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Is the patient-perceived impact of psoriatic arthritis a global concept? An international study in 13 Arab countries (TACTIC study)

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1 **Is the patient-perceived impact of Psoriatic Arthritis a Global Concept?**
2 **Validation of the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire**
3 **in Arabic, an International Study of 554 Patients**

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36

37

38 Introduction

39 Psoriatic arthritis (PsA) is a chronic inflammatory disease that impacts both the skin and joints
40 [1]. It affects about 0.1 to 1% of the global population, with no gender distinction, and typically
41 manifests between the ages of 30 and 50 [2]. PsA presents a highly heterogeneous clinical
42 profile, including peripheral arthritis, axial involvement, dactylitis, enthesitis, and skin and nail
43 involvement [3]. The majority of patients meet the CIASSification Criteria for Psoriatic Arthritis
44 (CASPAR) [4].

45 This disease has a significant multidimensional impact on patients, affecting the physical,
46 functional, psychological, and social aspects of their lives [5]. In severe cases, PsA can lead to
47 progressive joint damage, bone erosions, and disability. Its burden is further increased by
48 comorbidities such as cardiovascular problems, metabolic syndrome, liver disease, osteoporosis,
49 and depression [2,6,7].

50 Despite its prevalence, PsA is poorly understood and under-recognized in the Arab world, with a
51 lack of studies assessing the physical and psychosocial impact of this disease in the region [8].
52 Given that Arabic is the sixth most spoken language globally [9], with approximately 420
53 million speakers worldwide, there is a substantial need for tools to accurately evaluate the impact
54 of PsA and provide equitable access to appropriate care for Arabic-speaking PsA patients in
55 Arab countries and beyond.

56 Standardized outcome measures are increasingly used to assess PsA activity and its impact on
57 patients [10,11]. While these tools are valuable for evaluating treatment efficacy and guiding
58 therapeutic decisions [12], many predominantly reflect healthcare professionals' assessments. To
59 adequately assess patients' quality of life, incorporating their perspectives through Patient-
60 Reported Outcome Measures (PROMs) is crucial. PROMs collect information on symptoms,
61 functional status, and health-related quality of life [7], whether in a generic form for cross-
62 disease comparisons or in disease-specific forms like the Psoriatic Arthritis Impact of Disease
63 (PsAID).

64 The PsAID questionnaire, developed in 2014 in Europe under the aegis of the European Alliance
65 of Associations for Rheumatology (EULAR), is recommended by the Outcome Measures for
66 Arthritis Clinical Trials (OMERACT) and the Group for Research and Assessment of Psoriasis
67 and Psoriatic Arthritis (GRAPPA) [13]. It aims to evaluate the impact of PsA from the patients'
68 perspective and consists of 12 questions (PsAID-12) assessing the physical, psychological, and
69 social aspects of PsA's impact based on patient priorities. The population included in its
70 development was mainly from Europe. The PsAID-12 has shown excellent psychometric
71 properties, such as internal consistency, construct validity, and reproducibility [13–16].
72 However, most assessments were performed in Western cultures. To be usable in different
73 contexts, translations and cross-cultural validations are necessary. Moreover, as beliefs and
74 societal factors significantly influence patients' perceptions and treatment preferences,
75 evaluating the PsAID-12's performance in the Arab world offers insights into cultural nuances
76 influencing patients and demonstrates the questionnaire's validity and reliability across diverse
77 populations [17,18].

78 Therefore, this study aimed to TranslAte, CulTurally adapt, and validate the PsAID-12
79 questionnaire in ArabIC (TACTIC Study). It also aimed to investigate its psychometric
80 properties, including feasibility, internal consistency, construct validity, and test-retest reliability.
81 Additionally, the study sought to identify the patients' and disease characteristics associated with
82 high PsAID-12 scores in Arab countries, for comparison purposes with other countries [14–16].
83 This comprehensive evaluation promotes healthcare equity by providing standardized tools
84 suitable for varied cultural contexts, ensuring accurate measurement of PsA' multidimensional
85 impact on patients.

86 Methods

87 The study comprised two sequential phases. In the first phase, the PsAID was translated,
88 culturally adapted, and tested on a small sample of PsA patients from four Arab countries, using
89 a cross-sectional design, in August 2022. Subsequently, the Arabic PsAID was validated in a
90 larger patient cohort, with the examination of its psychometric properties and identification of
91 factors associated with high PsAID scores. The validation phase comprised a cross-sectional
92 section with a longitudinal component for test-retest reliability assessment and was conducted
93 between September and December 2022. The study adhered to the standards outlined in the
94 COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN)
95 checklist [19].

96 Translation and cultural adaptation

97 The translation and cross-cultural adaptation of the PsAID questionnaire into Arabic followed
98 the World Health Organization (WHO) guidelines for instrument translation and adaptation [20].
99 This process consisted of four main steps:

- 100 1- Direct translation: Two independent translators, one familiar with the subject matter and
101 the other not, translated the questionnaire from English to Arabic. A steering committee
102 of four rheumatologists and a medical student synthesized these translations through a
103 reconciliation process.
- 104 2- Backward translation: The translated Arabic version was backward translated into
105 English, and validated by the committee for accuracy.
- 106 3- Pilot testing and cognitive debriefing: Fifteen PsA patients from four Arab countries
107 representing different Arab regions (Iraq, Lebanon, Morocco, and Saudi Arabia)
108 participated in pilot testing. Their understanding of the questionnaire items was assessed,
109 along with the evaluation of feasibility and time needed to complete the questionnaire.
110 The PsAID questionnaire's feasibility was assessed using a 1 to 10 analogue visual scale
111 (with 10 indicating the greatest difficulty). Additionally, the time for PsAID completion
112 was recorded.
113 Complex or unclear questions were identified during this stage and modified accordingly.
- 114 4- Final validation: The PsAID questionnaire underwent further validation on a larger PsA
115 patient sample (validation phase described below).

116 Study design and inclusion criteria

117 The validation phase constituted a multicentric multinational cross-sectional study with a
118 longitudinal component for test-retest reliability assessment. Data collection was conducted in
119 2022 by the Arab League of Associations of Rheumatology (ArLAR) research group (ARCH) in
120 20 centers in 13 countries: Algeria, Bahrain, Egypt, Iraq, Jordan, Lebanon, Libya, Morocco,
121 Palestine, Saudi Arabia, Syria, Tunisia, and the United Arab Emirates (UAE).

