimizing the extent of the disease and reducing its impact on HRQoL.[5] The sensitivity of HRQoL instruments used in daily clinical practice will likely affect how patients are met in the clinic and how treatments are initiated and monitored. While psoriasis-specific instruments have been developed for adults,[6,7] no such measure exists for adolescents, except for one scalp-specific instrument designed for children (6–17 years old).[8] Existing studies on HRQoL in adolescent psoriasis have therefore been restricted to using general dermatology-related or generic measures.[9]

The most commonly used measure of HRQoL in adolescent psoriasis is the Children's Dermatology Life Quality Index (CDLQI), intended for children 4–16 years old.[10] Previous research in skin disease has highlighted adolescent-specific HRQoL issues distinct from those of both adults and children.[3,11] The validity of using the same instrument in both 4-year-old patients and 16-year-old patients can thus be questioned.

The adult parallel to the CDLQI is the Dermatology Life Quality Index (DLQI), which targets patients 16 years and older.[12] Confusion exists over whether to use the DLQI or the CDLQI in 16-year-old patients. Further complications arise, as several studies used the CDLQI in 17-year-old patients,[9] and another study compared scores for the CDLQI and the DLQI in patients aged 16 and 17 years, revealing a difference in total score between the two instruments.[13] The authors concluded that an HRQoL measure specifically designed for adolescents was necessary.[13]

To address this issue, the Teenagers' Quality of Life (T-QoL) instrument, which targets adolescents (patients aged 12–19 years) with skin disease, was recently developed.[14] However, very few adolescents with psoriasis contributed information during the development of this instrument; only two of 32 patients during the concept elicitation phase, and eight of 203 during the psychometric testing phase, had psoriasis.[11,14] In comparison, more than half of the patients (n = 105) in the psychometric testing phase had acne. This discrepancy suggests that the T-QoL instrument may be less sensitive to HRQoL issues experienced by patients with psoriasis than to HRQoL issues experienced by patients with other skin diseases, particularly acne.

This assumption is supported by our previous qualitative study aimed at developing a conceptual model of HRQoL in adolescents (patients aged 12–17 years old) with psoriasis.[15] Although many themes identified in our interviews are covered in existing HRQoL measures, several important issues are not, such as psoriasis-related worry, what implications having fluctuating physical symptoms has for daily life and planning, and important treatment-related concerns.

To address this knowledge gap, which is relevant to both research and clinical practice, we used a combination of qualitative and quantitative methods to develop and establish the preliminary validity of the Adolescent Psoriasis Quality of Life instrument (APso-QoL), which is the first disease-specific instrument designed to measure HRQoL in adolescent psoriasis (psoriasis in patients aged 12–17 years) via two scales: one that assesses psychosocial impact (APso-PI), and one assesses impact of physical symptoms and treatment (APso-PST).

Being both age appropriate and psoriasis specific, the APso-QoL is intended to support patient–clinician communication about HRQoL-related issues of importance for each individual patient, and aid treatment planning.

Patients and methods

The development of the APso-QoL was based on recommendations from regulatory agencies and experts within patient-reported outcomes.[2,16–19] It involved five main steps (Fig. 1), which were approved by the Danish National Committees on Biomedical Research Ethics under the exempt status (ID 15007705) and followed Danish Data Protection Agency guidelines (ID 2015-57-0002).

Qualitative data analysis was supported by NVivo software (versions 11 and 12; QSR International, Melbourne, Australia). Statistical analyses were conducted with SPSS (version 25; IBM, Armonk, NY, U.S.A.) and WINSTEPS (version 4·4·0; Winsteps.com, Beaverton, OR, U.S.A).

Patients and recruitment

Eligible participants were patients who were aged 12–17 years, had been diagnosed with psoriasis and were able to understand and read Danish. In order for the study to achieve

