El Miedany *et al.*
Egyptian Rheumatology and Rehabilitation (2022) 49:32
https://doi.org/10.1186/s43166-022-00128-y

Egyptian Rheumatology and Rehabilitation

RESEARCH Open Access

Psoriatic arthritis treatment to the target: a consensus, evidence-based clinical practice recommendations for the management of psoriatic arthritis and its concomitant clinical manifestations

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Abstract

Background: We aimed to provide up-to-date, evidence-based and consensus-based recommendations for Treat-to-Target management of psoriatic arthritis (PsA) and associated clinical manifestations.

In this recommendations, 14 key clinical questions were identified by scientific committee according to the Patient/Population, Intervention, Comparison, Outcomes and Timing (PICOT) approach. Literature Review team performed a systematic review to summarize evidence advocating the benefits and harms of available pharmacologic and non-pharmacologic therapies for psoriatic arthritis. Subsequently, recommendations were formulated. The level of evidence was determined for each section using the Oxford Centre for Evidence-based Medicine (CEBM) system. A 3-round Delphi process was conducted with 19 experts whom were drawn from different governorates and health centers across Egypt with diverse in their experiences, including private, governmental workplace, tertiary university hospitals, and insurance hospitals. All rounds were conducted online. A consensus was achieved on the direction and the strength of the recommendations.

Results: An online questionnaire was sent to an expert panel who participated in the three rounds (response rate 100%). At the end of round 3, a total of 51 recommendation items, categorized into 6 sections to address the main 6 psoriatic arthritis categories, were obtained. Agreement with the recommendations (rank 7–9) ranged from 89.5 to 100%. Consensus was reached (i.e., $\geq$ 75%of respondents strongly agreed or agreed) on the wording of all the 51 clinical standards identified by the scientific committee. Algorithms for the management of psoriatic arthritis have been suggested.

Conclusion: These recommendations provide an updated consensus on the pharmacological treatment of psoriatic arthritis and strategies to reach optimal treat-to-target outcomes in in common clinical scenarios, based on a combination of evidence and expert opinion. Best treatment decisions should be tailored to each individual patient situation.

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Keywords: Psoriatic arthritis, Therapy, Treatment guidelines, Treat-to-target, Outcomes, Egyptian guidelines for psoriatic arthritis

Background

Psoriatic arthritis (PsA) is a chronic, inflammatory, musculoskeletal disease that can affect up to 30% of subjects living with psoriasis over their lifetime course [1]. Psoriatic arthritis (PsA) is distinct from other inflammatory arthritic conditions in several aspects including pathogenesis, clinical manifestations as well as response to therapy [2]. Peripheral arthritis, spondylitis, dactylitis, and enthesitis are all musculoskeletal manifestations of PsA. Psoriatic skin patches and nail disease are two cutaneous symptoms of PsA. Patients with PsA have difficulties doing daily activities, which has a negative impact on their quality of life, and social involvement [3]. There are also other extra-articular symptoms of psoriasis, such as uveitis and inflammatory bowel disease (IBD). Obesity and metabolic syndrome, as well as depression and anxiety, are all linked to PsA [4]. All these factors play an important role in identifying the priorities to manage in psoriatic patients as well as their therapy selection [5–7].

The benefits of a treat-to-target approach for psoriatic arthritis were first revealed in the TICOPA trial (TIght COntrol of inflammation in early Psoriatic Arthritis) [8], but its translation into clinical practise necessitates a refinement of the conventional therapeutic routine. Given the disease's heterogeneity, it is possible that, under the Treat-to-Target (T2T) method, personalising therapy options to the individual's disease severity and accompanying comorbidities could improve this form of management.

Treatment guidelines are developed aiming at several goals: to educate clinicians, particularly in a landscape of changing therapeutics; to define 'best care' through processing of the best available scientific evidence and broad consensus; also, to simultaneously point out where there is little information to guide treatment decisions; to reduce inappropriate variation in care and set standards for quality control; to promote efficient use of resources; and to highlight the research that needs to be done to inform future care [6]. The overall objective of this guideline is to provide up-to-date, evidence-based recommendations for Treat-to-Target management of psoriatic arthritis and its associated clinical manifestations.

Methods

Design

The study design was developed using a qualitative synthesis of scientific evidence and consensus based on existing scientific evidence as well as clinical experience. This was a multi-step procedure that followed the protocol of the "Clinical, Evidence-based, Guidelines" (CEG) program, which aimed to establish an actionable clinical gold standard for Treat-to-Target management of rheumatic and bone disorders. The manuscript's evidence-based section followed the preferred reporting items for systematic reviews and meta-analyses criteria for publishing systematic reviews [9]. The Egyptian Academy of Rheumatology led the project.

Development stages

Core team

It is formed of 4 experts with recognized experience in rheumatology, particularly psoriatic arthritis. The core team supervised and coordinated the teamwork, assisted with developing the scope of the project and initial Patient/Population, Intervention, Comparison, Outcomes and Timing (PICOT) [10] clinical questions, reached a consensus on the key questions to include in the guidelines, nominated the expert panel, and drafted the manuscript.

Literature review team

The literature evaluation was undertaken with the proper help in methodology and was led by two experienced literature review consultants and based on particular research questions established to focus on the diagnosis and treatment of psoriatic arthritis [11]. The search for items lasted from January 2000 to July 2021.

Data sources and search strategies

The PICOT questions (Table 1) were used to conduct the literature search in PubMed, Embase, and Cochrane Library databases. Literature search strategies were carried out to locate randomized clinical trials evaluating the efficacy of psoriatic arthritis and associated clinical manifestations quality improvement strategies published from 1990 to June 2021. The language was limited to English for practical reasons. The search strategies were made to be broad in order to find relevant material with high sensitivity. We used the following medical terms: (1) population: psoriasis, psoriatic arthritis, polyarthritis, peripheral arthritis, spondylitis, spondyloarthritis, spondyloarthropathy, sacroiliitis, axial joint disease, enthesitis, nail, psoriatic nail, uveitis, prognosis, prognostic factors. (2) intervention: oral small molecules, methotrexate, leflunomide, salazopyrine/or Sulfasalazine, Phosphodiesterase 4 Inhibitors/PDE4/PDE Type IV/apremilast,

