



A Clinical Study to Assess the Efficacy of Cannabinoid based Formula in Patients with Active Rheumatoid Arthritis

Clinical Trial

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Created: 12th December 2024

Finalized: December 23, 2024

Abstract

This single-group study evaluated the impact of Raphael's formula (RA-Resolution) on rheumatoid arthritis (RA)-related health outcomes in 12 adult participants. Participants took 0.5 mL of Raphael's formula product daily for 8 weeks, completed questionnaires, and attended their local diagnostics testing center for blood biomarker assessment at designated intervals. Questionnaire results showed significant improvements in eight health parameters by Week 4, including pain levels, sleep quality, and overall well-being, with five parameters remaining significantly improved by Week 8. DAS28 scores decreased from high to moderate disease activity, representing a 19.2% reduction. Blood biomarker analysis revealed no statistically significant changes, though a general non-significant increase was observed across all markers. Participant perceptions were highly positive, with 83.33% willing to continue using the product and 91.67% recommending it to others with RA. While further research is necessary to confirm these findings and investigate mechanisms, this study suggests that Raphael's formula might offer symptom relief and improved quality of life for individuals with RA.

1. Introduction

Rheumatoid arthritis (RA) is a chronic, systemic inflammatory condition primarily affecting the joints¹. It is characterized by symmetrical polyarthritis, often involving the small joints of the hands and feet, although other presentation patterns may occur². Common symptoms include joint swelling, pain, and stiffness, which are frequently more pronounced in the morning^{3,4}. Radiographic features of rheumatoid arthritis seen on X-ray include juxta-articular osteopenia, soft tissue swelling, joint deformities, and narrowing of joint spaces^{5,6}. Histological examination of the synovium shows hypertrophy and infiltration by lymphocytes and plasma cells⁷. Disease severity is often assessed using a scoring

system such as the Disease Activity Score in 28 joints (DAS28)⁸.

Raphael's formula is based on a non-psychoactive cannabinoid derived from the cannabis plant. It has garnered significant interest due to its potential therapeutic benefits, which include anti-inflammatory, antibacterial, antifungal, and neuromodulatory effects across various medical conditions.

Cannabinoids exhibit significant anti-inflammatory properties by reducing the expression of pro-inflammatory proteins and cytokines. They have shown protective effects against oxidative stress in



rheumatoid arthritis synovial fibroblasts and peripheral blood mononuclear cells¹¹.

With this in mind, Raphael Pharmaceutical Inc. sought to investigate the efficacy of cannabinoid-based Raphael's formula to improve RA-related health outcomes.

2. Methods

2.1. Participants

A total of 12 male and female participants, aged 25 years or above, were recruited for this study. Statistical analysis was performed on all available data on an intention-to-treat (ITT) basis. All participants satisfied the following inclusion and exclusion criteria.

Inclusion

- Male or female.
- Over 25 years of age.
- Has an anti-CCp blood test of 9 or more units (EU/mL) at Baseline
- Active RA-related inflammation characterized by at least 2 swollen joints.
- Willing to comply with study requirements.
- No known allergies to the ingredients listed in the product.
- No severe allergies, including allergies requiring the use of an Epi-Pen.
- Able to read, understand, and sign an informed consent form.
- Willing to avoid any other cannabis products throughout the study period.
- Agrees to use birth control methods for the duration of the study.
- Resides in the USA.

Exclusion

- Anyone with pre-existing chronic conditions that would prevent participants from adhering to the protocol, including oncological and psychiatric disorders.