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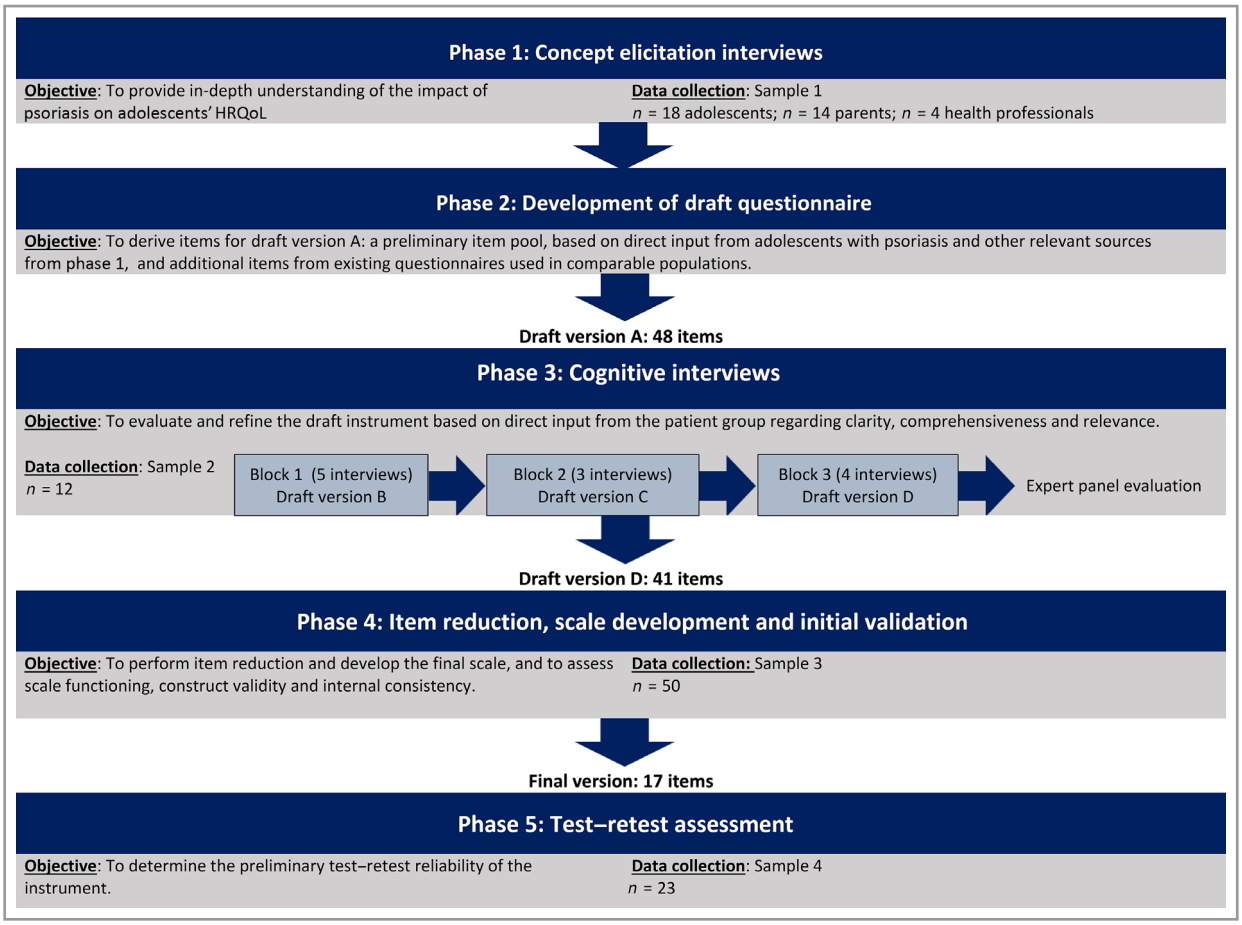

Fig 1. Overview of phases in the instrument development process. HRQoL, health-related quality of life.

maximum variation in participant demographic and clinical characteristics, participants were recruited from several sites and sources, including two dermatology hospital clinics, the Danish Psoriasis Association (via the summer school, e-mails to members, and social media), and the Psoriasis in Adolescents cohort.[20] Recruitment sources and demographic details of each sample of patients in the study are shown in Table 1.

For each participating adolescent with psoriasis, one parent/caregiver was asked to rate his/her child's HRQoL (proxy report). Healthy controls were recruited from the Danish Psoriasis Association (siblings, children of parents with psoriasis) and the Danish National Birth Cohort.[21]

Phase 1: concept elicitation interviews

HRQoL-related experiences of adolescents with psoriasis were explored using grounded theory data collection methods and inductive thematic analysis.[22–24] This phase has been described elsewhere.[15]

Phase 2: development of the draft questionnaire

Preliminary items were generated based on the concept elicitation interviews. To maximize respondent understanding, items and instructions were constructed using simple, age-appropriate language based on the adolescents' own wordings. Existing HRQoL questionnaires used in adult psoriasis or paediatric dermatology were screened to detect additional issues not identified from interviews.