Table 1 Key questions for PSA guidelines

1- Early diagnosis of psoriatic arthritis
2- Role of radiological studies in PSA assessment
3- Disease activity assessment
4- Cut off points of remission and low disease activity, high disease activity
5- Monitoring: clinical/radiographic/functional
6- Treat to target strategy (1ry and alternative target)
7- Communication, shared decision making, self-management and patient education
8- Management of PSA patient presented with peripheral arthropathy
9- Management of PSA patient presented with dactylitis or enthesitis
10- Management of PSA patient presented with axial affection
11- Management of PSA patient with predominant skin or nail affection
12- Management of PSA comorbidities
13- Best approach to management in standard practice
14- Personalized management

Cyclosporine, Tumo?r Necrosis Factor-alpha, Tumo?r necrosis alpha, TNF, TNF inhibitor, TNFi, adalimumab, etanercept, infliximab, Certolizumab Pegol, golimumab, Humira or Amjevita or "adalimumab-atto" or Enbrel or benepali, Remicade, inflectra, remsima, inflectra or Simponi, cimzia), monoclonal antibodies, interleukin-17, secukinumab, brodalumab, ixekexumab, cosentyx, interleukin 12 or IL12, ustekinumab or Stelara, Interleukin-23, IL12/23, JAK, JAK inhibitors, tofacitinib, xeljanz, non-steroidal anti-inflammatory drug therapy, NSAID, cyclooxygenase 2 inhibitors, cox-2 inhibitors, aspirin, diclofenac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, Naproxen, Piroxicam, etodolac; combination medication, combined therapy, co-intervention, diet, lifestyle measures, exercise, weight loss, smoking, smoking cessation, non-pharmacological intervention. (3) Comparator: randomized controlled trial, controlled clinical trial, randomized, placebo, drug therapy, trial, systematic review or meta-analysis, epidemiologic studies, case control studies, cohort studies, case control, cohort analysis, longitudinal, retrospective, cross-sectional studies. (4) Outcome: treat to target, remission, tight control, low, minimal, disease activity, disease activity score, intensive treatment/therapy. (5) Timing: early treatment, late treatment, long-term therapy, early versus late treatment.

The keywords were selected based on the PICOT elements that were utilised in various combinations. The PubMed and Cochrane Library databases were searched on May 24, 2021, while Embase was searched on May 28, 2021. Electronically, duplicate screening of literature search results was performed. Additional studies that fulfilled the inclusion requirements were found by looking through the reference lists of studies found using database search tools. Following the revision, each of the professionals involved in the literature review made recommendations for each part based on evidence (when available) or personal experience. The Oxford Centre for Evidence-based Medicine (OCEBM) approach was used to establish the level of evidence for each part (Table 2) [12].

Study selection

The relevant studies were selected by applying inclusion and exclusion criteria to the literature retrieved with the search strategies

Inclusion criteria

Studies published in English reporting on the ability to adopt treat to target management approach to induce remission in adult patients with psoriasis/psoriatic arthritis and its associated clinical manifestations. Systematic reviews, randomised controlled trials (RCTs), uncontrolled trials, observational studies such as cohort, case-control, and cross-sectional studies, and economic evaluations were among the articles considered. When numerous publications reported data from the same study, the most comprehensive data was used, while duplicate data was discarded. Studies were screened for inclusion or exclusion in two stages: first, titles and abstracts were evaluated, and then full-text reviews were conducted on those indicated as potentially relevant by the title/abstract screen.

Exclusion criteria

Editorials, commentaries, conference abstracts, and non-evidence-based narrative/personal reviews were excluded.

Study selection and data extraction

Two reviewers independently evaluated all reports for inclusion. A third investigator was consulted in the event of a disagreement. Year of publication, study design, number of patients, type, severity, and duration

Table 2 Levels of evidence according to Oxford Centre for Evidence-Based Medicine (OCEBM) [12]

Level of evidence	
1	Systematic review of all relevant randomized clinical trials or n-of-1 trials
2	Randomized trial or observational study with dramatic effect
3	Non-randomized controlled cohort/follow-up study (observational)
4	Case series, case-control study, or historically controlled study
5	Mechanism-based reasoning (expert opinion, based on physiology, animal, or laboratory studies)
Grades of recommendation	
A	Consistent level 1 studies
B	Consistent level 2 or 3 studies, or extrapolations from level 1 studies
C	Level 4 studies, or extrapolations from level 2 or 3 studies
D	Level 5 evidence or troubling, inconsistent or inconclusive studies of any level

of psoriasis, dosage and/or dosing scheme, therapy duration, definition of treatment success, result, side-effects, and the number and reasons for drop-outs were all documented from each report.

Expert panel

The core leadership team nominated 19 participants. The criteria for their selection included having professional knowledge and experience (at least 8 years of experience) in the field of rheumatology, management of inflammatory arthritis as well as active participation in scientific research on inflammatory arthritic conditions. The Delphi method and the project's aim were included in the invitation extended to the experts. Those who accepted the invitation were told that they had to answer to the first round in order to participate in the subsequent rounds of voting. The expert panel aided in the development of the project's scope, the refinement of the PICOT questions, and the voting on the recommendations.

Key questions used to develop the guideline

This guideline was based on a series of structured key questions that define the target population, classification criteria, the intervention, diagnostic test, or exposure under investigation, the comparison(s) used, the outcomes used to assess efficacy, effectiveness, or risk, as well as when the proper management should be implemented. Formulation of clinical questions, structure of questions, search for evidence, critical evaluation and selection of evidence, presentation of results, and recommendations were all used to gather evidence to answer the clinical questions. The systematic literature search and, as an outcome, clinical care guidelines are based on these questions, as indicated in Table 1.

Developing the clinical care standards framework

Based on the answers to the structured key questions and the literature review, a structured template was developed to facilitate standardized identification of the guideline components. For each component, the format in which the recommendations/information will be provided and extracted, have been identified.

Delphi process

The Delphi method's focus is to create consensus forecasts from a group of experts in a structured iterative manner. Its methodology is based on a sequence of "rounds" of questionnaires sent to experts. The stages of the Delphi technique are usually as follows: (1) a panel of experts is assembled. (2) Forecasting tasks/challenges are set and distributed to the experts. (3) Experts provide preliminary predictions and justifications. In order to provide input, these are collated and summarized. (4) The experts receive comments, which they consider when revising their forecasts. This process can be repeated until there is a reasonable degree of agreement. (5) The final forecasts are created by combining the forecasts of the experts. The anonymity of this method is one of its most important qualities.