122 Consecutive adult patients diagnosed with PsA, fulfilling the CASPAR criteria [4], were
123 included. Participants were required to be literate and willing to participate. Individuals under the
124 age of 18 years, unable to provide informed consent, whose participation could be affected by
125 neurological disorders or other severe medical conditions, or presenting non-PsA related
126 inflammatory joint diseases were excluded from the study.

127 Data collection

128 Patients filled out the Arabic PsAID questionnaire using an online form, with a question
129 assessing their priorities among the PsAID's 12 domains. They also completed the Patient Global
130 Assessment (PGA) [21] for PsA and psoriasis activity, Health Assessment Questionnaire (HAQ)
131 [22] for evaluation of functional status, Patient Health Questionnaire (PHQ-4) [23,24] for
132 depression and anxiety screening, and Fibromyalgia Screening Tool (FiRST) [25,26], available
133 in both English and validated Arabic versions.

134 Rheumatologists collected demographic and disease characteristics, and completed the Physician
135 Global Assessment (PhGA) for PsA and psoriasis activity, subjective assessment of the presence
136 of fibromyalgia, as well as 66-68 joint counts of tender and swollen joints to allow calculation of
137 the Disease Activity in Psoriatic Arthritis (DAPSA) score [27].

138 A study conducted by Salaffi et al. [28] demonstrated a similar performance between touch-
139 screen and paper versions of the PsAID questionnaire, with ICC ranging from 0.80 to 0.96.
140 Notably, the electronic version was preferred and took less time to fill out and analyze.

141 We chose to use online forms as they are easy to create and access, time-saving, and offer
142 standardized and automated responses. Strict measures were taken to ensure patients'
143 confidentiality and security of data.

144 Psychometric properties of the PsAID questionnaire

145 In addition to evaluating feasibility and time for completion, our study assessed the floor and
146 ceiling effects, internal consistency, and construct validity (correlation between the PsAID and
147 the DAPSA, FiRST, PGA, and HAQ).

148 Test-retest reliability also was examined by re-administering the PsAID after a one-week
149 interval.

150 Elements associated with high PsAID scores

151 The PsAID score was dichotomized using a threshold of four [13], where scores less than or
152 equal to four were considered acceptable, and scores greater than four were considered high.
153 Factors associated with a high PsAID-12 score were then analyzed.

154 Statistical analysis

155 The study aimed to include at least 500 patients (with a minimum of 20 patients from each
156 country to ensure a good representativity). This sample size calculation was justified by the
157 general guidelines of having ten times the number of variables in descriptive questionnaires and
158 also by considering previous similar studies [29]. A power calculation showed that a sample size
159 of 480 patients would allow to detect a correlation of 0.60 (expected with PGA) with a power of
160 95% for each of the 12 PsAID items.

161 The PsAID-12 addresses 12 domains: pain, fatigue, skin problems, work and/or leisure activities,
162 functional capacity, discomfort, sleep disturbance, coping, anxiety, fear and uncertainty,
163 embarrassment and/or shame, social participation, and depression. The total PsAID score was
164 computed. In line with the initial PsAID approach [13], missing data for a single questionnaire
165 item was substituted by the average score of the remaining 11 items. However, if more than two
166 elements were missing, the score was considered as missing. Floor and ceiling effects
167 represented the proportion of patients with a minimum (0/10) or maximum (10/10) score,
168 respectively, among all patients who completed the questionnaire. The internal consistency was
169 assessed using Cronbach's α . Construct validity was determined by Spearman's correlation
170 coefficient, hypothesizing a positive correlation between the PsAID and other measures such as
171 the PGA of pain, PGA of PsA activity, DAPSA, HAQ, PHQ4, FiRST, and PGA of psoriasis
172 activity. Test-retest reliability was analyzed using the intraclass correlation coefficient (ICC) for

173 continuous values and the Cohen's kappa coefficient for dichotomous values. These properties
174 were compared descriptively to those of the original PsAID.

175 Factors associated with a high PsAID-12 score (dependent variable) were first explored using
176 bivariate analyses which included the following independent variables: age, gender, marital
177 status, education, profession, country, major comorbidities (obesity, hypertension, current
178 smoking, dyslipidemia, diabetes, known history of depression, cardiovascular events, cancer
179 history), family history of psoriasis, PsA, axial spondyloarthritis, PsA disease duration, PsA
180 diagnostic delay, psoriasis duration, skin psoriasis, nail psoriasis, time gap between psoriasis and
181 PsA, PsA manifestations (polyarthritis, oligoarthritis, monoarthritis, enthesitis, dactylitis, axial
182 involvement), extra-musculoskeletal manifestations (uveitis, Crohn's disease, ulcerative colitis),
183 HLA-B27 status, C-Reactive Protein (CRP), Erythrocyte Sedimentation Rate (ESR), erosions on
184 X-rays, ever or current treatments (conventional synthetic (csDMARDs), biological
185 (bDMARDs), and targeted synthetic DMARDs (tsDMARDs), PGA for PsA pain, for PsA
186 activity, for psoriasis activity, PhGA for PsA activity and for psoriasis activity, DAPSA , HAQ,
187 PhQ4 and FiRST scores. The stepwise regression methodology was guided by both clinical and
188 statistical relevance to ascertain the most robust regression models. Variables that showed
189 significant associations with a high PsAID score in bivariate analyses ($p < 0.01$), and exhibited
190 correlations less than 0.7 between two continuous scores, while also not being part of a PsAID
191 domain (PGA) or a physician-related measure (PhGA), were included in a multivariable logistic
192 regression.

193 There was no imputation of missing data. Statistical analyses were performed using SPSS
194 version 25.0, with a significance threshold (p-value) of less than 0.05.

195 Ethical considerations and data protection

196 This project received approval from the Ethics Committees of Hôtel-Dieu de France hospital in
197 Beirut, Lebanon (Code Tfem/2022'/1) and the Institutional Review Boards of participating
198 countries, following their respective local requirements. Permission was obtained from the
199 authors of the original PsAID-12 questionnaire, which is not copyrighted.

200 Participants provided their consent before inclusion in the study, in accordance with the
201 standards of the Research Ethics Committee. Stringent measures were implemented to ensure
202 confidentiality, including the use of trial numbers/codes instead of patient names on all trial
203 documents, except for the signed informed consent forms.

204 Results

205 Translation and initial validation of the PsAID in Arabic

206 After the initial consensual translation of the PsAID, cognitive debriefing led to preliminary
207 validation. This process involved 15 PsA patients from four rheumatology centers in four
208 different Arab countries (Iraq, Lebanon, Morocco, and Saudi Arabia). Among these patients, 11
209 were women, median age was 51 years, and disease duration varied from 0 to 32 years.

