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Mental health, quality of life and self-management behaviours: online evaluation of inflammatory arthritis patients over 1 year of COVID-19 lockdowns

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Abstract

Objective: Patients with inflammatory arthritis were especially vulnerable to the psychosocial and health impacts of coronavirus disease 2019 (COVID-19) and the lockdowns. This study investigated the impact of these changes on mental health, physical health and quality of life for inflammatory arthritis patients over 1 year following the initial lockdown in the UK.

Methods: Three hundred and thirty-eight participants with inflammatory arthritis completed an ambidirectional study consisting of online questionnaires at four time points for 1 year. The questionnaires assessed demographic information, inflammatory arthritis condition, mental health, physical symptoms, self-management behaviours, COVID-19 status and impacts. Means, linear regressions and structural equation modelling for mediations were conducted over 12 months.

Results: Physical health concerns peaked during June 2020, then declined, but did not return to baseline. Depression was associated with worse quality of life at baseline, as shown by the beta coefficient, ($\beta = 0.94$, $P < 0.01$), September ($\beta = 0.92$, $P < 0.01$), November ($\beta = 0.77$, $P < 0.01$) and 1 year ($\beta = 0.77$, $P < 0.01$). Likewise, anxiety was associated with worse quality of life at baseline ($\beta = 1.92$, $P < 0.01$), September ($\beta = 2.06$, $P < 0.01$), November ($\beta = 1.66$, $P = 0.03$) and 1 year ($\beta = 1.51$, $P = 0.02$). The association between depression and quality of life was mediated by physical activity ($\beta = 0.13$, $P < 0.01$) at baseline. The association between anxiety and quality of life was also mediated by physical activity ($\beta = 0.25$, $P = 0.04$) at baseline.

Conclusion: Physical health continued to be worse 1 year later compared with before the COVID-19 lockdowns in patients with inflammatory arthritis. Mental health showed long-term effects on quality of life, with an impact for ≥12 months. Lastly, physical activity mediated between mental health and quality of life in the short term.

Lay Summary

What does this mean for patients?

People with inflammatory arthritis have greater risk of mental health and psychosocial difficulties owing to the additional barriers presented by the condition and its management. These challenges were especially increased during the coronavirus disease 2019 (COVID-19) pandemic because of the effects that lockdowns and shielding had on people with inflammatory arthritis. The impacts of the changes and stressors during COVID-19 led to more mental and physical health problems for rheumatoid arthritis patients. Worsened mental health was associated with lower quality of life. However, although mental health and quality of life changed throughout the pandemic, by 1 year later most people returned to nearly pre-pandemic levels of pain, mental health and quality of life. Self-management behaviours of diet and physical activity were studied to determine their roles. Diet was not found to link mental health and quality of life, but physical activity was shown to link both depression and anxiety with quality of life. For this reason, physical activity is considered an important part of self-management for rheumatoid arthritis symptoms.

Keywords: inflammatory arthritis, COVID-19, quality of life, mental health, depression, anxiety.

Key messages

- One year after COVID-19, inflammatory arthritis patients still have worse physical health.
- Mental health affects quality of life for ≥1 year.
- Physical activity mediates between mental health and quality of life.

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Introduction

The coronavirus disease 2019 (COVID-19) lockdowns affected populations around the world from March 2020 onwards. It has been estimated that the prevalence of mental health disorders rose by 8–34.7% during the lockdowns and has not returned fully to pre-COVID levels [1, 2]. Clinically vulnerable individuals, such as those with inflammatory arthritis, with increased risk of poor outcome of COVID-19 infection, were especially affected and experienced a greater elevation in risk of mental health impacts [3, 4]. Along with other clinically vulnerable groups, patients with inflammatory arthritis (a collection of chronic inflammatory autoimmune conditions) were recommended to follow varying levels of shielding or social distancing for long periods during 2020 and 2021 [5]. The effects of self-isolation on the disease activity, mental health and quality of life of inflammatory arthritis patients was unknown at the time of the initial lockdowns. Patients with inflammatory arthritis were already at increased risk of mental health problems and lower quality of life before the pandemic; therefore, ongoing monitoring of these factors through this period of social isolation and stress was needed [6, 7].

As the pandemic progressed, studies of inflammatory arthritis patients reported worsened mental health during the lockdowns, although most studies focused on short-term outcomes and results varied by country [8–12]. The lockdown restrictions also fluctuated in severity over the pandemic, but there have not been studies following patients over the long term to evaluate how symptoms changed through the relaxing and tightening of restrictions during the different lockdown periods. Research on the mental health and quality of life in inflammatory arthritis patients during the UK lockdowns can provide insight into whether these factors might affect the lives of patients in the long term. This could inform clinicians about symptoms and experiences of inflammatory arthritis patients in the aftermath of the pandemic in order that they can adjust to their care needs.

A prior study using initial data from this cohort examined changes in clinical care, mental health and physical health outcomes in inflammatory arthritis patients in the UK during the first 9 months of lockdowns [13]. Findings from the initial study showed that changes in clinical care owing to COVID-19 disruptions were associated with increased emotional distress, but only in the short term. It also found that worse mental health predicted worse physical health outcomes, with depression significantly affecting physical health for $\geq$5 months. A number of studies reported worsening of mental health for inflammatory arthritis patients [13–15], but several also demonstrated the impact of unique challenges, such as infection stress, social isolation and barriers to physical activity [8, 9, 12, 16]. The present study expands on the monitoring of physical health symptoms over time and examines the long-term changes in mental health, quality of life and self-management behaviours through the first year of the pandemic.