Consensus process

Three Delphi rounds were carried out to establish consensus regarding the T2T strategy in psoriatic arthritis. After the main aspects of the strategy were identified, a discussion group worked with the scientific committee to define the aspects that would be included in the questionnaire. The structured Delphi approach ensures that all participants' opinions are taken into account equally, and it is especially useful for geographically diverse centres like Egypt. Online surveys were used to conduct the Delphi procedure. Three survey rounds were used since this allows for enough contemplation on group responses and is thought to be the most effective method for reaching consensus [13]. In addition, free-text responses from Round 1 were included as new assertions in Round 2 and

re-evaluated in Round 3 in light of the group consensus. The 14 domains involved in the T2T strategy were included in the first round of the electronic questionnaire.

Voting process

Three rounds of live online voting were held, each with a strict time limit. All members of the task force were invited to participate, and the start and end times of each round of voting were announced ahead of time. Anonymous votes were gathered and evaluated, and unique access links were sent out. At the same time as the voting procedure, comments on rephrasing, potential ambiguity, and unidentified overlaps were received for each statement. The task force members were the only ones who could vote on the statements.

Rating

Each statement was scored on a scale of 1 to 9, with 1 representing "total disagreement" and 9 representing "complete agreement." Disagreement, uncertainty, and agreement are represented by the numbers 1–3, 4–6, and 7–9. It is not necessary for members to vote on all statements, and they are invited to abstain if they believe a statement is outside their area of competence. As a result, a vote of "uncertainty" indicates "inconvenience about the veracity of the recommendation." All statements allow for comments, which are reviewed by the scientific committee after each round of voting. In all of the voting rounds, members were also asked to make comments wherever they voted a disagreement. This will allow the panel to notice a misinterpretation of a statement and invalidate the vote on that statement.

Definition of consensus

Definition of consensus was established before data analyses. It was determined that consensus would be achieved if at least 75% of participants reached agreement (score 7–9) or disagreement (score 1–3) [11, 12, 14, 15]. If a statement received a mean vote of less than 3 or a 'low' level of agreement, it was retired. In view of the comments, statements with an uncertainty score of (4–6) were changed. The levels of agreement on each statement of recommendation were regarded as 'high' if all votes on a statement fell into the agreement bracket (7–9) following the second round of votes [16–18]. If the differences between round group responses were less than 10%, consensus was termed stable [19].

Chronogram of Delphi rounds

The first round took place between 10th and 13th July 2021 (4 days). The aspects about which respondents did not reach consensus in this first round were revised in view of the comments and included in the second round. The second round took place (1 week after the first round) and remained for 4 days, between 18nd and 21st July 2021 (4 days). The third round took place (2 weeks after the second round) and remained for 4 days between 28th and 30th July 2021 (4 days).

Ethical aspects

This study was performed in accordance with the Helsinki Declaration. This was a multistep process which followed the CEG initiative protocol (ethical approval code: 34842/8/21, ethical board Tanta University) aiming at setting up an actionable clinical gold standard for Treat-to-Target management of rheumatic and bone diseases. As per the Egyptian national Ethical Committee regulations, verbal informed consent was required from all the participants included in the study. All the participants included in the study gave their verbal informed consent. All the participants were kept anonymous, in compliance with data protection regulations.

Results

Literature research and evidence selection

In the study selection process, 7498 potentially relevant studies were found by search strategy. 7287 were excluded for duplicate or after screening the titles and abstracts. So, relevant 211 studies were included as full article review plus additional 3 studies identified in an updated literature search. 127 studies were excluded as studies did not examine population or intervention of interest, did not match study design of interest, or did not report outcome measures of interest. Therefore, we included 87 studies in this work (Fig. 1). Definitions and cut-off points of remission were identified (Table 3).

Expert panel characteristics

Online surveys were sent to expert panel ($n = 19$), who participated in the three Delphi rounds. Respondents were drawn from different governorates and health centres across Egypt: Cairo University (10.6%), Ain Shams University (31.1%), Tanta University (10.6%), Benha University (10.6%), Suez Canal University (5.3%), Aswan University (5.3%), Zagazig University (5.3%), Minia University (5.3%), Mansoura University (5.3%), Fayoum University (5.3%), and Assiut University (5.3%).

Delphi round 1

Round 1 was done on key clinical questions to be included in this work. The response rate for round 1 was 100% (19/19). Consensus was reached on the inclusion of clinical standards on 95% of the items (i.e., $\geq$ 75% of respondents strongly agreed or agreed). Comments (excluding minor editing suggestions) were more frequent for management of PSA comorbidities. Table 1 showed Key questions for PSA guidelines.

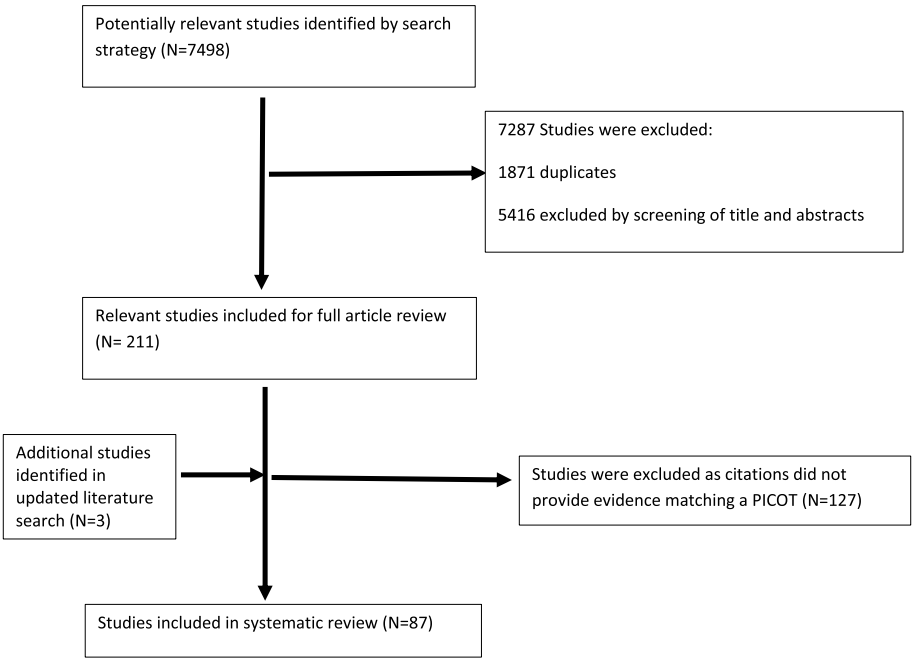

Fig. 1 Flowchart of the literature search and study selection process

Table 3 Definitions and cut-off points of disease remission and low disease activity [20–22]