210 Participants found completing the questionnaire relatively easy, with a median difficulty rating
211 of 1.00 (on a scale of 1 to 10), and ratings ranging from 1.00 to 6.00. The average time to
212 complete the questionnaire was 4 minutes and 9 seconds (SD 94 seconds).

213 Cognitive debriefing prompted modifications for clarity and cultural alignment, which included:

- 214 • Revising general phrasing to enhance politeness, such as changing “We want you to indicate”
215 to “Kindly indicate”.
- 216 • Using a male/female grammar formulation for all questions, as genders are addressed
217 distinctly in Arabic.
- 218 • Offering practical examples for question 4 (leisure activities) to make it more understandable
219 to the patients, such as reading, playing a musical instrument, engaging in physical exercise,
220 going on a trip or picnic in nature, etc.
- 221 • Making minor rephrasing in questions 6 and 9, adding a specification in questions 5 and 6,
222 and eliminating redundancy in questions 7 and 8.

223 The modifications and final Arabic version are presented in Appendix 1.

224 Some challenges were also noted during this phase:

- 225 • Religious context: Some patients struggled with expressing uncertainty about the future due
226 to their faith in God, potentially influencing the scores for question 9 about anxiety, fear, and
227 uncertainty.
- 228 • Symptoms attribution to PsA: Some patients faced challenges distinguishing whether their
229 feelings were attributed to PsA or other factors such as socio-economic status, personal
230 circumstances, or co-morbidities, potentially affecting the scores for sleep disturbance and
231 depression.

232 Validation study

233 Overall, 589 patients were included in the validation study between September and December
234 2022. After eliminating 8 duplicate entries and 27 cases with insufficient data, a total of 554
235 patients were analyzed.

236

237 Population characteristics

238 Participants were primarily from Iraq (n=154, 27.8%) and Egypt (n=54, 9.7%), with more than
239 half being females (59.0%) and a mean age of 45.5 years (SD 13.2) (Table 1). Compared to
240 patients from other Arab countries, Iraqi patients had a similar gender distribution (56.0% in Iraq
241 compared to 60.2% in other countries, $p=0.380$) and university education level (42.7% versus
242 51.2%, $p=0.077$), while having a slightly lower mean age (43.0 years versus 46.4 years,
243 $p=0.007$).

244 Patients reported a high prevalence of cutaneous psoriasis (91.7%) and a significant proportion
245 presented nail psoriasis (44.7%). During the course of their disease, 53.8% and 31.9% of patients
246 experienced polyarthritis and oligoarthritis, respectively. Additionally, 5.2% of patients had
247 uveitis and 4.0% were diagnosed with Inflammatory Bowel Disease (IBD). The Human
248 Leucocyte Antigen-B27 (HLA-B27) status remained unknown for 67.0% of patients, with a
249 positivity in 35 (17.1%) of tested patients. Among these 35 HLA-B27 positive patients, 21
250 (60.0%) had axial involvement. Elevated CRP levels were observed in 42.2% of cases, and
251 31.9% of patients presented radiological bone erosions.

252

253 PsAID score distribution

254 The mean PsAID score was 3.86 (SD 2.33). Based on the 4.00 cut-off limit, 245 patients (44.2%)
255 were considered to have a high PsAID score. There was no statistically significant difference
256 between the PsAID score in Iraqi patients and other Arab countries (3.99 versus 3.80,
257 respectively, $p=0.399$).

258 The mean score (SD) was calculated for each of the 12 PsAID questions, and illustrated in
259 Supplementary Table 1. The two higher scores were for pain which scored 4.66 (SD 2.63), and
260 fatigue, with a mean score of 4.50 (SD 2.76).

261

262 Psychometric properties

263 *Floor and ceiling effects*

264 In the validation study, 12 out of 544 patients scored 0/10 on PsAID, while no patient scored
265 10/10, indicating a floor effect of 2% and a ceiling effect of 0%.

266 *Ranking of PsAID domains*

267 Pain, fatigue, and skin problems were considered the top-ranked domains, with 151 (27.8%), 23
268 (4.2%), and 21 (3.9%) out of 544 patients ranking them as top priority, respectively (Figure 1).

269 *Internal consistency*

270 The analysis of the 12 PsAID questions revealed an excellent level of internal consistency with a
271 Cronbach's α coefficient of 0.95.

272 Furthermore, the item-total correlation, which is the correlation of PsAID items to the total
273 PsAID score, demonstrated high values (>0.8 for all). However, the correlation was slightly
274 lower for skin problems, with a score of 0.778.

275 When we conducted an analysis excluding one PsAID item at a time, the Cronbach's alpha for
276 the remaining 11 PsAID subscales remained substantial and consistent, with values ranging from
277 0.94 to 0.96 (Supplementary Table 1).

278 *Construct validity*

279 The correlation coefficients with other measures were moderate to strong, with Spearman's
280 correlation coefficients ranging from 0.63 to 0.78, with the lowest values for PGA psoriasis
281 activity and the highest for PGA pain (Table 2). The positive correlation between PsAID and
282 both DAPSA and PHQ4 categories is presented in Figure 2.

283 *Test-retest reliability*

284 To assess reliability, 138 patients were administered the PsAID questionnaire a second time after
285 a week. Test-rest reliability was excellent, with an ICC of 0.90 (95% CI 0.86-0.93), and
286 substantial agreement between the first and second measurements (Cohen's kappa coefficient of
287 0.80).

288

289 Factors associated with high PsAID scores

290 Variables that exhibited statistical significance in the bivariate analysis ($p < 0.01$) comprised
291 female gender, university education, axial involvement, elevated CRP levels, and high scores on
292 DAPSA, HAQ, PHQ4, and FiRST (Table 1). The correlation coefficient among the continuous
293 scores of DAPSA, HAQ, PHQ4, and FiRST was observed to be less than 0.6. Variables that
294 were excluded from the model were ESR (due to its correlation with CRP), known depression
295 (correlated with PHQ4), Patient Global Assessment (as it is part of the PsAID domains), and
296 Physician Global Assessment (a physician-related measure). DAPSA was incorporated into the
297 model using a 5-point interval score.

298 In the multivariable analysis, higher PsAID scores were associated with elevated HAQ (odds
299 ratio, OR 3.15, 95% CI 2.03-4.89), PHQ4 (OR 1.56, 95% CI 1.35-1.81), positive chronic pain
300 syndrome screening using the FiRST questionnaire (OR 1.31, 95% CI 1.12-1.53), and increased
301 DAPSA scores (OR 1.29, 95% CI 1.13-1.47) (Table 3).