Phase 3: cognitive interviews

To evaluate and refine the initial draft version, we asked the participants to complete it in front of an interviewer. To explore their understanding of each item, we asked participants to rephrase the items. Participants were also asked about the instructions and response options, as well as their ability and willingness to answer each item. All interviews were conducted by H.R. in a quiet meeting room at a hospital or university building or in the participants' home.

Interviews were conducted in blocks of three to five interviews and transcribed verbatim. After a thorough analysis of transcripts from each block (conducted by H.R.), consensus on revisions was based on group discussion (H.R., R.Z. and J.J.L.). If adolescents repeatedly used different words to describe existing items, we revised the item accordingly to improve understanding and their relevance. Selected items could be presented in a subsequent block of interviews along

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Table 1 Characteristics of the patients in the different samples

Characteristic	Sample 1[a]	Sample 2[b]	Sample 3[c]	Sample 4[d]
Sex				
Female, n	10	6	30	14
Male, n	8	6	20	9
Age (years)				
Mean ± SD	14·6 ± 1·5	14·8 ± 1·4	15·7 ± 1·3	15·7 ± 1·2
Median (IQR)	15·0 (2·0)	15·0 (2·0)	16·0 (2·0)	16·0 (2·0)
Range	12–17	12–17	12–17	13–17
Age at psoriasis onset (years)				
0–5	2	–	7	5
6–8	8	–	8	3
9–11	6	–	22	8
12–14	2	–	12	7
15–17	0	–	1	0
Disease severity				
PASI				
Mean ± SD	3·2 ± 2·8	–	–	–
Median (IQR)	2·4 (2·8)	–	–	–
saSPI-s				
Mean ± SD	–	–	1·5 ± 2·2	2·5 ± 3·3
Median (IQR)	–	–	0·75 (1·0)	1·50 (3·0)
Global question				
Mean ± SD	–	–	4·1 ± 2·4	3·3 ± 2·0
Median (IQR)	–	–	4·0 (4·0)	3·0 (3·0)
Current treatment				
Not in active treatment	0	5	14	4
Topical	13	5	26	13
Systemic	2	1	6	3
Biological	3	1	1	1
Phototherapy	0	0	1	0
CAM (e.g. acupuncture)	0	0	1	1
Do not know	0	0	1	1
Which doctor do you see for your psoriasis?				
General practice	–	–	9	4
Dermatologist (secondary referral)	–	–	10	5
Hospital clinic (tertiary referral)	–	–	16	8
Do not know	–	–	1	1
Not applicable (not in active treatment)	–	–	14	5
Recruitment setting				
Outpatient clinic	8	4	11	–
Danish Psoriasis Association	4	–	20	–
Psoriasis in Adolescents cohort[e]	6	8	19	–
From sample 3[f]	–	–	–	23

IQR, interquartile range; PASI, Psoriasis Area Severity Index, range 0–72; saSPI-s, self-assessed Simplified Psoriasis Index (severity subscale), range 0–50; CAM, complementary and alternative medicine. [a]Concept elicitation interviews (phase 1; n = 18); [b]cognitive interviews (phase 3; n = 12); [c]initial validation (phase 4; n = 50); [d]test–retest sample (phase 5; n = 23); [e]see the article by Blegvad *et al.*[20]; [f]sample 4 consisted of adolescents from sample 3 agreeing to complete a shorter version of the questionnaire package 14 ± 3 days later.

with one or more alternative items intended to be semantically identical, and participants were asked to comment on their potential similarities and/or differences. If the items were evaluated as identical, participants were asked which item they would prefer and why, and the most appropriate item was retained.

Following cognitive interviews, an expert panel (three dermatologists, a dermatology nurse and a psychologist) evaluated the revised version regarding the format, content, clarity and relevance of the questions and response categories. The experts were also invited to suggest additional items.