Disease remission:	• Clinical remission: PASDAS: ≤ 1.9 or reaching minimal disease activity (MDA) • Ultrasound remission: Grayscale grade 0 as well as grade 0 in power Doppler ultrasonography (PDUS • Functional good outcome: remission or minimal disease activity Health Assessment Questionnaire (HAQ, 0–3) < 0.5
Low disease activity:	■ Clinical: low disease activity (PASDAS): 1.9–3.2 or reaching minimal disease activity (MDA) ■ Ultrasound: grade I in power Doppler ultrasonography (PDUS) ■ Functional good outcome: remission or low disease activity Health Assessment Questionnaire (HAQ, 0–3) < 0.5
Ultrasound (enthesitis/arthritis)	■ Grayscale: 0 ■ Power Doppler: 0
Functional disability	■ HAQ < 0.5

Delphi round 2

The response rate for round 2 was 100% (19/19). Consensus was reached on the inclusion of clinical standards on 88.5% of the items (i.e., ≥ 75% of respondents strongly agreed or agreed). There were comments raised regarding the wording of some of the recommendations. Comments (excluding minor editing suggestions) were more frequent on the statements regarding patients with peripheral arthritis. Diversity of opinion was greatest for the item "using combination therapy in patients presented with peripheral arthritis." Two statements were retired, one statement for similarity to other statements and the other one was about Madrid sonography enthesitis index score. Three statements which were added, after round two, one of them were in overarching principles, another one in peripheral arthritis, and the third statement in patients with comorbidities. Several statements were revised after round two; most edited statements were in patients with peripheral arthritis: section (4 statements). The section of patients with dactylitis or enthesitis was divided further into two separate sections: one for patients with dactylitis and another one for patients with enthesitis sections).

Delphi round 3

The response rate for round 3 was 100% (19/19). Frequency of high rank recommendation (rank 7–9) ranged from 89.5 to 100. Consensus was reached (i.e., ≥ 75% of respondents strongly agreed or agreed) on all the clinical standards. Table 2 also shows the level of evidence assigned to each statement, in accordance with the Oxford Centre for Evidence-Based Medicine (CEBM) criteria as well as mean ± standard deviation and level of agreement. Agreement was unanimous

(>80% agreement) for the wording of the statements. Table 3 shows disease remission and low disease activity as clinical, ultrasonographic remission and functional response as we rely on these parameters on reaching the target of treatment.

Recommendations for management PSA

At the end of round 3, a total of 51 recommendation items, categorized into 6 sections (peripheral arthritis, dactylitis, enthesitis, axial affection, predominant skin or nail affection, and patients with comorbidities), were obtained. Tables 4 and 5 show the overarching principals and breakdown of statements of recommendations, its individual rank by Experts Opinion and level of agreement.

Application of the primary recommendations to standard clinical practice and personalized management

Clinical practice guidelines include recommendations meant to optimize patient care that are informed by the benefits and harms of alternative care options. Table 6 shows how personalized management can be applied on PSA and shows a scheme to treat psoriatic arthritis manifestations and its associated clinical manifestations, adopting a treat-to-target approach and identifying the cut-off points of remission. Clinical practice recommendations provide an assessment of the quality of the relevant scientific literature, as well as an assessment of the likely benefits and harms of a particular treatment, rather than prescribing a one-size-fits-all approach to patient care. This information allows health care clinicians to choose the best treatment for a specific patient based on their own preferences and in consultation with the patient. Therapy should be more customized based on the most presenting domain, prognostic variables, genetics, responsiveness to therapy, and comorbidity for each individual. Figure 2 shows an algorithm for personalized management approach presenting with PSA patients and/or one of its clinical manifestations.

Discussion

This work was carried out aiming at helping healthcare professional in managing their patients living with active PsA, including optimizing therapy to achieve treatment targets. PsA is distinct from other inflammatory arthritis in terms of pathogenesis, clinical manifestations and response to treatment [2]. The diversity of PsA manifestations, as well as its known associated comorbidities, make the patients respond variably to different lines of management. Despite the breakthroughs in treatment alternatives that have changed PsA management over the last two decades, there is still a scarcity of comparative efficacy/effectiveness data to guide treatment decisions [23]. As a result, it was critical to use an evidence-based, consensus decision-making approach, which is the best way to ensure that daily practice follows the clinical recommendations. The connection that closes the circle between evidence in the literature, clinical research, writing of guidelines, distributing them, and putting them into clinical practice will be the expert consensus [24]. Furthermore, despite evidence of efficacy of several therapy modalities from randomized controlled trials, the place of new medications in the treatment algorithm is now defined only by expert opinion [25].

All international treatment recommendations have supported the treat-to-target concept but have concluded that there is a lack of evidence to support what should be the primary target of PsA. Furthermore, since, for many PsA patients, complete remission may be difficult to attain, MDA, low or very low disease activity (VLDA) have been proposed as alternative goals. The ACR suggested that the clinically meaningful endpoint to assess the impact of interventions on PsA disease activity (treatment target) would be minimal disease activity (MDA) [26, 27]. Despite an increase in drug-related side effects, the Tight Control of PsA (TICOPA) research [8] found that treatment to target using the minimal disease activity (MDA) criteria improved clinical and patient-reported outcomes in PsA. The MDA criteria, on the other hand, include both remission and low disease activity and are not comparable to clinical remission/inactive illness. Disease Activity in Psoriatic Arthritis (DAPSA; focuses solely on arthritis), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PASDAS), Psoriatic Arthritis Response Criteria (focuses solely on arthritis), and GRAPPA Composite Exercise Index are some of the composite disease measures that have been proposed. Additional instruments, such as the Psoriasis Area Severity Index (PASI) and assessments for the existence of dactylitis and enthesopathy, are added in RCTs to assess these manifestations [28–30]. These measures are all continuous and remission is generally defined as a score below a cut-off value; for example, very low disease activity (VLDA) is defined as meeting all 7 MDA cut-off points [20], Disease Activity in PsA (DAPSA) remission (≤ 4) [27], or PsA Disease Activity Score (PASDAS) near remission (≤ 1.9) [20]. VLDA and PASDAS are designed as composite measures of psoriatic disease, while DAPSA is a measure of peripheral arthritis disease activity only. This work considered 3 parameters as a target for therapy. These are clinical, ultrasonographic, and functional remission. Bearing in