302 Discussion

303 This study introduced a validated Arabic version of the PsAID questionnaire, addressing the gap
304 and providing valuable insights into the impact of PsA on patients' lives in Arab countries. An
305 overview of the study findings can be found in Appendix 2. Our findings underscore the
306 significant effects of PsA across various domains, with pain and fatigue being particularly
307 impactful. The primary drivers of high disease impact were disability, disease activity,
308 widespread pain, and depression, aligning with findings from other studies conducted in different
309 cultural contexts [16]. These results emphasize the importance of assessing the patient's
310 perspective in PsA management and demonstrate the applicability of the PsAID questionnaire
311 among Arabic-speaking patients [9].

312 Our study's strength lies in its good representativeness, encompassing 554 patients from 13 Arab
313 countries with diverse Arabic dialects, enhancing the generalizability and reliability of our
314 findings. Although spoken Arabic varies across regions, written Arabic, also known as Modern
315 Standard Arabic, remains constant and universal. This ensures the applicability of the Arabic
316 PsAID across all Arabic-speaking countries in the world. The demographic characteristics of our
317 population align with existing literature, with an average age of 45.5 years, which is consistent
318 with the typical age range for PsA patients in studies (40-50 years) [13,16]. The relatively high
319 proportion of females (59%) in our study may reflect increased female participation in Arab
320 research studies [30]. The notable percentage of retired or unemployed patients (46.4%)
321 highlights the significant impact of PsA on functionality and professional life [31]. The
322 prevalence of obesity was 35.1%, aligning with previous findings [16]. The HLA-B27 status was
323 mostly unknown, reflecting its lesser significance in PsA compared to axial spondyloarthritis
324 [32]. When available, the prevalence of HLA-B27 in our study was similar to international
325 studies, i.e. 17.1% vs 18.2% in the Peripheral involvement in Spondyloarthritis (PerSpA) study,
326 despite previously lower reported rates in Arab countries [33,34].

327 One limitation of the study is the overrepresentation of patients from Iraq, attributable to the
328 larger number of investigators and participating centers from this country (three centers).
329 However, we did not observe a country bias, as the demographic characteristics and PsAID
330 scores of the Iraqi patients were similar to those from the other Arab countries. Another
331 limitation is that the study did not explicitly require disease stability for the reliability
332 assessment, which could potentially impact reproducibility. However, patients did not undergo
333 any treatment changes during this period, and a one-week interval between measurements
334 typically ensures disease stability. Furthermore, the study's cross-sectional design and time

335 constraints precluded the evaluation of discriminative ability and sensitivity to change, which
336 was also the case in the Brazilian study [16]. Sensitivity change assessment, which evaluates
337 disease evolution two to four months after a treatment change, is not usual in the initial stages of
338 cross-cultural validation, and was not a main focus in our paper.

339 The Arabic version of PsAID showed excellent psychometric properties and could be completed
340 rapidly within 5 minutes. Notably, floor and ceiling effects were minimal at 2% and 0%,
341 respectively, compared to 1% and 0% in the original PsAID study [13]. Internal consistency
342 showed excellent performance with a Cronbach's α coefficient of 0.95, slightly surpassing the
343 reported value of 0.93 in the literature [13,15,16]. All items in the PsAID were found to have a
344 significant correlation with the total PsAID score, but the correlation was slightly lower for skin
345 problems with a score of 0.778. These findings align with the Turkish study of Güler et al. [35],
346 which reported weaker correlations between the overall PsAID and skin assessment tools such as
347 the Psoriasis Area Severity Index (PASI) and the Dermatology Life Quality Index (DLQI). In
348 terms of internal consistency, measured by Cronbach's alpha, the PsAID subscales showed
349 excellent results ranging from 0.94 to 0.96. This is notably higher than the range of 0.76 to 0.90
350 observed in the Turkish PsAID. Moreover, the Cronbach's alpha was consistent for PsAID
351 subscales, unlike the Turkish study where the subscale for depression was found to be the least
352 reliable as the Cronbach's alpha markedly increased when this item was removed.

353 The questionnaire effectively mirrored the priorities of Arab patients, with pain emerging as the
354 top concern, followed by fatigue and skin problems. These findings underscore the need for
355 greater emphasis on pain and fatigue in PsA questionnaires, as these core domains hold
356 significant importance for patients and are often underestimated by physicians [12]. The PsAID
357 showed moderate to strong correlations with other assessment tools, with coefficients ranging
358 from 0.63 to 0.78, consistent with the findings of the original study [13] (range from 0.55 to
359 0.84). Correlations were higher with PGA pain and lower in psoriasis activity, suggesting that
360 rheumatologists are more at ease evaluating rheumatic conditions compared to skin involvement.
361 Reproducibility was excellent, with an ICC coefficient of 0.90 (95% CI 0.86-0.93), compared to
362 an ICC of 0.95 (95% CI 0.92-0.96) in the original PsAID and a Cohen's kappa coefficient of
363 0.80, showing very good agreement between two measurements. The slightly lower reliability
364 score was due to the absence of a specific question ensuring disease stability, a feature present in
365 the original study.

366 The mean PsAID score in our study was 3.86 (SD 2.33), with 44.2% of patients having a high
367 score, consistent with the findings of Holland et al., who reported a mean of 3.92 (SD 2.36) [14].

368 The demographic characteristics were comparable in terms of gender distribution (59.0%
369 females in the current study vs. 57.4% in Holland et al.'s study) and BMI values (28.7 (SD 5.7)
370 vs. 29.2 (SD 5.9)). However, the current study population was younger, with an average age of
371 45.5 (SD 13.2) compared to 52.1 (SD 13.3), resulting in a shorter disease duration (8.8 (SD 7.3)
372 vs. 10.2 (SD 8 years)).

373

374 Factors associated with high PsAID scores were disability, depression, chronic widespread pain,
375 and disease activity assessed by DAPSA, underscoring the internal and construct validity of the
376 PsAID. The influence of disability, depression, and fibromyalgia on PsAID scores has been
377 emphasized in previous studies. Fibromyalgia, reported in one-fifth of our study population,
378 would mainly affect pain scores [16].