We also conducted cognitive interviews on our Danish translation of the disease severity indicator of the self-assessed Simplified Psoriasis Index (saSPI-s; n = 4), which is the only existing disease severity measure validated for paediatric psoriasis and only exists in Dutch.[25]

Phases 4 and 5: item reduction, scale development, initial validation and test–retest assessment

Based on the qualitative phases (phases 1 and 3), we hypothesized that HRQoL in adolescent psoriasis would be best

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captured using a three-dimensional framework focusing on (i) psychosocial impact, (ii) impact of physical symptoms and (iii) treatment-related impact, and the fact that it might be possible to operationalize the latter two as a single subscale. An electronic questionnaire package consisting of the initial version of the APso-QoL, a background survey and comparator instruments were completed by an independent cohort (sample 3; see Table 1). Using these data, we aimed to refine our instrument by reducing the number of items. We relied on the following decision rules.

Firstly, we inspected Spearman's rank inter-item correlations. Items with low correlations (< 0·20) with most other items were suspected of measuring a different construct than hypothesized and removed. Next, item pairs with strong correlations (> 0·80) were taken to indicate that one item was redundant and could be removed. Likewise, items with several moderate-to-strong inter-item correlations were removed as it was felt the content of the items might be contained in other items. The decision to retain or discard any item was determined by discussion (by H.R. and R.Z.) of the qualitative content and importance of each individual item, and a review of cognitive interview transcripts.

Secondly, we examined the response distribution of items and excluded items displaying floor or ceiling effects, as such items cannot be used to distinguish between different levels of the measured construct. Floor and ceiling effects were defined as ≥ 80% of adolescents endorsing one of the two extreme scores.

Thirdly, for each hypothesized subscale, a one-parameter Andrich Rating Scale Rasch model was fitted to items to evaluate unidimensionality and individual item fit. Items with mean-square fit values between 0·6 and 1·4 were considered acceptable.[26] Items with values outside this range were removed in a stepwise manner. Furthermore, we inspected the expected score item characteristic curves of the individual items to evaluate whether item information was appropriately captured by the model.

Fourthly, evidence of local response dependence was evaluated by calculating the $Q_{3,*}$ index.[27] Items with high residual correlations were evaluated and removed if redundancy was considered the cause of the local response dependence, as violations might lead to inflated estimates of reliability and problems with construct validity.

Rasch analyses were also used to evaluate how well the instrument distinguished between different levels of HRQoL impairment. A low person separation index (< 2, and person reliability < 0·8) implies that the instrument may not be sensitive enough to distinguish among several levels.[28] Although less than the recommended values, a person separation index of 1·5 and a reliability coefficient of 0·7 were considered the minimum values required to divide the patients in the sample into two distinct strata.[29] In addition, the item separation index was used to verify the item hierarchy. Low item separation (< 3, and item reliability < 0·9) was taken to imply that the number of patients in the sample was not large enough to confirm the item difficulty hierarchy (i.e. construct validity) of the instrument.

Construct validity

Three comparator instruments were used to evaluate the construct validity of the instrument. The CDLQI is a 10-item dermatology-specific instrument,[10] with a total score ranging from 0 to 30, and is the most commonly used measure of HRQoL in paediatric psoriasis. Furthermore, we used validated Danish versions of the Pediatric Quality of Life Inventory (PedsQL) and the World Health Organization (Five) Well-being Index (WHO-5) to assess generic HRQoL and mental wellbeing, respectively.[30,31] We hypothesized that the APso-QoL would correlate most strongly with the CDLQI, less so with the PedsQL and least with the WHO-5.

As indicators of disease severity, we used the saSPI-s and a global question. The global question asked adolescents to evaluate the overall severity of their psoriasis during the last 4 weeks on a 10-point visual analogue scale. Based on previous research in adult psoriasis,[32] we hypothesized that there would be a small-to-medium correlation between the APso-QoL and self-assessed disease severity.

Agreement between adolescent self-reports and parent proxy ratings was assessed with the intraclass correlation coefficient (ICC; two-way mixed effects, absolute agreement, single measure).[33] An ICC of ≤ 0·41 was considered to indicate poor-to-fair agreement, 0·41–0·60 was considered to indicate moderate agreement, 0·61–0·80 was considered to indicate good agreement, and 0·81–1·00 was considered to indicate excellent agreement. The proxy version was constructed purely for validation purposes and was created as a parallel version of the APso-QoL in which words such as 'I' and 'my psoriasis' were replaced with 'my child' and 'my child's psoriasis', respectively. Based on the results of previous studies,[33,34] we hypothesized that there would be moderate agreement between self- and proxy reports, with higher agreement for the more easily observable APso-PST than for the APso-PI.