- Anyone with known severe allergic reactions, including those that require an Epi-Pen.
- Anyone with any allergies to the study product ingredients.
- Women who are pregnant, breastfeeding, or trying to conceive. This includes any time up until the commencement of the study, the full duration of the study, and up to one month after the study has finished.
- Unable to read, understand, and sign an informed consent form.
- Any use of opiates in the last 4 weeks.
- Any regular use of cannabis for any reason in the last 4 weeks.
- Anyone with surgery or invasive procedures planned in the next 12 weeks or during the study period.
- Anyone with heart, lung, gastrointestinal, liver, kidney, or metabolic diseases.
- Anyone with active malignancy or active oncology treatment.
- Anyone using cytochrome P450 or 3A4 inhibitors, e.g., clarithromycin, erythromycin, diltiazem.
- Anyone with a lack of access to peripheral veins.
- Anyone unwilling to follow the study protocol.
- Anyone currently participating or planning to participate in a research study prior to or during the study period.
- Anyone taking Disease-Modifying Antirheumatic Drugs (DMARDs), like Remicase (infliximab), Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab pegol), and Simponi (golimumab).
- Anyone taking monoclonal antibody therapies.
- Anyone taking steroid treatment.



2.2. Study Design & Intervention Procedure

This single-group, hybrid study required participants to complete questionnaires and attend their local Quest Diagnostics Center for blood testing. The blood biomarkers analyzed were:

- C-Reactive Protein (CRP).
- Interleukin 6 (IL6).
- Sedimentation Rate-Westergren (ESR).
- Tumor Necrosis Factor-alpha (TNF- α).

Consent forms describing the study process, instructions, evaluation methods, and bill of rights were provided to participants before study onboarding.

At the screening stage, potential participants were instructed to attend their local Quest Diagnostics Center to undergo a Cyclic Citrullinated Peptide (CCP) antibody test, which is typically used to diagnose or rule out rheumatoid arthritis (RA). Originally, the study was designed to recruit participants with a minimum anti-CCP level of 20; however, due to slow recruitment and challenges in identifying eligible participants, this criterion was adjusted to a minimum anti-CCP level of 9 to facilitate enrollment. Anyone with an anti-CCP value of 9 units or more was included in the study. The upper limit of detection for this test was 250 units, so any participant with a value >250 was marked as 250 for the purposes of screening. Demographic information about the anti-CCP results can be seen in Table 1.

Following the consent process, participants were instructed to begin using the test product as directed. Participants took 0.5 milliliters once daily in the evening for eight weeks.

During the study, participants completed questionnaires at Week 4 and Week 8 and attended

a local Quest Diagnostics Center for blood testing at Week 2, Week 4, Week 6, and Week 8.

For the questionnaires, 16 individually analyzed questions were asked. A series of further questions were asked, constituting a total score for the Disease Activity Score (DAS28) questionnaire for Rheumatoid Arthritis¹². The DAS28 is calculated using a specific formula that incorporates the number of tender and swollen joints (out of 28), a measure of inflammation (ESR or CRP), and the patient's own assessment of their health or global disease activity. The resulting score ranges from approximately 0 to 10, with higher scores indicating more active disease. Scores under 3.2 generally suggest low disease activity, and scores below 2.6 are indicative of remission. For the purposes of this study, the online DAWN DAS28 calculator was used¹³.

2.3. Data Analysis & Statistics

Data from the questionnaires were collected using a textual 5-point Likert scale for each question. The textual Likert data was transformed into numerical values from 1 to 5, whereby a score of '1' represents the worst answer and a score of '5' the best. Statistical analysis compared participant outcomes at each check-in to their Baseline response. First, numerical questionnaire data were checked for normality using the D'Agostino & Pearson test. Normally distributed data were analyzed using a mixed-effects analysis with Dunnett's multiple comparisons tests, while non-normally distributed data were analyzed using a Kruskal-Wallis test with Dunn's multiple comparisons corrections.

For questions evaluated only at Week 8 pertaining to the product, results were presented as the percentage of subjects reporting a "Yes" answer.

Data from the blood tests were checked for normality using the D'Agostino & Pearson test. Normally distributed data were analyzed using a mixed-effects analysis with Dunnett's multiple comparisons tests, while non-normally distributed data were analyzed



using a Kruskal-Wallis test with Dunn's multiple comparisons corrections. Statistical analyses were performed in GraphPad Prism 10, and the significance level was set at 0.05.