379 Our study demonstrated that the Arabic PsAID is a consistent, reliable, and feasible measure for
380 PsA impact. Its correlation with disease activity and legacy outcome measures appears consistent
381 across cultures and languages, supporting its significance in clinical practice and research
382 purposes. The development of a validated Arabic version of the PsAID-12 questionnaire extends
383 its applicability to Arabic-speaking patients worldwide. This promotes the inclusion of diverse
384 patient populations in international research studies, fostering a comprehensive understanding of
385 PsA. This study serves as an important step towards enhancing the global understanding of
386 PsA's multifaceted effects on diverse patient populations, improving the quality of life and
387 healthcare outcomes for patients with PsA, and ensuring more personalized and effective care
388 strategies.

389 Further studies are warranted to assess the sensitivity to change of the Arabic PsAID and to
390 explore the role of cultural influences on PROMs. In particular, studying the discordance
391 between patient and physician perspectives among the Arab population could provide valuable
392 insights for better management and optimal care of PsA patients.

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Table 1. Factors associated with a high PsAID score in the bivariate analysis (statistically significant associations are shown in bold characters).

Variable	All	High PsAID	Low PsAID	p-value
Age (mean, SD)	45.5 (13.2)	45.3 (13.0)	45.7 (13.3)	0.707
Female gender (N, %)	318 (59.0%)	157 (49.5%)	160 (50.5%)	0.003
Married (N, %)	432 (80.1%)	204 (47.3%)	227 (52.7%)	0.043
University education (N, %)	263 (48.8%)	103 (39.2%)	160 (60.8%)	0.006
Profession (N, %)				
- White collar	210 (39.0%)	82 (39.0%)	128 (61.0%)	0.087
- Blue collar	79 (14.7%)	39 (49.4%)	40 (50.6%)	
- Retired	47 (8.7%)	19 (41.3%)	27 (58.7%)	
- Unemployed	203 (37.6%)	103 (50.7%)	100 (49.3%)	
Country (N, %)				
- Iraq	154 (27.8%)	74 (48.4%)	79 (51.6%)	0.098
- Egypt	54 (9.7%)	31 (57.4%)	23 (42.6%)	
- Jordan	47 (8.5%)	22 (46.8%)	25 (53.2%)	
- UAE	44 (7.9%)	13 (29.5%)	31 (70.5%)	
- Libya	41 (7.4%)	12 (29.3%)	29 (70.7%)	
- Syria	40 (7.2%)	20 (50.0%)	20 (50.0%)	
- Algeria	37 (6.7%)	19 (51.4%)	18 (48.6%)	
- Morocco	28 (5.1%)	9 (32.1%)	19 (67.9%)	
- Saudi Arabia	25 (4.5%)	9 (36.0%)	16 (64.0%)	
- Lebanon	22 (4.0%)	7 (31.8%)	15 (68.2%)	
- Palestine	22 (4.0%)	9 (40.9%)	13 (59.1%)	
- Bahrain	20 (3.6%)	11 (55.0%)	9 (45.0%)	
- Tunisia	20 (3.6%)	9 (45.0%)	11 (55.0%)	
Comorbidities (N, %)				
- Obesity (BMI \geq 30 kg/m ²)	189 (35.1%)	86 (45.7%)	102 (54.3%)	0.943
- Hypertension	157 (29.1%)	74 (47.1%)	83 (52.9%)	0.399
- Current smoking	99 (18.4%)	50 (50.5%)	49 (49.5%)	0.170
- Dyslipidemia	86 (16.0%)	38 (44.2%)	48 (55.8%)	0.981
- Diabetes	84 (15.6%)	39 (46.4%)	45 (53.6%)	0.670
- Known depression	34 (6.3%)	25 (73.5%)	9 (26.5%)	<0.001
- Cardiovascular events	33 (6.1%)	15 (45.5%)	18 (54.5%)	0.891
- Cancer history	7 (1.3%)	2 (28.6%)	5 (71.4%)	0.471
Family history (N, %)				
- Psoriasis	232 (43.0%)	113 (48.9%)	118 (51.1%)	0.294
- PsA	90 (16.7%)	48 (53.3%)	42 (46.7%)	0.202
- Axial spondylarthritis	28 (5.2%)	19 (67.9%)	9 (32.1%)	0.028
PsA duration (mean, SD)	8.8 (7.3)	8.9 (7.4)	8.6 (7.3)	0.708
PsA diagnostic delay (mean, SD)	2.6 (4.5)	3.1 (5.3)	2.2 (3.7)	0.026
Psoriasis duration (mean, SD)	14.6 (10.9)	14.5 (11.3)	14.7 (10.6)	0.837
Skin psoriasis (N, %)	494 (91.7%)	227 (46.0%)	266 (54.0%)	0.176
Nail psoriasis (N, %)	241 (44.7%)	118 (49.2%)	122 (50.8%)	0.294
Time gap between psoriasis and PsA (mean, SD)	5.9 (10.1)	5.8 (10.5)	5.9 (9.7)	0.928
PsA manifestations (N, %)				
- Polyarthritits	298 (53.8%)	135 (45.5%)	162 (54.5%)	0.557
- Oligoarthritis	177 (31.9%)	81 (45.8%)	96 (54.2%)	0.636
- Monoarthritis	24 (4.3%)	7 (29.2%)	17 (70.8%)	0.127
- Enthesitis	183 (33.0%)	93 (50.8%)	90 (49.2%)	0.030