Discriminative validity assesses the ability of an instrument to distinguish between groups differing according to a certain factor. We used a Mann–Whitney U-test to evaluate whether the APso-QoL would be able to distinguish between adolescents with psoriasis and those without. In the nonpsoriasis version of the questionnaire, the word 'psoriasis' was replaced with 'my skin'.

Reliability

Internal consistencies of the final instrument were assessed with Cronbach's α coefficient. Values above 0·70 were considered acceptable.[35]

Test–retest reliabilities were estimated for each subscale, and the total score was based on the ICC for agreement. Values > 0·7 are generally considered acceptable,[35] and correlations ≥ 0·85 indicate suitability for use in clinical trials.[36]

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Results

Concept elicitation interviews (phase 1)

Analysis of 36 interviews (18 adolescents with psoriasis, 14 parents of adolescents with psoriasis, and four health professionals) resulted in a conceptual framework consisting of six main themes (physical symptoms, feeling different, psoriasis-related worry about the future, increased attention, attempts to conceal skin, and treatment-related frustration and worry) (Table 1). For further details, see Randa *et al.*[15]

Development of the draft questionnaire (phase 2)

A preliminary 48-item instrument was constructed. The recall period was set to 1 month. All items were answered on a five-point categorical response scale ranging from 'not at all' to 'very much'.

Cognitive interviews (phase 3)

Three blocks of cognitive interviews conducted between March and June, 2017, were necessary to achieve saturation, that is, so that all adolescents found items, response options and instructions to be straightforward, easy to understand and relevant. Interviews lasted 31–103 min (median 55 min). The characteristics of the 12 adolescent patients who participated are described in Table 1.

During this phase, one new item was added, seven items underwent minor language revisions, four items were merged into a single item, and five items were discarded. For example, one item ('I have to be especially careful to prevent my psoriasis from bleeding') was omitted, as it was raised only briefly by a single participant during concept elicitation, and none of the adolescents participating in the cognitive interviews found it relevant. Overall, this phase resulted in a reduction from 48 items to 41 items. In addition, the recall period was changed to 'within the last four weeks', as participants interpreted 'within the last month' in various ways. Finally, four professionals with expertise in paediatric psoriasis and a psychologist reviewed and approved the 41-item questionnaire.

Item reduction, scale development and initial validation (phases 4 and 5)

Data used for item reduction, scale development and initial validation were collected between January 2018 and February 2019. Table 1 shows the characteristics of the patients in the sample (n = 50). Inter-item correlations confirmed the hypothesized framework and showed that HRQoL could be reflected in two preliminary scales: (i) psychosocial impact (APso-PI; 33 items) and (ii) impact of physical symptoms and treatment (APso-PST; seven items). One item ('I have quarrels with my parents regarding my psoriasis or my psoriasis treatment') was discarded, owing to the fact that it had low correlations with the remaining items.

Several examples of item groups with moderate-to-high inter-item correlations were identified. For example, the three items 'I think it is embarrassing to have psoriasis', 'I worry about what other people might think about me when seeing my psoriasis', and 'I feel uncomfortable when people are looking at my psoriasis' had high inter-item correlations (> 0·80), as well as several moderate-to-high correlations with other items. Omitting the second and third of these resulted in the most optimal solution, as the first item showed fewer moderate-to-high inter-item correlations with the other items. This step resulted in nine items from the APso-PI being discarded. Four additional items from the APso-PI were discarded due to floor effects. No items from the APso-PST were omitted during these steps.

Based on independent Rasch analyses, seven items from the APso-PI (out of 20 items) and two items from the APso-PST (out of seven items) were discarded due to misfit. Calculation of the $Q_{3,*}$ revealed strong evidence of local dependence for the APso-PI ($Q_{3,*}$ = 0·63). For the APso-PST subscale, there was less evidence ($Q_{3,*}$ = 0·25). After inspection of item content and location, this led to the removal of one item in the APso-PI. The APso-PST subscale was retained. No items displayed unexpected distributions according to their expected score item characteristic curves.