Further analysis was conducted to assess the percentage of participants reporting "negative" answers or severe symptoms at all time points, as presented in Table 2. This includes participants who selected responses such as "severe" and "distracting", "very bad" and "bad", and 9 or 10 on the pain scale. Additionally, the percentage of participants classified within each disease activity level based on the DAS28 score is also presented.

3. Results

3.1. Impact of Raphael' formula on Joint and Overall Health Parameters as Evaluated by Questionnaires

The effect of the product on 16 joint and overall health-related parameters was evaluated through questionnaires completed by participants at Baseline, Week 4, and Week 8.

By Week 4, 8 of 16 parameters were significantly improved from Baseline. These included pain levels, the ability to live life to the fullest, the ability to pursue your passions and hobbies, the ability to enjoy relationships, the ability to enjoy life on a daily basis, sleep, and relaxation (Figure 1, Table 2).

By Week 8, 5 of the 16 parameters remained significantly different from Baseline. These included quality of life, overall well-being, the ability to live life to the fullest, and the ability to enjoy life daily (Figure 1, Table 2).

This suggests that the test product might have more substantial benefits over a short period of time, which might plateau in the long term.

The percentage of participants who selected the two most negative answers for each question was also evaluated at Baseline, Week 4, and Week 8. At Week 8, all 16 questions showed fewer participants choosing a negative result. In particular, pain levels dropped from 75% of participants choosing negative results to 50% in Week 8, indicating a potential for Raphael's formula to improve pain outcomes, although the Likert data was non-significant. Another notable reduction is participants who chose negative results for morning stiffness from 75% at Baseline to 41.67% at Week 8, indicating a notable improvement.

3.2. Impact of Raphael's formula on DAS28 Score

Participants were asked to respond to questions from the DAS28 questionnaire to assess their disease activity. A total score of <2.6 indicates remission, ≥ 2.6 to <3.2 indicates low disease activity, ≥ 3.2 to ≤ 5.1 indicates moderate disease activity, and >5.1 indicates high disease activity.

At the Baseline, the mean DAS28 score was 5.52 ± 1.33 , indicating high disease activity overall for participants. This score significantly decreased at Week 4 to 4.51 ± 1.55 compared to the Baseline. Week 8 also showed a significant improvement from the Baseline, with a mean overall score of 4.46 ± 2.09 , indicating a total decrease from high disease activity to moderate disease activity. This improvement was a 19.2% reduction in DAS28 score (Table 2, Figure 2).

The percentage of participants classified according to disease activity was also evaluated. The percentage of participants classified as in remission increased from 0% at Baseline to 16.67% at Week 8. The percentage of participants classified as having low disease activity increased from 8.33% to 16.67%. A decrease was observed in the percentage



of participants classified as having high disease activity from 66.67% at Baseline to 41.67% at Week 8.

3.3. Impact of Raphael' formula on Blood Biomarkers

Participants attended their local Quest diagnostics center for blood testing at Baseline, Week 2, week 4, Week 6, and Week 8. The markers examined were CRP, IL-6, ESR, and TNF- α .

No significant differences were observed in any of the blood biomarkers compared to the Baseline. All of the biomarkers showed an overall non-significant percentage increase from the Baseline, ranging from 7.56 to 45.15% (Figure 3, Table 3).

3.4. Participants' Overall Reception of Raphael' formula

At the end of the study, participants were asked 2 questions about whether they would like to continue using the product or recommend it to other people with RA. Participants responded either "Yes" or "No" to the questions. The percentage of participants who responded "Yes" was then calculated.

Overall, the participants responded favorably to each question (Table 4). 83.33% of participants responded "Yes" to the question "Would you continue using this product?". 91.67% of participants responded "Yes" to the question, "Would you recommend this product to other people with rheumatoid arthritis?" (Table 4).