The objectives of this study were as follows: (i) to examine changes in self-reported health outcomes (disease activity, pain, fatigue and emotional distress) over time starting before the first lockdown through to 1 year after the end of the first lockdown; (ii) to determine the effects of mental health on quality of life over 1 year from the end of the first lockdown; and (iii) to identify behavioural mediators of the relationship between mental health and quality of life over the 12 month period.

Methods

Design and recruitment

The IA-COVID study was an online ambidirectional longitudinal mixed-methods series of questionnaires completed approximately every 3 months for 1 year from the end of the first lockdown to assess mental health, physical health and quality of life of inflammatory arthritis patients during the COVID-19 lockdowns in the UK. The baseline questionnaire was distributed in early June 2020, during a period of easing of restrictions. Follow-up questionnaires were distributed in early September 2020, late November 2020, early March 2021 and early June 2021. The follow-ups corresponded approximately to periods of lighter restrictions in September 2020, tighter restrictions during a second lockdown in November 2020, an easing of restrictions in March 2021, then lighter restrictions again in June 2021. Owing to an issue with the linkage of identification numbers, as a result of the survey being transferred between accounts owing to a change in institutional Qualtrics licence, it was not possible to include data from the March 2021 follow-up survey in the analysis.

Participants were recruited through social media and relevant charities. Eligibility criteria were as follows: age $\geq$18 years, living in the UK and having a self-reported inflammatory arthritis condition. The conditions included were RA, PsA, SpA, CTD and JIA. The questionnaire included only adults, but the JIA participants were classified according to their original diagnosis. Although the criteria specified that respondents must be residents in the UK, three respondents were included from crown dependencies that form part of the British Isles but are not in the UK. Informed consent was obtained from all participants for this study and additional related studies. Ethical approval was obtained from King's College London Research Ethics Committee (LRS-19/20-18186). Informed consent was obtained online before the start of the questionnaire. Subsamples of participants were also included in a qualitative study and an ecological momentary assessment study [17].

Measures

Topics covered by the questionnaire were as follows: details of condition, clinical care, self-management, disease outcomes, mental health, quality of life, COVID-19 clinical information and COVID-19 experience. All questions were self-report.

Arthritis symptoms and quality of life

Visual analogue scales (VASs) were completed for the previous week for patient global assessment of disease activity (PGA), pain and fatigue at each time point. The baseline survey also included retrospective assessments of pre-lockdown and peri-lockdown time points: first week of March 2020 and first week of April 2020. Visual analogue scales are commonly used in rheumatic conditions and considered to be appropriate measures for intensity of an experience, such as disease activity and pain [18]. The VASs for PGA and fatigue, for example, both have an intraclass correlation coefficient (ICC) for reliability of 0.74 [19].

In addition to VAS measures, the musculoskeletal health questionnaire (MSK-HQ) was completed at each time point, but not retrospectively. The MSK-HQ is a 14-item tool that measures the impact of disease on various aspects of

wellbeing, such as washing and dressing, sleep and emotional functioning. However, in this study it was shortened to 12 questions for brevity of the overall questionnaire by removing questions about emotional wellbeing and fatigue because they were covered by other questions. The MSK-HQ has been demonstrated to have high reliability (ICC = 0.84) and good validity in relationship to other measures [20].

Lifestyle measures

Inflammatory diet was evaluated by a shortened healthy eating assessment, which is an eight-item food frequency questionnaire that evaluates dietary patterns. It has been shown to have a moderate correlation compared with the National Cancer Institute (NCI) screener ($r = 0.39$) [21, 22]. The baseline questions also compared how the diets of participants changed from before the COVID-19 lockdowns. Physical activity was evaluated with one question ('How many hours did you spend sitting or lying down during the daytime per day on average?') modified from the international physical activity questionnaire (IPAQ), a valid ($r = 0.9$) and reliable (ICC = 0.67–0.81) measure [23].

Mental health measures

As with the disease outcome measures, emotional distress in the past week was measured with a VAS at each time point and retrospectively in the baseline questionnaire. Depressive symptoms were evaluated with the personal health questionnaire depression scale (PHQ-8). The PHQ-8 is a shortened version of the PHQ-9 scale, omitting the item regarding suicidal ideation, and has been validated for use as a depression screening tool in various contexts [24]. Anxiety symptoms were assessed by the GAD-2, which is the first two questions from the generalized anxiety disorder assessment (GAD-7) and has shown good sensitivity (89%) and specificity (82%) [25].

Statistical analysis

The mean VAS scores for PGA, pain, fatigue and emotional distress were calculated for each time point, including retrospectively at pre- and peri-lockdown (March and April 2020, respectively). The means for the PHQ-8 and MSK-HQ were also calculated. Plots of these means over time were created. Mixed-model regressions were run to examine the effects of baseline PHQ and GAD scores on MSK-HQ at each follow-up, controlling for confounders of age, sex and inflammatory arthritis condition.

Structural equation models were then used to examine mediators between PHQ/GAD scores and MSK-HQ outcomes, using the PHQ or GAD score at the prior visit to predict the MSK-HQ at the subsequent visit. Behavioural factors of inflammatory diet and physical activity at the prior visit were used as mediators. The models controlled for age, sex and condition. These were conducted for the baseline and each follow-up. Student's unpaired *t*-tests were conducted to determine differences in demographics between participants who were included in the sample compared with those who dropped out of the study. All analyses were conducted in STATA v.17.0 (StataCorp LLC, College Station, TX).