Table 4 Overarching principles and communication, shared decision-making, self-management, and patient education in PsA recommendations

No.	standard	Statement	LE	GoR	Mean rate ±SD	% of agreement
Overarching principles						
1		1. **Early diagnosis and optimum management of psoriatic arthritis have a great impact on disease progression and severity** 2. **The targeted subjects are patients who have psoriatic skin lesions and/or any psoriatic inflammatory musculoskeletal disorders** 3. **Treatment strategies are treat-to-target, and the targets should be sustained clinical remission or low disease activity.** 4. **The goals of treating patients with PsA are to control signs and symptoms; to prevent structural damage; to avoid comorbid conditions and drug toxicities; and to optimize function, growth and development, quality of life, and social participation.** 5. **It's advisable to use the cost effective therapy whenever possible.** 6. **Treatment to target by regularly assessing disease activity and adapting therapy accordingly is important to achieve these goals.** 7. **The primary target for treatment of patients with PsA is disease sustained remission, (clinical, ultrasonographic and functional)** 8. **Alternative target is reaching Minimal (or low) disease activity (clinical, ultrasonographic, and functional) particularly in patients with resisted, long-standing disease** 9. **Consider making the target remission rather than low disease activity for people with adverse/poor prognostic factors (> 5 active joints, radiographic damage, elevated acute phase reactants, extra-articular manifestations especially dactylitis)** 10. **In adults with active PsA, measure disease activity and screening for extra-articular manifestations monthly by specialist until the target of remission or low disease activity is achieved.** 11. **Monitor for comorbidities: obesity, DM, hypertension, gout, and metabolic syndrome.**	4	C	8.74±0.45	100
Communication, shared decision making, self-management, and patient education						
2		**1- Explain the risks and benefits of treatment options to adults with PsA in ways that can be easily understood. Throughout the course of their disease, offer them the opportunity to talk about and agree all aspects of their care, and respect the decisions they make.** **2. Implement shared decision making in the management process. Offer verbal and written information to adults with PsA to:** **· Improve their understanding of the condition and its management** **· Counter any misconceptions they may have.** **3. Adults with PsA who wish to know more about their disease and its management should be offered the opportunity to take part in existing educational activities, including self-management programmes.**	4	C	8.53±±0.69	100

LE level of evidence according to the Oxford Centre for Evidence-Based Medicine (CEBM) criteria. *H* high level of agreement. *GoR* grade of recommendations, *PsA* psoriatic arthritis

Table 5 Breakdown of statements of recommendations, its individual rank by experts' opinion and level of agreement

No.	Standard	Statement	LE	GoR	Mean Rate ±SD	% of agreement	Level of agreement
Recommendations of management							
1	**Patients with peripheral arthritis:**	1.1. Start with csDMARDs at an early stage, with methotrexate in the dose of 15–25 mg/week preferred in those with relevant skin involvement for first-line treatment, MTX can be given orally, subcutaneous or Intramuscular route. Shared decision-making is advisable to agree which methotrexate administration form is preferable (oral vs subcutaneous vs intramuscular). Methotrexate should be taken for 12 weeks to judge the patient response to treatment. (LE:1 .GOR: A) 1.2. In patients with a contraindication to MTX or show intolerance; other csDMARDs including sulfasalazine, leflunamide, cyclosporine should be considered as first line of treatment strategy(LE: 1.GOR: A) 1.3. Methotrexate has been shown to increase the risk of developing liver fibrosis in patients with psoriasis, and should be used with caution in obese patients, patients who consume alcohol, and patients with other risk factors for hepatotoxicity such as diabetes and hepatitis. (LE:1 .GOR: A) 1.4. If biological therapy is not available; offer another cDMARDs (methotrexate, leflunomide, sulfasalazine, or cyclosporine) or in combination in a step-up strategy when the treatment target (remission or low disease activity) has not been achieved despite dose escalation within 3 months. (LE:4 .GOR: C) 1.5. Significant improvement [detected by PsA response criteria (PsARC) using tender and swollen joint count and patient and physician global assessment.] using csDMARDs should be achieved by 3 months. If no significant improvement has been achieved, by 3 months, adding another DMARD to MTX or use a different combination DMARD therapy is advised. DMARDs doses should be optimized to the maximum tolerable licensed levels (LE: 3.GOR: C) 1.6. Combined DMARD therapy means: MTX + SSZ, MTX + CSP, SSZ + CSP, or MTX + LEF (LE: 4 .GOR: C). 1.7. Consider oral non-steroidal anti-inflammatory drugs (NSAIDs, including traditional NSAIDs and cox II selective inhibitors), when control of pain or stiffness is inadequate. Take account of potential gastrointestinal, liver and cardio-renal toxicity, and the person's risk factors, including age and pregnancy. (LE: 4 .GOR: D). 1.8. When using oral NSAIDs: (LE:1.GOR: A) • Offer the lowest effective dose for the shortest possible time • Offer a proton pump inhibitor (PPI) • Review risk factors for adverse events regularly. 1.9. Local glucocorticoid injections should be considered when there is resisted oligo or monoarthritis. (LE:1 .GOR:A) 1.10. If the treatment target not achieved after 3 months of csDMARD therapy; switching to a bDMARD should be considered with or without MTX. (LE: 1.GOR: A) 1.11. Starting biological therapy from the first may be considered in severe cases (PASDAS score ≥ 5.4) with poor prognostic factors (LE: 2.GOR: B) 1.12. The cut-off point of starting biologic therapy is moderate Disease Activity: PASDAS: 3.2 to 5.4, and associated with adverse/poor prognostic factors (> 5 active joints, radiographic damage, elevated acute phase reactants, extra-articular manifestations especially dactylitis) functional disability (HAQ or equivalent) score > 2, US Doppler activity > 2 in > 3 joints. (LE: 5 .GOR: D) 1.13. First line biologic therapy: Use TNF-inhibitors, IL-17 inhibitor, IL-12/23 inhibitor, IL-23 inhibitor, CTLA4-ig, JAK inhibitor, or PDE4 inhibitor (IL-17 inhibitor, IL-12/23 inhibitor, or IL-23 inhibitor are advised/preferable if extensive skin affection identified by PASI score). (LE: 1.GOR: A) 1.14. Significant improvement (i.e., reaching minimal disease activity MDI, or low disease activity PASDAS: 1.9–3.2) using bDMARDs should be achieved by 3 months and the target should be achieved by 6 months. Treatment should be continued only if there is an adequate response at 6 months following initiation of therapy. (LE: 3.GOR: C) 1.15. If the patient has an inadequate initial response not reach even minimal disease activity (primary failure), switch out of therapeutic class considering a drug with other working mechanism is advised. (LE: 3.GOR: C) 1.16. In case of secondary failure to anti-TNF agent initially verify if the symptoms are due to active disease and confirm compliance. If verified, therapeutic drug monitoring is advised. In case of low drug levels with high antibodies, switching to another anti-TNF. However, if there is adequate drug level, no antibodies, it is advisable to switch out of the therapeutic class. (LE: 3.GOR: C) 1.17. In patients with persistent active disease, a tsDMARD, such as tofacitinib and PDE4-inhibitor (apremilast), should be considered. (LE: 3.GOR: C) 1.18. Treatment should normally be initiated with the least expensive drug (taking into account administration costs, required dose and product price per dose). This may need to be varied in individual cases due to differences in the mode of administration and treatment schedules. (LE: 5.GOR: D) 1.19. When switching from an anti-TNF drug (originator) to a biosimilar of that originator, one has to take into consideration that antidrug antibodies against the originator will cross-react with the biosimilar, causing treatment failure (LE:4 .GOR: D) 1.20. Non-pharmacological management (LE:4 .GOR: D) • Physiotherapy: adults with PsA should have access to specialist physiatrist, with periodic review to: improve general fitness and encourage regular exercise, learn about the short-term pain relief provided by methods such as transcutaneous electrical nerve stimulators (TENS). • Psychological interventions: offer psychological interventions (for example, relaxation, stress management, and cognitive coping skills) to help adults with PSA adjust to living with their condition. • Diet therapy: Patients could be encouraged to follow the principles of a Mediterranean diet (more bread, fruit, vegetables and fish; less meat; and replace butter and cheese with products based on vegetable and plant oils, and it may be of value in management metabolic comorbidities.			8.42 ±0.77	89.5	H