4. Discussion

This study provides preliminary data on the impact of Raphael's formula on RA-related health outcomes, as assessed by blood biomarker analysis, DAS28 disease activity scores, and participant-reported outcomes through questionnaires.

The findings from the blood biomarker testing were inconclusive regarding the direct anti-inflammatory effects of Raphael's formula. None of the biomarkers analyzed (CRP, IL-6, ESR, or TNF- α) exhibited statistically significant changes compared to the Baseline. In fact, all biomarkers displayed a non-significant overall percentage increase, with IL-6 demonstrating the highest increase. These results suggest that the potential anti-inflammatory benefits of Raphael's formula may not be directly measurable through these specific biomarkers within the study's duration. It is important to note that inflammatory biomarkers are influenced by many external and individual factors, which may obscure the isolated effects of the product. Furthermore, the relatively small sample size may have limited the statistical power of the study. However, as this study was designed as a pilot, these limitations are acceptable and provide valuable insights to inform the design of future studies, including the need for larger sample sizes and extended study durations.

Future research could explore longer study durations or larger sample sizes.

Despite the lack of significant biomarker changes, participant-reported outcomes reflected the positive effects of Raphael's formula on several health-related parameters. By Week 4, significant improvements were observed in 8 of 16 parameters, including pain levels, sleep quality, and overall enjoyment of life. However, these benefits diminished by Week 8, with only 5 parameters showing significant improvements. This trend may suggest an initial response to Raphael's formula that either plateaus over time or indicates the need for dose adjustments to sustain its effects. Additionally, the DAS28 scores showed a meaningful reduction in disease activity from high to moderate. Notably, there was a decrease in the percentage of participants reporting negative symptoms across all parameters from Baseline to later time points. This demonstrates the potential of Raphael's formula to support symptom management and improve the



quality of life for individuals with RA, even without significant biomarker changes.

Most participants responded favorably to the product, further highlighting the perceived benefits of Raphael's formula as an adjunct to RA management.

Overall, the results of the study suggest that Raphael's formula may have beneficial effects on symptom management and overall well-being for individuals with RA, even if its direct impact on inflammatory biomarkers remains unclear. Future studies could aim to investigate the mechanisms of Raphael's formula's action further, perhaps by using a gold-standard randomized controlled study method.

5. Conclusion

The results of this study demonstrate that Raphael's formula may provide beneficial support to individuals with RA, particularly in improving symptom-related parameters. While blood biomarker changes were not significant, reductions in DAS28 scores highlight Raphael's formula's potential to improve disease activity and quality of life. Participant reception was overwhelmingly positive, with the majority expressing satisfaction with the product and willingness to continue its use. This preliminary study suggests that Raphael's formula is a promising adjunctive option for managing RA symptoms.

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Table 1. Anti-CCP levels at the start of the study (units).

Anti-CCP Ab (Units)	
Mean	107.9
Minimum	9
Maximum	250
Range	241
STD	122.41



Table 2: Statistical Outcomes of Changes in RA-Related Parameters According to Questionnaire Data. % Change indicates a change in mean values from the Baseline.

An increase in score indicates an improvement. Green cells highlight statistically significant outcomes ($P \leq 0.05$). The percentage of participants who selected the two most “negative” answers is also presented alongside the percentage of participants classified into each disease activity category as measured by the DAS 28. This table provides the numerical data presented in Figures 1 and 2.