Results

Table 1 displays the baseline characteristics of the sample by inflammatory arthritis condition. A total of 338 participants completed the baseline assessment in June 2020. Fig. 1 shows a flowchart of the recruitment process. Data were available for 203 (60.0%), 173 (51.2%) and 143 (42.3%) participants at the September 2020, November 2020 and June 2021 follow-ups, respectively. The analysis sample included 260 (77.0%) participants who completed the baseline survey and at least one follow-up survey. The sample was mostly female (90.2%), White (97.5%), and had an average age of 47.9 years old, with an age range of 19–77 years. Supplementary Table S1, available at *Rheumatology Advances in Practice* online, displays χ^2 tests comparing demographics of participants included in the study with participants who dropped out, with the only difference being that younger participants were more likely to drop out. Thus, only age appeared to be affected by bias from the dropout at follow-ups.

Physical and mental health

The plots of the mean VAS scores from March 2020 to June 2021 are shown in Fig. 2. For Patient Global Assessment, pain, fatigue and emotional distress, scores were all increased during the initial lockdown (shown in the initial upward trend in panels a–d) compared with retrospectively reported pre-lockdown levels. Levels of PGA, pain and distress then improved slowly over the following 12 months, but without returning to pre-lockdown levels. This slight increase is also shown across all of the panels a–d. Fatigue levels remained high during the 12 months of follow-up.

Fig. 3A–C shows the mean scores for the depression (PHQ-8), anxiety (GAD-2) and quality of life (MSK-HQ) (Fig. 3A–C, respectively) over 12 months following the initial lockdown. Both depression and anxiety symptoms declined slightly over time, but were mostly stable, as shown in panels a and b which show slight downturns in scores. The MSK-HQ also stayed fairly stable throughout the year of lockdowns, as displayed in panel c showing little variation in scores over time.

Quality of life

Linear mixed-effects models were used to assess the association between baseline mental health and MSK-HQ over time. Table 2 displays the coefficients of the mixed-effects models at each time point. All the time points were significant, but the larger beta coefficients indicate a stronger relationship with the MSK-HQ. Additionally, all the results have positive beta coefficients, indicating that as mental health scores increased, the MSK-HQ scores increased accordingly. Greater depressive symptoms (PHQ-8) at baseline were associated with worse quality of life (MSK-HQ) at all time points over 1 year, even after controlling for age, gender and condition. Likewise, higher anxiety symptoms (GAD-2) at baseline were also associated with worse quality of life at all time points throughout the year, again controlling for age, sex and condition.

Behavioural mediators

The relationship between depression (PHQ) in June 2020 and quality of life (MSK-HQ) in September 2020 was mediated by physical activity ($\beta = 0.13$, $P < 0.01$) but not diet at baseline (Fig. 4). The small beta coefficient indicates that although the mediating relationship of physical activity between depression and the MSK-HQ was significant, it was not a strong effect; therefore, physical activity was a mediator, but

Table 1. Demographics of the sample

Characteristic	Total sample	RA	PsA	SpA	CTD	JIA
n	338	100	98	50	85	5
Age, mean (s.d.), years	47.90 (13.64)	53.06 (13.37)	46.39 (11.97)	41.18 (12.09)	48.68 (12.67)	28.2 (11.52)
Female sex, %	90.2	92.0	85.7	82.0	97.6	100
Education, %						
No formal qualifications	3.5	2.0	3.1	4.0	5.9	0.0
O level or GCSE	21.3	22.0	23.5	16.0	21.2	20.0
A level	21.0	23.0	25.5	16.0	16.5	20.0
Undergraduate degree	32.2	27.0	30.6	45.0	31.8	40.0
Postgraduate degree	21.9	26.0	17.4	18.0	24.7	20.0
Baseline social distancing, %						
None of the time	1.58	3.1	2.1	0	0	0
Some of the time	4.75	2.1	8.6	6.6	1.2	25
Most of the time	39.56	41.5	43.0	37.8	33.7	50
All the time	54.11	53.2	46.2	55.6	65.0	25.0