- Dactylitis	128 (23.1%)	61 (47.7%)	67 (52.3%)	0.384
- Axial involvement	179 (32.3%)	95 (53.1%)	84 (46.9%)	0.004
Extra-musculoskeletal manifestations (N, %)				
- Uveitis				0.048
- Crohn's disease	29 (5.2%)	18 (62.1%)	11(37.9%)	0.361
- Ulcerative colitis	11 (2.0%)	3 (27.3%)	8 (72.7%)	0.549
	11 (2.0%)	6 (54.5%)	5 (45.5%)	
Positive HLA-B27* (N, %)	35 (17.1%)	20 (57.1%)	15 (42.9%)	0.287
High CRP** (N, %)	234 (42.2%)	134 (57.3%)	100 (42.7%)	<0.001
ESR (mean, SD)	30.3 (22.8)	35.2 (25.0)	26.1(19.9)	<0.001
Erosions on x-rays (N, %)	172 (31.9%)	86 (50.0%)	86 (50.0%)	0.222
Treatment (ever) (N, %)				
- csDMARDs	468 (84.5%)	215 (46.0%)	252 (54.0%)	0.282
- bDMARDs	250 (45.1%)	125 (50.0%)	125 (50.0%)	0.015
- tsDMARDs	14 (2.5%)	6 (42.9%)	8 (57.1%)	0.316
Treatment (current) (N, %)				
- csDMARDs	318 (57.4%)	143 (45.1%)	174 (54.9%)	0.744
- bDMARDs	327 (59.0%)	152 (46.6%)	174 (53.4%)	0.638
- tsDMARDs	11 (2.0%)	5 (45.5%)	6 (54.5%)	0.833
PGA for PsA activity (mean, SD)	4.7 (2.5)	6.4 (1.8)	3.3 (2.1)	<0.001
PGA for PsA pain (mean, SD)	4.7 (2.7)	6.6 (2.0)	3.2 (2.1)	<0.001
PGA for psoriasis activity (mean, SD)	4.0 (2.8)	5.5 (2.7)	2.7 (2.2)	<0.001
PhGA for PsA activity (mean, SD)	4.0 (2.4)	5.4 (2.0)	2.8 (2.1)	<0.001
PhGA for psoriasis activity (mean, SD)	3.1 (2.6)	4.2 (2.7)	2.2 (2.2)	<0.001
DAPSA score (mean, SD)	19.3 (16.1)	27.9 (17.5)	12.2 (10.7)	<0.001
HAQ score (mean, SD)	1.1 (0.8)	1.6 (0.6)	0.6 (0.6)	<0.001
PHQ4 total score (mean, SD)	3.3 (2.9)	5.1 (2.8)	1.8 (1.9)	<0.001
FiRST positive screening (N, %)	102 (18.4%)	85 (83.3%)	17 (16.7%)	<0.001

bDMARDs: biological disease-modifying anti-rheumatic drugs, CRP: C-Reactive Protein, csDMARDs: conventional synthetic DMARDs, DAPSA: Disease Activity in Psoriatic Arthritis, FiRST: Fibromyalgia Rapid Screening Tool, HAQ: Health Assessment Questionnaire, HLA-B27: Human Leucocyte Antigen-B27, IQR: Interquartile range, PGA: Patient Global Assessment, PhGA: Physician Global Assessment, PHQ-4: Patient Health Questionnaire- 4, PsA: Psoriatic Arthritis, tsDMARDs: targeted synthetic DMARDs.

**HLA-B27 data was available for 205 patients.*

*** The categorization of "high CRP" was based on the specific cut-off values for abnormal values, established by the respective laboratory centers involved in the study.*

Table 2. Correlation between PsAID and other instruments for construct validity.

Item 1	Item 2	Correlation Coefficient	p-value
PsAID	PGA Pain	0.780	<0.001
PsAID	PGA PsA activity	0.775	<0.001
PsAID	DAPSA	0.718	<0.001
PsAID	HAQ	0.702	<0.001
PsAID	PHQ4	0.697	<0.001
PsAID	FiRST	0.629	<0.001
PsAID	PGA Psoriasis activity	0.627	<0.001

Correlation cutoffs were: 0.00-0.10 (negligible), 0.10-0.39 (weak), 0.40-0.69 (moderate), 0.70-0.89 (strong), 0.90-1.00 (very strong) [36].

Table 3. Factors associated with a high PsAID score in the multivariable analysis (statistically significant associations are shown in bold characters).

Variable	OR	95% CI	p-value
Health Assessment Questionnaire (HAQ)	3.152	2.031 – 4.891	<0.001
Depression screening (PHQ4)	1.562	1.347 – 1.811	<0.001
Fibromyalgia screening (FiRST)	1.311	1.121 – 1.532	<0.001
Disease activity (DAPSA)*	1.288	1.126 – 1.473	<0.001
Axial involvement	1.657	0.900 – 3.051	0.105
Female gender	1.206	0.653 – 2.226	0.549
Education (university)	1.101	0.616– 1.965	0.746
High CRP**	1.010	0.559 – 3.051	0.687

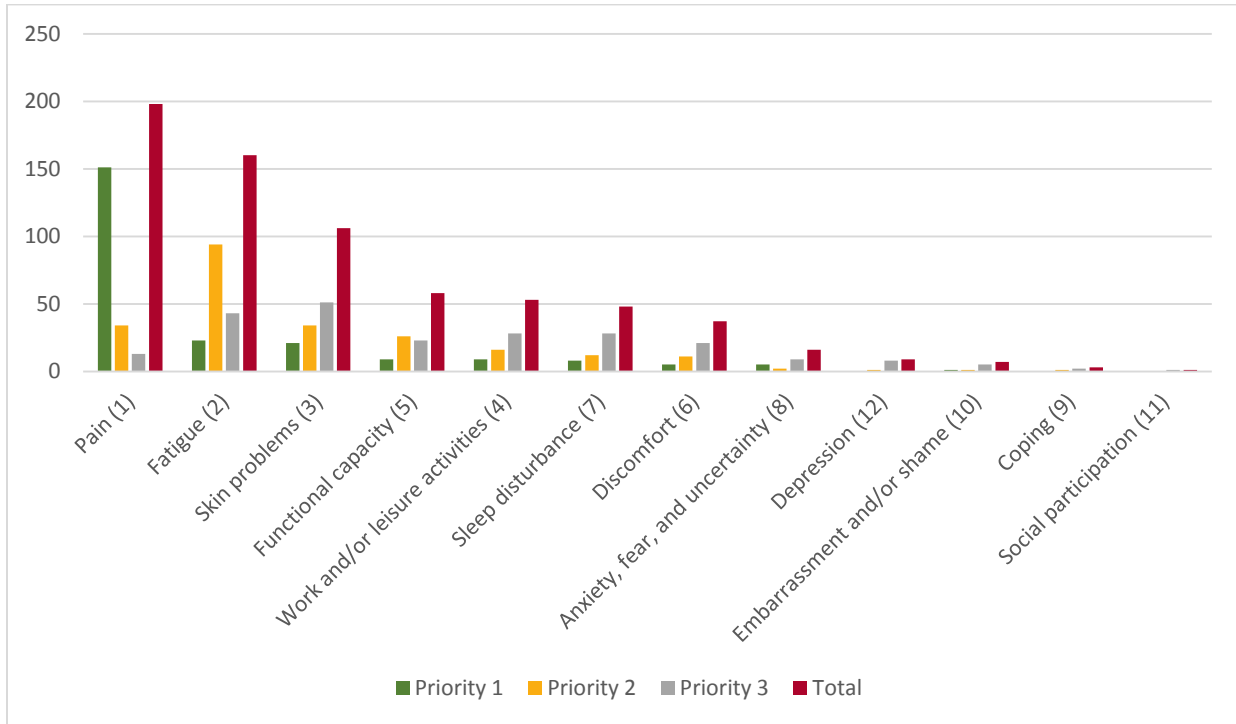
Variables that were statistically significant in the bivariate analysis ($p < 0.01$) were included in the multivariable binary logistic model: female gender, university education, axial involvement, high CRP, DAPSA, HAQ, PHQ4, and FiRST.