Question	Baseline (n=12)			Week 4 (n=12)			% of participants who selected negative answers	Week 8 (n=12)				% of participants who selected negative answers
	Mean	SD	% of participants who selected negative answers	Mean	SD	P-value		Mean	SD	P-value	% Change	
How would you rate your Quality of Life?	3.08	1.08	33.33	3.50	1.00	0.2309	16.67	3.67	0.89	0.0486	19.16	16.67
How would you rate your overall wellbeing	2.83	1.03	41.67	3.42	1.16	0.0819	33.33	3.58	0.90	0.0101	26.50	16.67
How would you rate your pain levels?	1.83	0.83	75.00	2.50	1.00	0.0234	41.67	2.50	1.17	0.0957	36.61	50.00
How would you rate your stiffness levels	2.08	1.00	66.67	2.67	1.23	0.1884	33.33	2.58	1.31	0.2343	24.04	41.67
How would you rate your fatigue levels?	2.08	0.79	66.67	2.75	0.75	0.0690	33.33	2.92	1.16	0.0608	40.38	41.67
How would you rate your ability to live life to the fullest?	2.42	1.00	58.33	3.25	1.14	0.0099	33.33	3.25	1.14	0.0038	34.30	25.00
How would you rate your ability to complete your everyday activities?	2.50	1.00	50.00	3.33	0.98	0.0608	25.00	3.08	1.16	0.2218	23.20	33.33
How would you rate your ability to pursue your passions and hobbies?	2.17	0.94	66.67	3.00	1.35	0.0099	33.33	2.83	1.19	0.0690	30.41	41.67
How would you rate your ability to enjoy the relationships in your life?	2.92	1.24	41.67	3.42	1.24	0.0127	16.67	3.58	1.44	0.0690	22.60	25.00
How would you rate your emotional wellbeing?	2.83	1.27	50.00	3.58	1.16	0.0981	25.00	3.33	1.23	0.2343	17.67	16.67
How would you rate your mental wellbeing?	3.00	1.35	41.67	3.83	1.11	0.0608	16.67	3.67	1.30	0.2038	22.33	16.67
How would you rate your ability to enjoy life on a daily basis?	3.00	1.28	33.33	3.58	1.08	0.0212	16.67	3.67	1.07	0.0234	22.33	16.67
How would you rate your sleep?	2.50	1.09	50.00	3.58	1.16	0.0444	16.67	3.42	1.16	0.0605	36.80	16.67
How would you rate your levels of relaxation?	2.58	0.90	41.67	3.33	1.07	0.0379	8.33	3.08	1.24	0.2343	19.38	25.00
How would you rate your stress levels?	2.50	1.45	50.00	3.08	1.24	0.1535	25.00	3.08	1.16	0.1535	23.20	25.00
How would you rate your morning stiffness?	2.00	0.95	75.00	2.83	1.19	0.0608	33.33	2.58	1.31	0.1884	29.00	41.67
DAS28 Score	5.52	1.33		4.51	1.55	0.0194		4.46	2.09	0.0305	-19.20	

DAS 28: Percentage of Participants Classified According to Disease Activity			
% In Remission	0	8.33	16.67
% Low Disease Activity	8.33	8.33	16.67
% Moderate Disease Activity	25.00	41.67	25.00
% High Disease Activity	66.67	41.67	41.67



Table 3: Statistical Outcomes of Changes in Blood Biomarkers. % Change indicates a change in mean values from the Baseline. A decrease in value indicates an improvement. Green cells highlight statistically significant outcomes ($P \leq 0.05$). This table provides the numerical data presented in Figure 3.