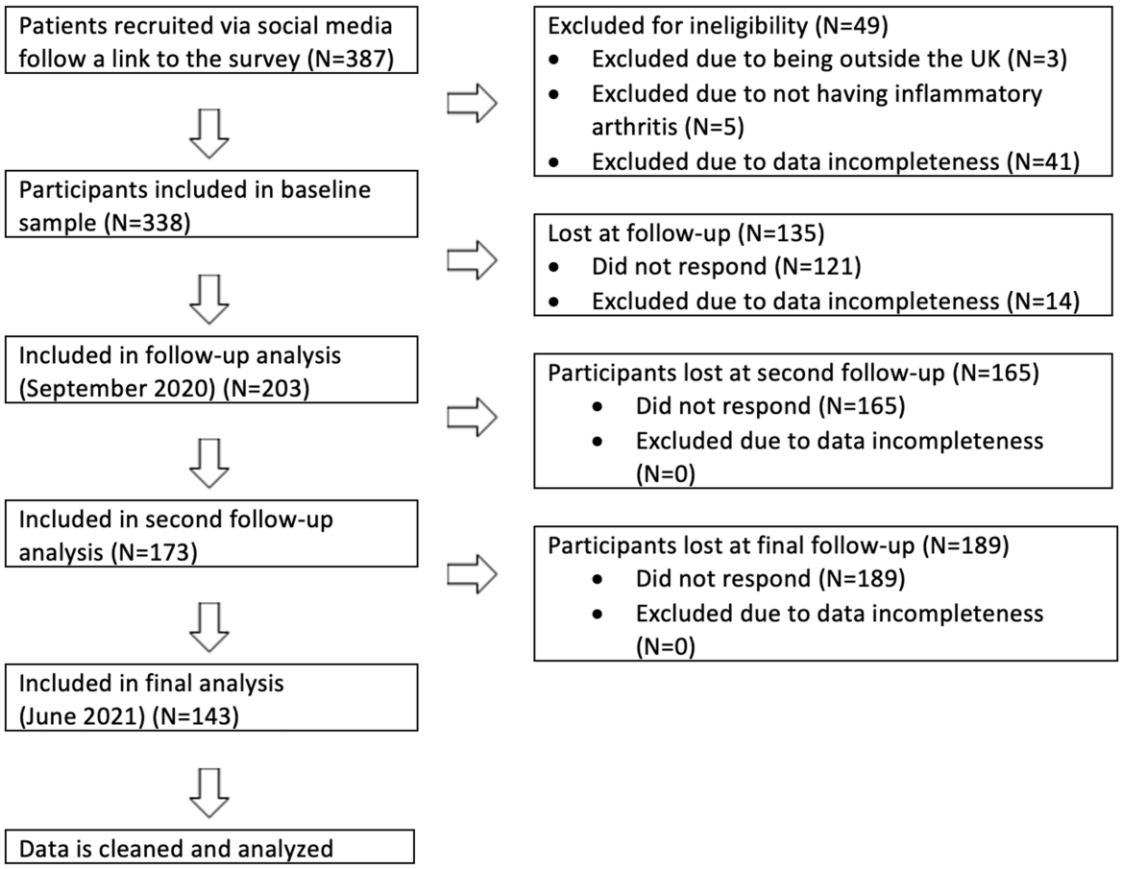

Figure 1. Recruitment flowchart

its role was not large. Likewise, the relationship between anxiety in June 2020 and quality of life (MSK-HQ) in September 2020 was also mediated by physical activity ($\beta = 0.25$, $P = 0.04$) but not diet at baseline. This beta coefficient was slightly larger, indicating a larger effect compared with the mediating role of physical activity between depression and the MSK-HQ.

The later follow-ups did not show any significant mediations by diet or physical activity between the depression score and quality of life at the following time point. Anxiety scores also showed no significant mediations after the baseline time point.

Discussion

Mental health for inflammatory arthritis patients during the COVID-19 lockdowns appears to have a long-lasting and complex relationship with quality of life, physical symptoms and self-management behaviours. Our previous publication showed that mental health had worsened during the first several months of COVID-19 lockdowns [13], and the present results show that this effect persisted for ≥12 months, with impacts on quality of life.

Emotional distress nearly returned to baseline after 1 year, whereas physical symptoms remained elevated. This is reflective of our previous study, showing delayed effects on