The variables that were not included were: ESR (correlation with CRP), known depression (correlation with PHQ4), Patient Global Assessment (part of PsAID domains), and Physician Global Assessment (physician-related measure).

**DAPSA: The Odds Ratio for an increase with 5-points in DAPSA is reported here.*

*** The categorization of "high CRP" was based on the specific cut-off values for abnormal values, established by the respective laboratory centers involved in the study.*

Figure 1. Top priorities cited by 544 PsA patients.



The numbers on the y-axis represent the frequency of patient citations for each item. Additionally, priorities 1, 2, and 3 indicate the three domains of the PsAID that patients identified as the most important for them. The numbers in parentheses indicate the order of importance assigned to each domain in the original PsAID study [13].

Figure 2-A. Distribution of Psoriatic Arthritic Impact of Disease (PsAID) scores across Disease Activity in Psoriatic Arthritis (DAPSA) categories (among 432 patients).

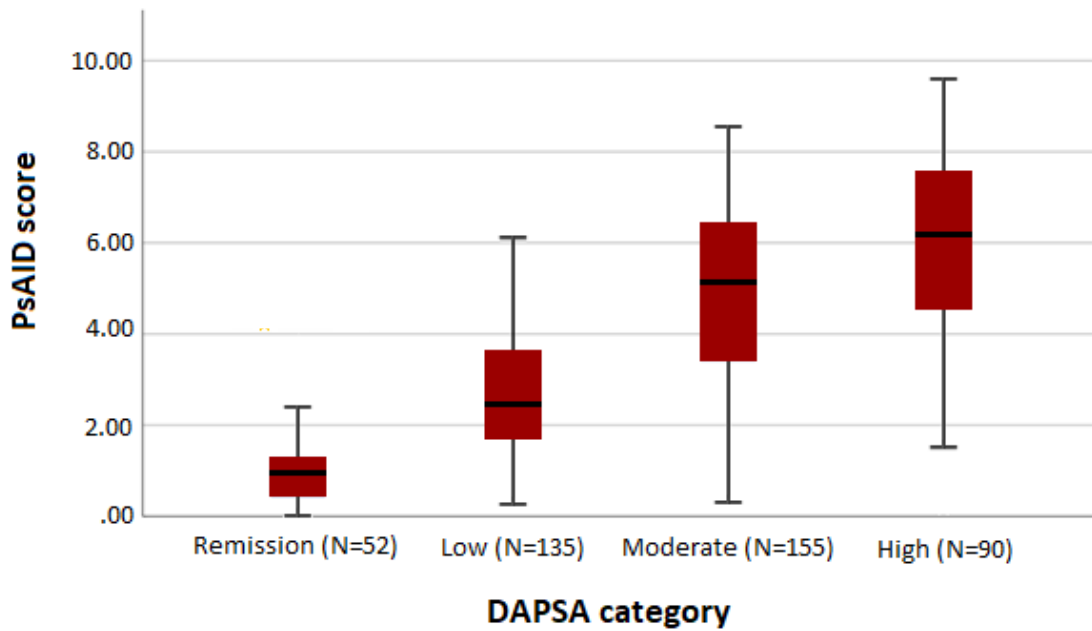
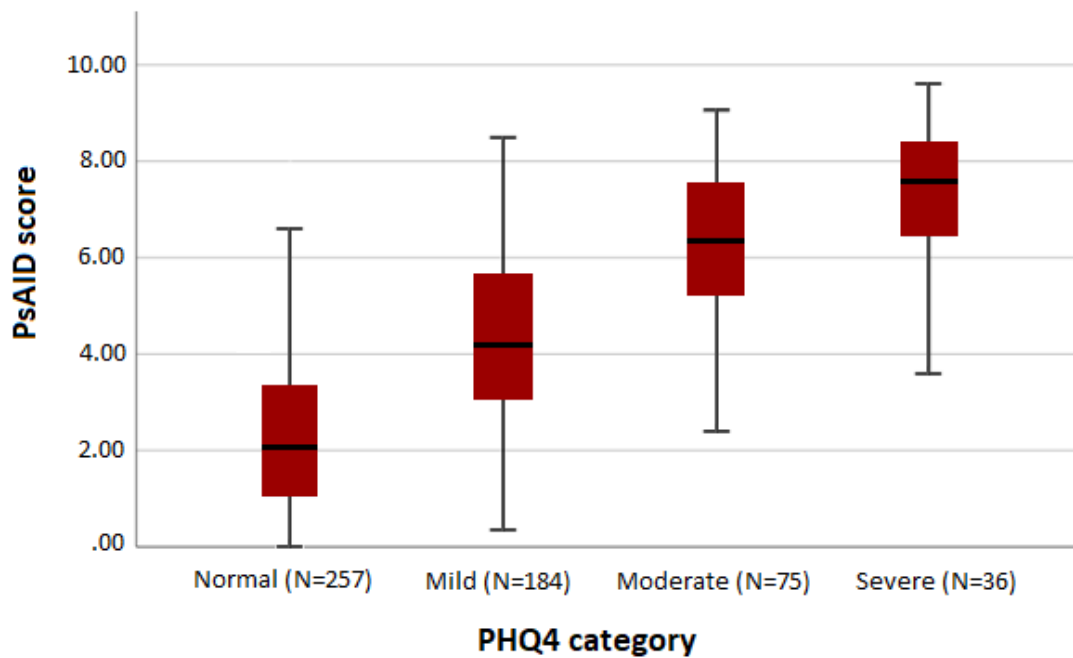


Figure 2-B. Distribution of Psoriatic Arthritic Impact of Disease (PsAID) scores across Patient Health Questionnaire (PHQ4) categories (among 552 patients).



Appendix 1. The English version and Arabic translation of the PsAID questionnaire. The changes are highlighted in yellow, and the explanations for each change are presented in the Arabic section (in italic). Male and female grammar formulation was applied where appropriate.