Table 5 (continued)

No.	Standard	Statement	LE	GoR	Mean Rate ±SD	% of agreement	Level of agreement
2	**Patients with dactylitis:**	2.1. Start with NSAIDs at an early stage 2.2. Local glucocorticoid injections should be considered when there is resisted dactylitis 2.3. csDMARDs (methotrexate, leflunomide, sulfasalazine or cyclosporine) may be tried in management of dactylitis for 3 months although csDMARDs have not been proven efficacious in treating these aspects of dactylitis. 2.4. If the treatment target not achieved after 3 months of cDMARD; adding or switching to a bDMARD should be considered. 2.5. First line biologic therapy: TNF-inhibitors, IL-17 inhibitor, IL-12/23 inhibitor, IL-23 inhibitor, CTLA4-ig, JAK inhibitor, or PDE4 inhibitor (IL-17 inhibitor, IL-12/23 inhibitor, or IL-23 inhibitor are more recommended if extensive skin affection) 2.6. Assess response to bDMARDs every month for 3 months, if inadequate response (not reach even minimal disease activity); switch between biologics is considered	2	B	8.47±0.77	100	H
3	**Patients with enthesitis:**	3.1 Start with NSAIDs at an early stage 3.2 Local glucocorticoid injections should be considered when there is resisted enthesitis 3.3 csDMARDs (methotrexate, leflunomide, sulfasalazine or cyclosporine) may be tried in management of enthesitis for 3 months although csDMARDs have not been proven efficacious in treating these aspects of enthesitis. 3.4 If the treatment target not achieved after 3 months of cDMARD; adding or switching to a bDMARD should be considered. Ultrasonographic assessments of the entheses should follow the Madrid Sonographic Enthesitis Index (MASEI) 3.5 First line biologic therapy: TNF-inhibitors, IL-17 inhibitor, IL-12/23 inhibitor, IL-23 inhibitor, CTLA4-ig, JAK inhibitor, or PDE4 inhibitor (IL-17 inhibitor, IL-12/23 inhibitor, or IL-23 inhibitor are more recommended if extensive skin affection) 3.6 Assess response to bDMARDs every month for 3 months, if inadequate response (not reach even low disease activity); switch between biologics is considered 3.7 Physiotherapy has an important issue in management of enthesitis.	2	B	8.21±1.31	89.5	H
4	**Patients with axial affection:**	4.1.Start with NSAIDs and physiotherapy at an early stage 4.2.treatment target (disease remission BASDAI < or ASDAS < 1.3) should be assessed monthly by BASDAI and ASDAS for 3 months 4.3. If the treatment target not achieved after 1 month; addition of a bDMARD should be considered (with the cut-point ASDAS value > 2.1 and (BASDAI value > 4((4.4. First line biologic therapy: TNF-inhibitors, IL-17 inhibitor, or JAK inhibitor, (IL-17 inhibitor is more recommended if extensive skin affection(4.5.In patients who fail to respond adequately to a bDMARD, (marked improvement in 3 months or reach target in 6 months switching to another bDMARD should be considered, including switching between TNFis. 4.6.Assess response to bDMARDs every month for 3 months, if inadequate response; switch between biologics may be considered after 6 months.	1	A	8.58±0.77	100	H
5	**patients predominant skin or nail affection:**	5.1.Start with topical (keratolytics, steroids, vitamin D analogues, emollients, calcineurin i) at an early stage 5.2.If the treatment target not achieved start csDMARDs (methotrexate, cyclosporine, acitretin, fumaric acid esters) 5.3.If the treatment target not achieved after 3 months of csDMARD; addition of a bDMARD should be considered as (TNF-inhibitors, IL-17 inhibitor, IL-12/23 inhibitor, IL-23 inhibitor, CTLA4-ig, JAK inhibitor, or PDE4 inhibitor(5.4.IL-17 inhibitor, IL-12/23, or IL-23 inhibitor are more recommended if extensive skin affection. 5.5In patients who fail to respond adequately to a bDMARD, switching to another bDMARD, tsDMARD, or PDE4-inhibitor should be considered.	1	A	8.42±±0.76	100	H

Table 5 (continued)