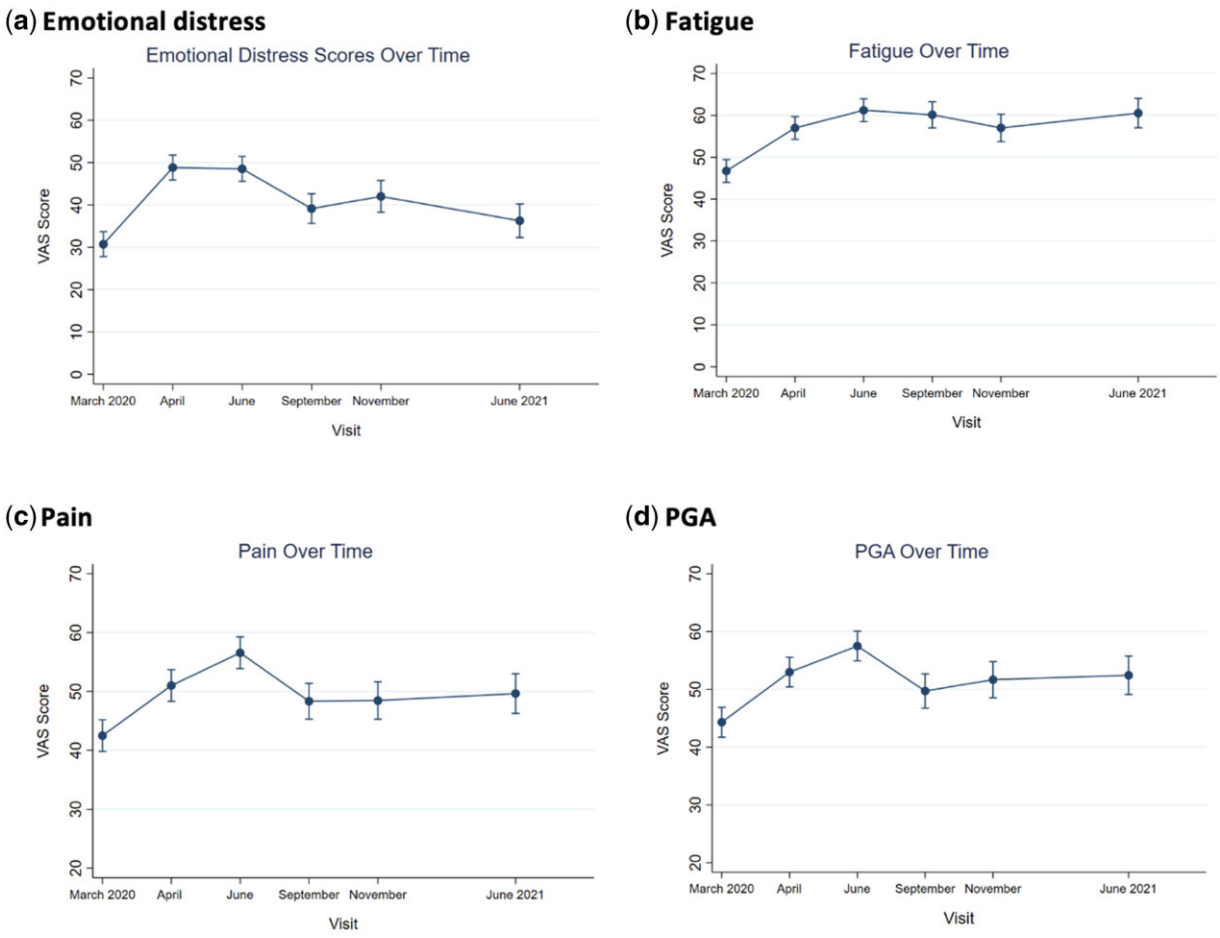

Figure 2. Visual analogue scale scores from pre-lockdown March 2020 to June 2021

physical health continuing, although diminishing over time, in addition to other studies showing that physical health can remain impacted by mental health in the longer term [13, 26, 27]. Although the PHQ and GAD were not collected retrospectively at the baseline for March and April 2020, the emotional distress VAS score suggests that scores peaked in April–June 2020, then slowly decreased. This might be reflective of people adapting to the COVID-19 uncertainty and lockdown stressors as people developed new coping skills and routines despite the ongoing changes [28].

The relationship between mental health and quality of life over time was consistent for both depression and anxiety, in that worse depression and anxiety were both linked with later worse quality of life. Given that the MSK-HQ has several questions about routine, such as sleep, work and socializing, it is likely that those scores would be affected by depression and anxiety, given the overlap in symptoms or areas of life. However, the long-lasting impact of baseline depression or anxiety on quality of life a year later is notable and consistent with another study on mental health and quality of life during lockdowns in this population [29]. The impact does decrease over time, but the persistence of influence is important for clinicians to be aware of for patients recovering from lockdown stressors. There are few studies that have investigated the longitudinal impact of mental health on quality of life in this population, but the results are in line with prior studies also showing long-term effects of mental health on quality of life and self-management [30, 31].

Finally, physical activity was shown to mediate between depression and quality of life at baseline, but not at later time points. This might be because emotional distress, depression and anxiety all peaked at the start of the lockdowns, then gradually decreased as people seemed to adjust over time; therefore, the impacts of mediators might have been more amplified at that time and faded alongside emotional distress. Alternatively, as restrictions loosened, other possible mediators, such as increased social support, might have taken on a stronger influence. Finally, 70% of participants made changes in physical activity at baseline, and the effects of the changes would probably have been most apparent initially, then faded as people became accustomed to the changes. A fading of the effect of changes in self-management behaviours on quality of life would be important for clinicians to note in order that they can encourage patients to maintain healthy habits in the long term for the benefits on physical health outcomes. Future research could also include more detailed questionnaires about physical activity and changes to elucidate the nuances better.

In contrast, diet was not a significant mediator at any time point. This might be because of the complexity of measuring diet accurately compared with physical activity, such as measuring the frequency of items eaten, participants' memory of them, and variety in food product quality. Furthermore, the measure used for diet was short compared with other measures, such as food frequency questionnaires, which would lead to more thorough assessment and thus more accurate