Following item reduction, the final version of the APso-QoL consisted of 17 items across two subscales: APso-PI (12 items) and APso-PST (five items; Appendix S1, Figs S1 and S2; see Supporting Information). Both subscales showed adequate fit to the model (mean-square range 0·62–1·36 and 0·61–1·25, respectively) and acceptable item separation (4·00 and item reliability 0·94, and 3·65 and item reliability 0·95). There was some evidence of local response dependence for the APso-PI [three item pairs (numbers 2 and 10, 15 and 17, and 9 and 6) had $Q_{3,*}$ values just above 0·3; results not shown].

While the value of the person separation index was acceptable for the APso-PI (2·53, with person reliability 0·86), the results for the APso-PST (1·55, with person reliability 0·71) suggest that adding more items may result in better discrimination. Item difficulty ranged from −1·38 to 1·54 for the APso-PI and from −0·99 to 1·44 for the APso-PST (Figs S1 and S2; see Supporting Information). Scores on the APso-PI ranged from zero to 48, and those on the APso-PST ranged from zero to 20, with higher scores representing greater impairment.

Construct validity

The APso-QoL total score was most strongly correlated with the CLDQI (r = 0·87), less so with the PedsQL (r = 0·62) and least with the WHO-5 (r = 0·50). The APso-QoL correlated moderately with the saSPI (r = 0·61) and the global question (r = 0·56). Furthermore, a Mann–Whitney U-test showed that the APso-QoL (item 15 was omitted from this analysis, as no healthy control parallel version could be created) was able to distinguish adolescents with psoriasis (n = 50, mean age 15·7, 60% female, median APso-QoL total score 14·5, interquartile

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range 18·3) from those without psoriasis (n = 38, mean age 16·1, 61% female, median APso-QoL total score 4·0, interquartile range 9·0; $P < 0·001$ for all).

Parents and adolescents (dyad n = 19; all parents were mothers) showed moderate agreement on both subscales (APso-PI ICC = 0·49 and APso-PST ICC = 0·57) as well as for the total score (total ICC = 0·49).

Reliability

Internal consistency was high for both the APso-QoL total score ($\alpha = 0·95$) and the subscales APso-PI ($\alpha = 0·94$) and APso-PST ($\alpha = 0·81$).

Test–retest coefficients of the total score (ICC = 0·96), APso-PI (ICC = 0·97), and APso-PST (ICC= 0·89) indicated acceptable reliability and stability over time.

Discussion

This study presents the development and initial validation of the APso-QoL, the first age- and psoriasis-specific instrument for measuring HRQoL in adolescents (patients aged 12–17 years) with psoriasis. Using state-of-the-art methods,[2,17,18,22] our initial validation study found the APso-QoL to be psychometrically sound and to have good preliminary support for construct validity. Furthermore, the test–retest reliability of our instrument was good. Due to their nonuniform nature, the two subscales should ideally be scored separately. Yet, it has been suggested that using a combined summary score may be acceptable for instruments of similar structure, such as the T-QoL and the Skindex-Teen,[14,37] and thus may be justified for the APso-QoL as well.

The 17-item APso-QoL includes a comprehensive set of items directly reflecting views and experiences of adolescents with psoriasis in ways not previously captured in a single HRQoL instrument. For example, one of the most prevalent HRQoL issues mentioned by adolescents in our qualitative phases was receiving questions and comments from others regarding their psoriasis.[15] In general, adolescents found that most comments and questions arose from ignorance rather than harmful intentions, and only very few adolescents in our samples reported being teased or bullied. This issue is not covered in the skin-specific T-QoL instrument. While CDLQI item 8 includes experiencing troubles from 'people asking questions', the instrument does not cover other important issues. For example, the CDLQI employs a narrow perspective on social relations by focusing on existing friendships only. An important qualitative finding from our research was that, while most adolescents felt at ease showing their psoriasis to friends and family, many reported having great difficulties displaying their psoriasis to people from outside their closest social network and that this negatively affected their ability to form new friendships and feel at ease in larger groups of people.[15]

For a scale to be appropriately targeted towards specific patient groups, responses should show adequate variability in a range that is appropriate to its intended use.[16] For this reason, we excluded items where ≥ 80% of adolescents endorsed the lowest response category. In comparison, six out of 10 CDLQI items violated this criterion and hence had poor discriminative value in our sample. This finding may reflect differences in recruitment strategies used in the validation studies. While the CDLQI recruited patients from a specialized paediatric dermatology setting, we aimed at including a broader section of patients. For example, 28% of the participants in our study were not in active treatment.