No.	Standard	Statement	LE	GoR	Mean Rate ±SD	% of agreement	Level of agreement
6	**Patients with comorbidities:**	**6.1.Inflammatory bowel disease:** 6.1.1.Common medications are being used to treat both conditions with two issues; be cautious with NSAIDs as they may exacerbate IBD symptoms, etanercept was not shown to be effective in treatment of IBD. Also, caution should be exercised when prescribing IL-17 inhibitors to patients with IBD. 6.1.2.First line biological treatment are (TNF monoclonal antibodies, IL-12/23, IL-23 inhibitor, or JAK inhibitor. 6.1.3.In patients who fail to respond adequately to a bDMARD, switching to another bDMARD. **6.2.Uveitis** 6.2.1.Using TNF monoclonal antibody is beneficial with special consideration to adalimumab and infliximab. 6.2.2.Topical treatment with corticosteroids and/or cyclosporine should be considered **6.3. Liver disease:** extra caution should be used when prescribing NSAIDs, DMARDs especially patients using methotrexate with regular monitoring for liver function tests abnormalities. **6.4.Cardiovascular comorbidities:** an association of methotrexate treatment with reduced cardiovascular risk has been found among patients with PsA. TNF inhibitors are associated with a significant lower risk of cardiovascular events with take in consideration TNF inhibitors issues in heart failure state grade III and IV. Take in consideration that there is may be increased risk of serious heart-related events when using JAK inhibitors. **6.5.Regular monitoring** of uric acid, blood pressure, and lipid profile during management of psoriatic arthritis is recommended.	2	B	8.53±0.77	100	H

LE Level of evidence according to the Oxford Centre for Evidence-Based Medicine (CEBM) criteria, *H* high level of agreement, *GoR* grade of recommendations, *PsA* psoriatic arthritis, *MTX* methotrexate, *bDMARDS* biological disease modifying anti-rheumatic drugs. *csDMARDs* conventional synthetic disease modifying anti-rheumatic drugs, *tsDMARDS* target synthetic disease modifying anti-rheumatic drugs, *PsARC* PsA response criteria, *SSZ* Salphasalazine, *LEF* leflunamide, *CSP* cyclosporine, *TNF* tumor necrosis factor, *IL* interleukin, *PDE4* phosphodiesterase-4, *NSAIDs* non-steroidal anti-inflammatory drugs, *PASDAS* Psoriatic Arthritis Disease Activity Score, *TENS* transcutaneous electrical nerve stimulation. *Cs* corticosteroids. *JAKi* janus kinase inhibitors

Table 6 Personalized management. A suggested management approach to psoriatic patients tailored to their clinical manifestations and prognostic markers

N	Status	Recommendation	LE	GoR	Mean rate ±SD	% of agreement	Level of agreement
1	Patient resisted/intolerable to csDMARDs without poor prognostic factor	Consider combined DMARDs therapy	2	B	8.42 ±0.96	89.5	H
2	Patient resisted/intolerable to csDMARDs with poor prognostic factor	Consider biological therapy	2	B	8.42 ±0.77	89.5	H
3	Patient is mainly presented with axial affection mainly	Choosing biological therapy among TNFi, IL-17i, or JAKi as not all biological therapy has good response with axial affection	2	B	8.58 ±0.77	100	H
4	Patient is presented with skin affection	IL-17 inhibitor, IL-12/23, or IL-23 inhibitor are more recommended among biologics.	2	B	8.42 ±0.76	100	H
5	Patient is presented with monoarthritis or enthesitis	Using local CS injection is considered	2	B	8.21 ±.31	89.5	H

GoR grade of recommendation, *bDMARDS* biological disease modifying anti-rheumatic drugs. *csDMARDS* conventional synthetic disease modifying anti-rheumatic drugs, *tsDMARDS* target synthetic disease modifying anti-rheumatic drugs. *Cs* corticosteroids, *JAKi* janus kinase inhibitors, *TNF* tumor necrosis factor, *IL* interleukin

	Disease Activity Score	T2T Target	1st Line	2nd Line	3rd Line	Switch
Peripheral Arthritis	PASDAS	Clinical remission: PASDAS: ≤ 1.9 or reaching minimal disease activity	NSAIDs / local injections	cDMARDs: mono or combined. MTX (alternatives: LEF, SSZ, CyA)	TNF, IL-12/23, IL-17, IL-23, JAK or PDE-4	Switch biologic, JAK or PDE4
Enthesitis	(MASEI)	Score 0, no enthesitis	NSAIDs / local steroid injections	cDMARDs: MTX, (alternatives: LEF, SSZ, CyA) for 3-months	TNF, IL-12/23, IL-17, IL-23, JAK or PDE-4 *(IL-17 inhibitor, IL-12/23 inhibitor, or IL-23 inhibitor are more recommended if extensive skin affection)	Switch biologic, JAK or PDE4
Dactylitis	simple counts of dactylitic digits or Leeds Dactylitis Instrument	Score 0 (no dactylitis)	NSAIDs	Methotrexate (alternatives: LEF, SSZ, CyA) for 3-months	TNF, IL-12/23, IL-17, IL-23, JAK or PDE-4	Switch biologic, JAK or PDE4
Axial spondylitis	ASDAS/ BASDAI	disease remission ASDAS <1.3 or BASDAI <4	NSAIDs	Biologic therapy: TNF-inhibitors, IL-17 inhibitor, or JAK inhibitor, *(IL-17 inhibitor is more recommended if extensive skin affection)	Biologic therapy: TNF-inhibitors, IL-17 inhibitor, or JAK inhibitor	Switch biologic or JAK
Psoriasis	PASI/ BSA	PASI ≤ 2 (concordant with PASI 90) and PASI ≤ 4 (concordant with PASI 75)	Topical (Keratolytics, steroids, vitamin D analogues, emollients, Calcineurin inhibitor	Phototherapy or cDMARDs	-IL-17 inhibitor, IL-12/23 inhibitor, or IL-23 inhibitor are more recommended if extensive skin affection -TNF, JAK or PDE-4	Switch biologic, JAK or PDE4
Nail disease	NAPSI	NAPSI-75, and NAPSI-90	Topical	DMARDs (methotrexate, cyclosporine, acitretin, fumaric acid esters)	TNF, IL-12/23, IL-17, IL-23, JAK or PDE-4	Switch biologic, or PDE4
Uveitis	Anterior chamber cells/flare	Anterior chamber cells/flare 0 Remission: Inactive disease for >3-mS after discontinuing all treatments for eye disease	Topical steroids	methotrexate	TNF (adalimumab/ infliximab)	
IBD	UC/ CD scoring systems	remission	DMARDs	TNF (not enanercept),	IL-12/23, IL-23, JAK	Switch biologic

Fig. 2 algorithm for personalized management approach presenting with PSA patients and/or one of its clinical manifestations

mind the diversity of PsA manifestations, the treatment targets varied accordingly subject to the affected organ. Therefore, specific targets were identified for arthritis (PASDAS), enthesitis: Madrid Sonographic Enthesitis Index (MASEI), skin (PASI), nails (NAPSI), spine (ASDAS). Ultrasonography Grayscale grade 0, as well as power Doppler (PDUS) grade 0, was identified as treatment targets. Similarly, functional good outcome was identified as remission or minimal disease activity at Health Assessment Questionnaire (HAQ, 0–3) score of < 0.5.