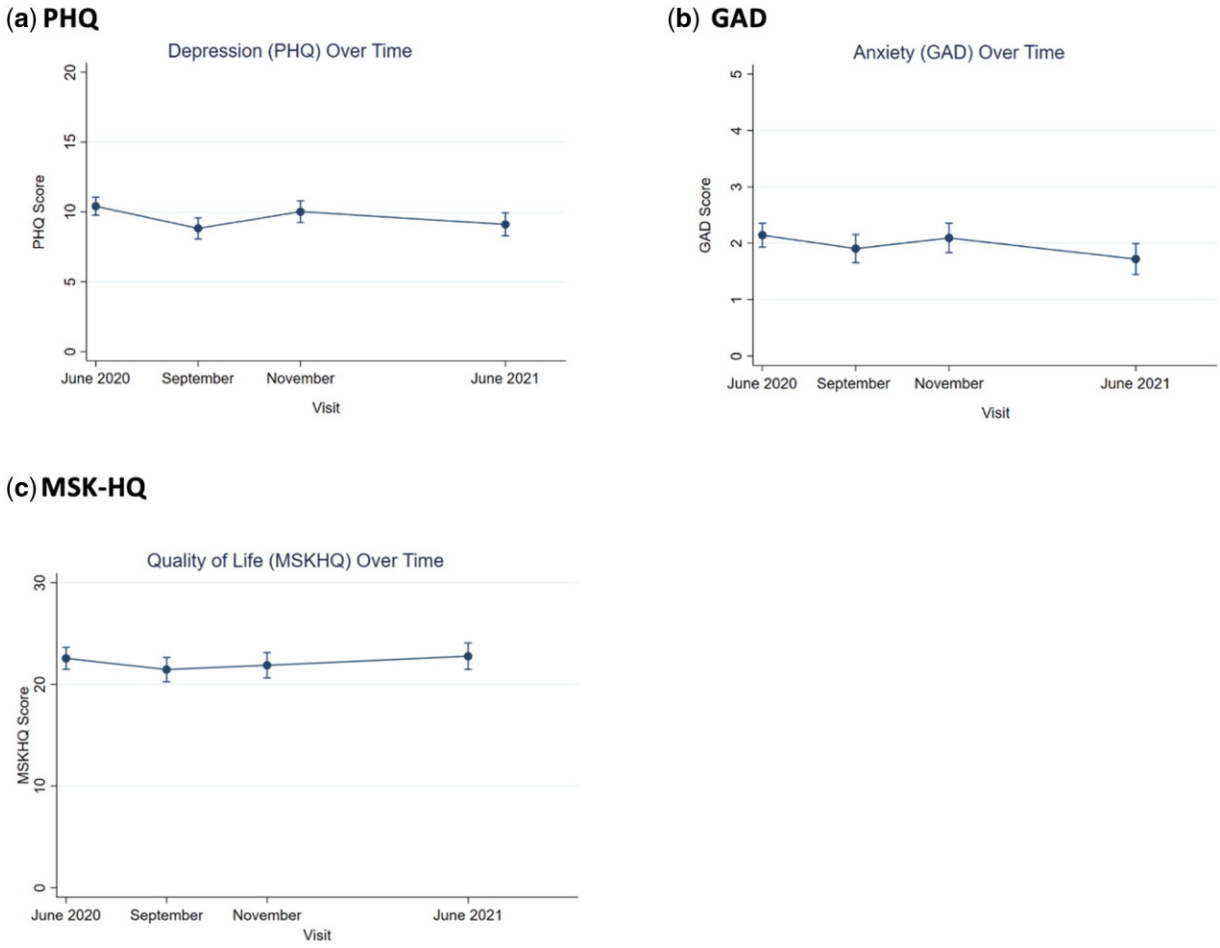

Figure 3. Mean mental health and quality of life scores from June 2020 to June 2021

Table 2. Regression coefficients for mental health factors on musculoskeletal health questionnaire scores over 1 year

	June 2020	*P*-value	September 2020	*P*-value	November 2020	*P*-value	June 2021	*P*-value
Baseline PHQ	0.94	<0.01	0.92	<0.01	0.77	<0.01	0.70	<0.01
Baseline GAD	1.92	<0.01	2.06	<0.01	1.66	0.03	1.51	<0.01

GAD: generalized anxiety disorder assessment; PHQ: personal health questionnaire depression scale.

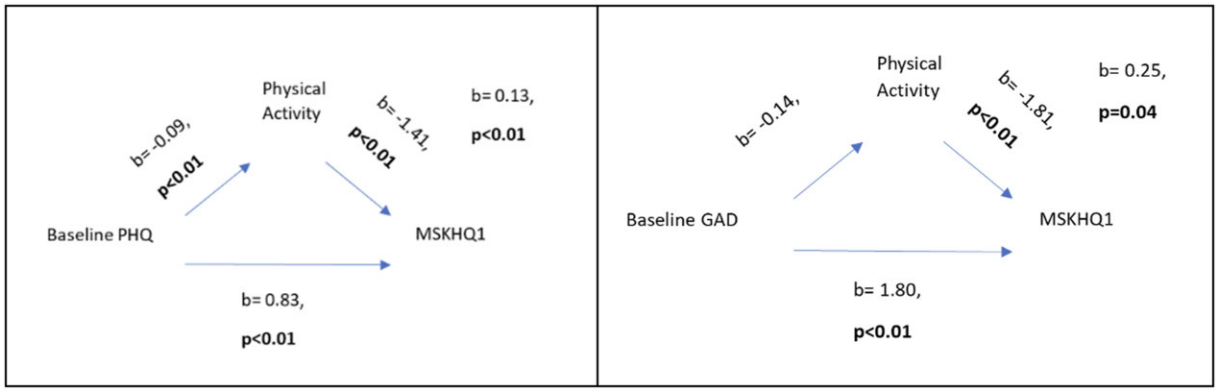

Figure 4. Mediations

results. Future research with a greater focus on diet would benefit from more extensive measurement. It is also possible that diet and physical activity have different mechanisms or time frames in which they exert an effect.

This study benefitted from having several follow-ups over a relatively long period of time. Future research could investigate further whether there are effects that manifest beyond 1 year. The study also had a large sample size. Although there

was some bias in gender, age and ethnicity, it did include a range of inflammatory arthritis conditions. Although bias was tested for in dropout and was found only to affect age, the original sample could still contain bias from the baseline. The most notable bias was in sex. Although there is a higher rate of inflammatory arthritis conditions in women, the online format of the study appears to have resulted in a self-selection bias towards female participants. Thus, the results might not be generalizable to men, because they were a small minority of the sample. Additionally, the measures were all self-reported, and some were limited further by also being retrospective. The pre- and peri-lockdown questions were completed retrospectively and might have differences compared with those collected non-retrospectively. Recall bias in retrospective questions appears to be especially true for affective experiences; therefore, these results should be interpreted more cautiously in comparison to those obtained non-retrospectively. Owing to the recruitment being online during COVID-19, the diagnoses were self-reported; therefore, there is also a limitation in the inability to validate the disease activity or diagnoses. Lastly, many of the questions on the questionnaire were shortened or adapted to the context of COVID-19; therefore, they might not reflect the same validity as other contexts.