When the clinical disease severity (PASI and saSPI-s) and HRQoL data for our samples are compared with published data, the differences are striking. To illustrate, a recent systematic review and meta-analysis based on 17 studies of 1185 paediatric patients with psoriasis, who had mainly been recruited from dermatology clinics, revealed a mean CDLQI score of 7·7 (with higher scores indicating greater impairment of HRQoL) and a mean PedsQL score of 74·5 (with higher scores indicating better HRQoL).[9] In comparison, the median scores in our validation sample were 2 for CDLQI and 81 for PedsQL. As our sample is less affected, our instrument may be more sensitive for detecting subtle HRQoL issues experienced by adolescents in the general population, making it relevant to individuals seen not only in specialized dermatology hospitals but also in primary care, where most paediatric patients are managed. Future studies could provide more information about the comprehensiveness of the APso-QoL in more severely affected patients.

Some limitations should be mentioned. Firstly, while we aimed at recruiting more patients than we did for the validation, data collection proved to be more challenging than expected, and time limits forced us to terminate data collection before reaching our goal. The difficulty of recruiting adolescent patients with psoriasis is reflected in previous studies on paediatric psoriasis, with a systematic review revealing that only eight of the 17 available studies were based on samples of more than 50 patients.[9] Furthermore, in validation studies of CDLQI, Skindex-Teen and T-QoL, patients with psoriasis only accounted for 10·7% or less of the total number of patients with skin disease.[10,14,37]

The small sample size in our validation study influenced our analytical choices, for example, we did not evaluate response category functioning and differential item functioning,[38,39] which may limit the generalizability of our results. Although the Rasch model used for validation purposes has been shown to produce relatively robust item calibrations even with small samples,[40] this view has also been challenged,[41] and it is possible that validation studies with larger samples could show evidence of item misfit or local response dependence. The present 17-item APso-QoL should therefore be considered preliminary.

Yet, Rasch analyses, in combination with other techniques, allowed us to reduce our item pool into a 17-item instrument that confirmed our hypotheses regarding dimensionality and showed promising psychometric properties. Due to the robust methods used during the qualitative phases that ensured strong

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face and content validity,[17,18,22] we feel confident that the APso-QoL in its present form will be highly informative when used in clinical practice. To illustrate, scores on the different items might alert clinicians regarding issues of importance for each individual patient, facilitating patient–physician communication about issues that otherwise could be left undetected. The APso-QoL can also be used as a screening instrument to identify patients who might need referral to additional services such as a psychologist or peer support groups.

Although the ages of the participants during qualitative phases were evenly distributed, most participants in our validation study were older adolescents, and only a few 12- and 13-year-old patients participated. Further validation of the APso-QoL in independent samples is thus essential, especially in younger adolescents.

For the APso-QoL to be used in clinical trials, future studies should evaluate additional psychometric properties. These include differential item functioning, response category functioning, responsiveness, interpretability and administrative burden. Future studies should also test the validity of using a combined APso-QoL summary score. As the APso-QoL was developed and preliminarily validated in Danish-speaking patients, future studies should also examine its cross-cultural validity.

We were unable to confirm the diagnosis of psoriasis in the subgroup of participants recruited from the Danish Psoriasis Association. However, participants in a psoriasis-specific patient organization are likely to have the disease, and all adolescents confirmed that they had received the diagnosis from a physician. Furthermore, self-selection bias may have limited the representativeness of our samples, especially in sample 3, as many of these adolescents were invited to participate via e-mail and social media.

In conclusion, our results indicate the promising psychometric properties of the APso-QoL, the first age-appropriate and disease-specific HRQoL instrument for use in adolescents (patients aged 12–17 years old) with psoriasis. Further testing in independent samples of larger size is needed, and additional attributes of the APso-QoL should be examined. However, in both clinical and nonclinical settings, the APso-QoL could be a valuable and sensitive tool for evaluating HRQoL impairment in adolescents with psoriasis.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website:

Appendix 1 The Adolescent Psoriasis Quality of Life instrument.

Fig S1. Person-item map of the Adolescent Psoriasis Quality of Life instrument scale that assesses psychosocial impact.

Fig S2. Person-item map of the Adolescent Psoriasis Quality of Life instrument scale that assesses impact of physical symptoms and treatment.

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