In 2021, The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) provide up to date, evidence-based guidance to providers who manage and treat adult patients with PsA [31] the GRAPPA has suggested treatment based on the manifestations (domains): peripheral arthritis, dactylitis, enthesitis, skin and nail involvement, and axial

arthritis, also updated GRAPPA added uvitis and IBD as new domains. In our recommendations; we agreed to GRAPPA recommendations in many subjects, but in our work we add other target to treat upon them as we consider clinical and ultrasonographic remission and functional response to reach the target of treatment. Also, we consider an important issue to non-pharmacological treatment modalities, and also in communication, shared decision-making, self-management, and patient education. Also, in this recommendation, we develop an algorithm which contain methods of assessment and disease activity measures which is not present in the updated GRAPPA recommendations. Also, we tried to be more personalized medicine manner by giving more focus on other comorbidities.

Regarding the European League against Rheumatic Diseases (EULAR) which had published recommendations for the PsA management with pharmacological therapies [25, 32]. On the other hand, traditionally, EULAR adopted an algorithmic approach that focused mainly on peripheral arthritis [25], and in the recent updated recommendation, more considerations have been given to the other manifestations, namely polyarthritis, oligoarthritis, enthesitis, dactylitis, and axial diseases [32]. Bearing in mind the high degree of heterogeneity in the presentation and course of PsA coupled with the involvement of multiple domains in a single patient, this guideline relied on a different strategy to choose the right treatment for every patient. This was achieved by individualising the choice of therapy by matching the most severely affected domains of the patients with the best available evidence of efficacies of therapies for those domains. In cases who do not respond to a medical therapy, cycling or shifting through other alternatives would be the rational steps. The treatment decision also considered the associated comorbidities, and the positive/negative impact of the chosen therapy.

The terminology used to describe the outcome of this work was "recommendations". The terms 'guidelines' and 'recommendations' are used differently by variable research groups. The American College of Rheumatology adopted the term 'guidelines' to describe to the full set of recommendations within the research work [23]. The term 'recommendations' which has been used by the EULAR [25]. The term recommendation is more malleable as leaves the final decision up to the physician and patient the rather than enforcing a 'guideline', which is felt to be a term that is more stringent.

The main strengths of the study are related to the diversity as well as the expertise of the participants, the high levels of consensus achieved, and the agreement with the most recently published recommendations. Also, the adoption of the PICOT methodology approach as well as the Treat-to-Target outcome as the main pillars of this work.

Limitations of the guideline: Though the guideline reflects the best data available at the time the report was prepared, one of its limitations is the limited comparative evidence to inform selection of therapies. This incorporates the primary comparative benefit/efficacy and harms evidence. In view of the absence of head-to-head comparative studies identified in the literature review, indirect comparisons among trials/therapies were used for the purpose of this work. Another limitation is that we searched only English-language literature. Interpreting the data should be done with caution; the findings of future studies may need changes to the conclusions or recommendations in this report. In the interests of unique patients and special circumstances, it may be necessary or even advantageous to deviate from the standards.

In conclusion, this evidence/consensus-based recommendations did take into account the full complexity of PsA and the full range of possible therapies. It endorsed an individualized treatment approach tailored to the patient's predominant clinical manifestation and associated morbidity. The main objective is to help health care professionals as well as patients in making challenging disease management decisions and achieve remission of their disease activity status.

Abbreviations

bDMARDS: Biological disease modifying anti-rheumatic drugs; Cs: Corticosteroids; csDMARDS: Conventional synthetic disease modifying anti-rheumatic drugs; CSP: Cyclosporine; H: High level of agreement; IL: Interleukin; JAKi: Janus kinase inhibitors; LE: Level of evidence according to the Oxford Centre for Evidence-Based Medicine (CEBM) criteria; LEF: Leflunamide; MTX: Methotrexate; NSAIDs: Non-steroidal anti-inflammatory drugs; PASDAS: Psoriatic Arthritis Disease Activity Score; PDE4: Phosphodiesterase-4; PsA: Psoriatic arthritis; PsARC: PsA response criteria; SoR: Strength of recommendations; SSZ: Salphasalazine; TENS: Transcutaneous electrical nerve stimulation; TICOPA: TIght COntrol of inflammation in early Psoriatic Arthritis; TNF: Tumor necrosis factor; tsDMARDS: Target synthetic disease modifying anti-rheumatic drugs.

Acknowledgements

Not applicable

Authors' contributions

Conceptualization and design Yasser El Miedany, Mohammed Hassan Abu-Zaid. Acquisition of data: Yasser El Miedany, Mohammed Hassan Abu-Zaid. Formal analysis: Maha El Gaafary. Investigation: Naglaa Gadalla and Mona Mansour. Methodology: all authors. Writing—original draft: Yasser El Miedany, Mohammed Hassan Abu-Zaid, and Samar Tabra. Final approval of the version to be submitted: all authors.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Availability of data and materials
The data will be available upon reasonable request.

Declarations

Ethics approval and consent to participate
This study was performed in accordance with the Helsinki Declaration. This was a multistep process which followed the "Clinical, Evidence-based, Guidelines" (CEG) initiative protocol (ethical approval code: 34842/8/21, ethical board Tanta University) aiming at setting up an actionable clinical gold standard for Treat-to-Target management of rheumatic and bone diseases. As per the Egyptian national Ethical Committee regulations, verbal informed consent was required from all the participants included in the study. All the participants included in the study gave their verbal informed consent. All the participants were kept anonymous, in compliance with data protection regulations.

Consent for publication
Not applicable

Competing interests
The authors declare that the corresponding author Mohammed Hassan Abu-Zaid is Associate Editor in the Egyptian Rheumatology and Rehabilitation, while Mohammed Mortada and Yasser El Miedany are on the Editorial Board of the journal.

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Received: 15 February 2022 Accepted: 21 April 2022
Published online: 01 June 2022

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