Overall, the present study has confirmed some of the findings from our earlier analysis, such as the persistence of worsened mental and physical health symptoms in inflammatory arthritis patients during the COVID-19 lockdowns. The additional analyses also highlighted the importance of distinguishing between mental health measures in terms of anxiety *vs* depression in future inflammatory arthritis studies, owing to possible differences in outcomes. Future research could be completed with objective clinical measures that could validate the results found in this study. Although inflammatory arthritis patients seem to be recovering over time from the stressors that affected their mental and physical health, clinicians should keep in mind that they might still be presenting with worsened symptoms and might need additional support in the longer term.

Supplementary material

Supplementary material is available at *Rheumatology Advances in Practice* online.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

Author contributions

All the authors were involved in drafting the article. S.N., L. C., M.S., H.C., S.d.S. and L.H. were responsible for the study design. Acquisition of data, analysis and interpretation were completed by M.S. and S.N.

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The key clinical manifestations of PsA are joints, axial, skin, enthesitis, dactylitis and nails.[1]

Joint relief in PsA:

68% of patients achieved **ACR50** with Cosentyx® (secukinumab) at **Year 1** (observed data)[2]

Results from ULTIMATE (N=166). The primary endpoint of GLOESS mean change from baseline vs placebo at Week 12 was met (−9 vs −6, p=0.004)[2,3]

Click here to visit our HCP portal and learn more

Skin clearance in PsO:

55% of patients achieved **PASI100** at **Week 52** with Cosentyx 300 mg AI (secondary endpoint, observed data, N=41)[4]

Results from MATURE. The co-primary endpoints PASI 75 and IGA mod 2011 0/1 at Week 12 were met for Cosentyx 300 mg (N=41) vs placebo (N=40), (95% vs 10% and 76% vs 8% respectively, p<0.0001)[4]

Axial joint relief in PsA:

69% of patients achieved **ASAS40** at **Week 52** with Cosentyx 300 mg (secondary endpoint, observed data, N=139)[1]

Results from MAXIMISE. The primary endpoint of ASAS20 with Cosentyx 300 mg (N=164) vs placebo (N=164) at Week 12 was met (63% vs 31% respectively, p<0.0001)[1]

Cosentyx is the first and only, fully human biologic that directly blocks IL-17A regardless of its source[5–10]

8 years

A **consistent safety profile** with **over 8 years** of real-world experience[5,6,11]

The most frequently reported adverse reactions are upper respiratory tract infections (17.1%) (most frequently nasopharyngitis, rhinitis).[5,6]

Cosentyx licensed indications in rheumatology: Cosentyx is indicated for the treatment of active psoriatic arthritis in adult patients (alone or in combination with methotrexate) when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; moderate to severe plaque psoriasis in children and adolescents from the age of 6 years, and adults who are candidates for systemic therapy; active enthesitis-related arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate conventional therapy; active juvenile psoriatic arthritis in patients 6 years or older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.[5,6]

ULTIMATE (N=166), a multicentre, randomised, double-blind, placebo-controlled, 52-week Phase III trial in patients with PsA. Patients were randomly assigned to receive either weekly subcutaneous Cosentyx (300 mg or 150 mg according to the severity of psoriasis) or placebo followed by 4-weekly dosing thereafter. The primary outcome of mean change in the ultrasound GLOESS from baseline to Week 12 was met (−9 vs −6; p=0.004).[2,3]
MATURE (N=122), a 52-week, multicentre, double-blind, randomised, placebo-controlled, Phase III trial in patients with PsO. Eligible patients were randomised to Cosentyx 300 mg or placebo. The co-primary endpoints were PASI75 and IGA mod 2011 0/1 responses at Week 12. The study met the co-primary endpoints: PASI75 and IGA mod 2011 0/1 response at Week 12 were met for Cosentyx 300 mg vs placebo (95% vs 10% and 76% vs 8% respectively, p<0.0001).[4]
MAXIMISE (N=498) a double blind, placebo-controlled, multicentre, Phase IIIb study in patients with PsA. Patients were randomised in a 1:1:1 ratio to receive Cosentyx 300 mg, 150 mg or placebo. The primary endpoint of the proportion of patients achieving and ASAS20 response with Cosentyx 300 mg at Week 12 vs placebo was met (63% vs 31% respectively, p<0.0001).[1]

ACR, American College of Rheumatology; AI, auto-injector; ASAS, Assessment of SpondyloArthritis International Society; BASDAI, Bath; ankylosing spondylitis disease activity index; EULAR, European Alliance of Associations for Rheumatology; GLOESS, Global EULAR and OMERACT synovitis score; IGA mod 2011 0/1, investigator global assessment modified 2011 0/1; OMERACT, outcome measures in rheumatology; PASI, psoriasis area and severity index; PsA, psoriatic arthritis; PsO, plaque psoriasis.

References: 1. Baraliakos X, et al. *RMD open* 2019;5:e001005; **2.** Conaghan PG, et al. Poster 253. *Rheumatology* 2022;61(Suppl1). DOI:10.1093/rheumatology/keac133.252; **3.** D'Agostino MA, et al. *Rheumatology* 2022;61:1867–1876; **4.** Sigurgeirsson B, et al. *Dermatol Ther* 2022;35(3):e15285; **5.** Cosentyx® (secukinumab) GB Summary of Product Characteristics; **6.** Cosentyx® (secukinumab) NI Summary of Product Characteristics; **7.** Lynde CW, et al. *J Am Acad Dermatol* 2014;71(1):141–150; **8.** Fala L. *Am Health Drug Benefits* 2016;9(Special Feature):60–63; **9.** Schön M & Erpenbeck L. *Front Immunol* 2018;9:1323; **10.** Gorelick J, et al. *Practical Dermatol* 2016;12:35–50; **11.** European Medicines Agency. European public assessment report. Medicine overview. Cosentyx (secukinumab). Available at: https://www.ema.europa.eu/en/documents/overview/cosentyx-epar-medicine-overview_en.pdf [Accessed May 2024].