English (original) [13]	Arabic (translation)
The EULAR Psoriatic Arthritis Impact of Disease: PsAID12 for clinical practice	تأثير التهاب المفاصل الصدفي على المرضى EULAR PsAID12 للأعراض السريرية <i>We added "على المرضى" (on the patients) in the title.</i>
We want you to indicate how much your psoriatic arthritis impacts your health. Please tell us how you have been feeling this last week.	نرجو منك أن تشير/ تشير إلى مدى تأثير التهاب المفاصل الصدفي على صحتك. من فضلك أخبرنا/ أخبرينا كيف كنت تشعر/ تشعرين في الأسبوع الماضي. <i>We formulated the instruction in a more courteous way.</i>
1. Pain Circle the number that best describes the pain you felt due to your psoriatic arthritis during the last week	١. الألم ضع/ ضعي دائرة حول الرقم الذي يصف على أفضل وجه الألم الذي شعرت به بسبب التهاب المفاصل الصدفي خلال الأسبوع الماضي
2. Fatigue Circle the number that best describes the overall level of fatigue due to your psoriatic arthritis you have experienced during the last week	٢. التعب ضع/ ضعي دائرة حول الرقم الذي يصف بشكل أفضل المستوى العام للتعب الذي عانيت به بسبب التهاب المفاصل الصدفي خلال الأسبوع الماضي
3. Skin problems Circle the number that best describes the skin problems including itching you felt due to your psoriatic arthritis during the last week	٣. المشاكل الجلدية ضع/ ضعي دائرة حول الرقم الذي يصف المشاكل الجلدية بأفضل شكل بما في ذلك الحكة التي شعرت بها بسبب التهاب المفاصل الصدفي خلال الأسبوع الماضي
4. Work and/or leisure activities Circle the number that best describes the difficulties you had to participate fully in work and/or leisure activities due to your psoriatic arthritis during the last week	٤. العمل و / أو الأنشطة الترفيهية ضع/ ضعي دائرة حول الرقم الذي يصف على أفضل وجه الصعوبات التي واجهتها عند المشاركة بشكل كامل في العمل و / أو الأنشطة الترفيهية (على سبيل المثال المطالعة، عزف آلة موسيقية، ممارسة التمارين الرياضية، الذهاب لرحلة أو نزهة في الطبيعة، إلخ) بسبب التهاب المفاصل الصدفي خلال الأسبوع الماضي <i>We added practical examples.</i>
5. Functional capacity Circle the number that best describes the difficulty you had in doing daily physical activities due to your psoriatic arthritis during the last week	٥. القدرة الوظيفية ضع/ ضعي دائرة حول الرقم الذي يصف على أفضل وجه الصعوبة التي واجهتها في ممارسة الأنشطة البدنية اليومية (لا تقتصر على الأنشطة الرياضية) بسبب التهاب المفاصل الصدفي خلال الأسبوع الماضي <i>We added a specification.</i>
6. Discomfort Circle the number that best describes the feeling of discomfort and annoyance with everyday tasks due to your psoriatic arthritis during the last week	٦. الانزعاج وعدم الارتياح ضع/ ضعي دائرة حول الرقم الذي يصف على أفضل وجه الشعور بالانزعاج وعدم الارتياح من المهام اليومية بسبب التهاب المفاصل الصدفي خلال الأسبوع الماضي <i>We added a specification in the title.</i>

<p>7. Sleep disturbance Circle the number that best describes the sleep difficulties (i.e., resting at night) you felt due to your psoriatic arthritis during the last week</p>	<p>٧. اضطرابات النوم ضع/ ضعي دائرة حول الرقم الذي يصف على أفضل وجه صعوبات النوم التي شعرت بها بسبب التهاب المفاصل الصدفي خلال الأسبوع الماضي <i>We adjusted the title to “اضطرابات النوم” instead of “صعوبات في النوم” (after back-translation). We eliminated redundancy (“resting at night”).</i></p>
<p>8. Coping Considering your psoriatic arthritis overall, how well did you cope (manage, deal, make do) with your psoriatic arthritis during the last week?</p>	<p>٨. التأقلم بالنظر إلى التهاب المفاصل الصدفي الذي تعانیه /تعانيه بشكل عام، ما مدى قدرتك على التأقلم معه خلال الأسبوع الماضي؟ <i>We eliminated redundancy (“manage, deal, make do”).</i></p>
<p>9. Anxiety, fear and uncertainty Circle the number that best describes the level of anxiety, fear and uncertainty (for example about the future, treatments, fear of loneliness) due to your psoriatic arthritis you have experienced during the last week</p>	<p>٩. القلق، الخوف وعدم اليقين ضع/ ضعي دائرة حول الرقم الذي يصف بشكل أفضل مستوى القلق، الخوف وعدم اليقين (على سبيل المثال حول المستقبل والعلاجات والخوف من الشعور بالوحدة) بسبب التهاب المفاصل الصدفي الذي عانيته خلال الأسبوع الماضي <i>We found that “عدم اليقين” was the best way to translate “uncertainty”, instead of “الخوف من المجهول”.</i></p>
<p>10. Embarrassment and/or shame Considering your psoriatic arthritis overall, circle the number that best describes the level of embarrassment and/or shame due to your appearance experienced during the last week</p>	<p>١٠. الإحراج و / أو الخجل بالنظر إلى التهاب المفاصل الصدفي الذي تعانیه /تعانيه بشكل عام، ضع/ ضعي دائرة حول الرقم الذي يصف على أفضل وجه مستوى الإحراج و / أو الخجل الذي شعرت به بسبب مظهرك خلال الأسبوع الماضي</p>
<p>11. Social participation Circle the number that best describes the difficulties you had to participate fully in social activities (including relationships with family and/or people very close to you) due to your psoriatic arthritis during the last week</p>	<p>١١. المشاركة الاجتماعية ضع/ ضعي دائرة حول الرقم الذي يصف بشكل أفضل الصعوبات التي واجهتها عند المشاركة بشكل كامل في الأنشطة الاجتماعية بسبب التهاب المفاصل الصدفي خلال الأسبوع الماضي (بما في ذلك العلاقات مع العائلة و / أو الأشخاص المقربين جدًا منك)</p>
<p>12. Depression Circle the number that best describes the level of depression due to your psoriatic arthritis you have experienced during the last week</p>	<p>١٢. الاكتئاب ضع/ ضعي دائرة حول الرقم الذي يصف بشكل أفضل مستوى الاكتئاب الذي شعرت به بسبب التهاب المفاصل الصدفي خلال الأسبوع الماضي</p>
<p>THANK YOU FOR ANSWERING THIS QUESTIONNAIRE</p>	<p>شكراً للإجابة على هذا الاستبيان</p>

Appendix 2. Overview of study findings.