NOVARTIS

Prescribing information, adverse event reporting and full indication can be found on the next page.

UK | May 2024 | 425034

Cosentyx® (secukinumab) Great Britain Prescribing Information.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active enthesitis-related arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Presentations:** Cosentyx 75 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 75 mg dose is given as one injection of 75 mg. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. *Plaque Psoriasis:* Adult recommended dose is 300 mg. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight ≥ 50 kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight < 50 kg, recommended dose is 75 mg. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFα inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. *Ankylosing Spondylitis:* Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. *nr-axSpA:* Recommended dose 150 mg. *Enthesitis-related arthritis and juvenile psoriatic arthritis:* From the age of 6 years, if weight ≥ 50 kg, recommended dose is 150 mg. If weight < 50 kg, recommended dose is 75 mg. *Hidradenitis suppurativa:* Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. **Contraindications:** Hypersensitivity to the active substance or excipients. Clinically important, active infection. **Warnings & Precautions:** *Infections:* Potential to increase risk of infections; serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. *Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):* New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. *Latex-Sensitive Individuals:* The removable needle cap of the 75mg and 150 mg pre-filled syringe and 150mg pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. **Interactions:** Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. **Fertility, pregnancy and lactation:** *Women of childbearing potential:* Use an effective method of contraception during and for at least 20 weeks after treatment. *Pregnancy:* Preferably avoid use of Cosentyx in pregnancy. *Breast feeding:* It is not known if secukinumab is excreted in human breast milk. A clinical decision should be made on continuation of breast feeding during Cosentyx treatment (and up to 20 weeks after discontinuation) based on benefit of breast feeding to the child and benefit of Cosentyx therapy to the woman. *Fertility:* Effect on human fertility not evaluated. **Adverse Reactions**: *Very Common (≥1/10):* Upper respiratory tract infection. *Common (≥1/100 to <1/10):* Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon (≥1/1,000 to <1/100):* Oral candidiasis, lower respiratory tract infections, neutropenia, inflammatory bowel disease. *Rare (≥1/10,000 to <1/1,000)*: anaphylactic reactions, exfoliative dermatitis (psoriasis patients), hypersensitivity vasculitis. *Not known:* Mucosal and cutaneous candidiasis (including oesophageal candidiasis). *Infections:* Most infections were non-serious and mild to moderate upper respiratory tract infections, e.g. nasopharyngitis, and did not necessitate treatment discontinuation. There was an increase in mucosal and cutaneous (including oesophageal) candidiasis, but cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients (0.015 serious infections reported per patient year of follow up). *Neutropenia:* Neutropenia was more frequent with secukinumab than placebo, but most cases were mild, transient and reversible. Rare cases of neutropenia CTCAE Grade 4 were reported. *Hypersensitivity reactions:* Urticaria and rare cases of anaphylactic reactions were seen. *Immunogenicity:* Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. *Other Adverse Effects:* The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. **Legal Category:** POM. **MA Number & List Price:** PLGB 00101/1205 – 75 mg pre-filled syringe x 1 - £304.70; PLGB 00101/1029 - 150 mg pre-filled pen x2 £1,218.78; PLGB 00101/1030 - 150 mg pre-filled syringe x2 £1,218.78; PLGB 00101/1198 – 300 mg pre-filled pen x 1 £1218.78. **PI Last Revised:** June 2023. Full prescribing information, (SmPC) is available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

UK | 290802 | June 2023

Adverse Event Reporting:

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report.

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com

Cosentyx® (secukinumab) Northern Ireland Prescribing Information.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active enthesitis-related arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Presentations:** Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. *Plaque Psoriasis:* Adult recommended dose is 300 mg monthly. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight ≥ 50 kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight < 50 kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFα inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. *Ankylosing Spondylitis:* Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. *nr-axSpA:* Recommended dose 150 mg. *Enthesitis-related arthritis and juvenile psoriatic arthritis:* From the age of 6 years, if weight ≥ 50 kg, recommended dose is 150 mg. If weight < 50 kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. *Hidradenitis suppurativa:* Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. **Contraindications:** Hypersensitivity to the active substance or excipients. Clinically important, active infection. **Warnings & Precautions:** *Infections:* Potential to increase risk of infections; serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab than placebo in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. *Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):* New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. *Latex-Sensitive Individuals:* The removable needle cap of the 150mg pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. **Interactions:** Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. **Fertility, pregnancy and lactation:** *Women of childbearing potential:* Use an effective method of contraception during and for at least 20 weeks after treatment. *Pregnancy:* Preferably avoid use of Cosentyx in pregnancy. *Breast feeding:* It is not known if secukinumab is excreted in human breast milk. 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Rare cases of neutropenia CTCAE Grade 4 were reported. *Hypersensitivity reactions:* Urticaria and rare cases of anaphylactic reactions were seen. *Immunogenicity*: Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. *Other Adverse Effects:* The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. **Legal Category:** POM. **MA Number & List Price:** EU/1/14/980/005 - 150 mg pre-filled pen x2 £1,218.78; EU/1/14/980/010 – 300 mg pre-filled pen x 1 £1218.78. **PI Last Revised:** May 2023. Full prescribing information, (SmPC) is available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

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If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com