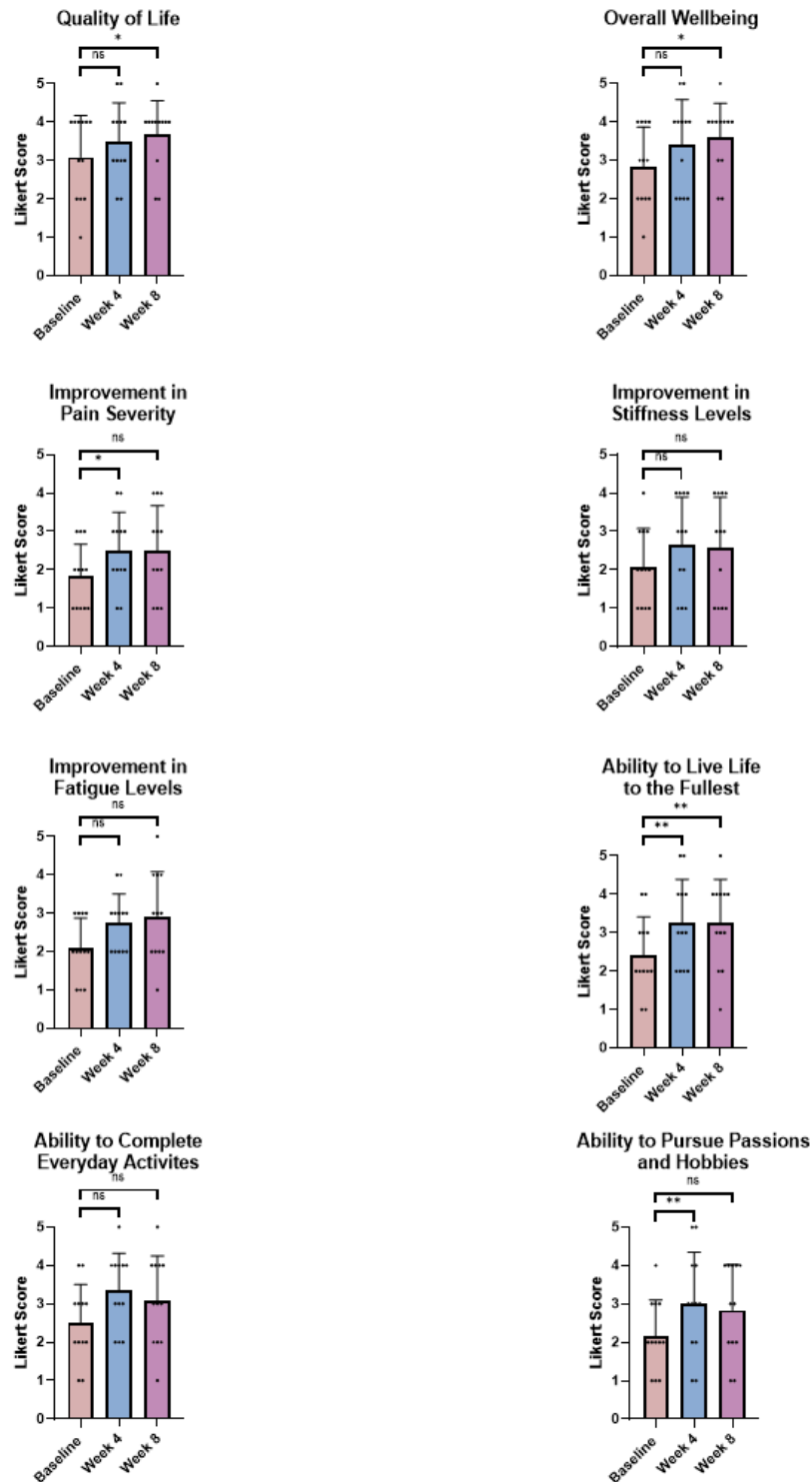
Biomarker	Baseline			Week 2				Week 4				Week 6				Week 8				
	Mean	SD	N	Mean	SD	N	P-value	Mean	SD	N	P-value	Mean	SD	N	P-value	Mean	SD	N	P-value	%Change
CRP (mg/L)	2.25	3.84	12	5.00	6.05	11	0.3377	2.00	3.10	12	>0.9999	2.10	3.25	10	>0.9999	2.42	3.45	12	>0.9999	7.56
IL-6 (pg/mL)	2.68	3.19	12	3.54	4.07	11	0.9664	2.16	2.58	11	0.7765	5.46	8.57	9	0.7751	3.89	4.42	11	0.6633	45.15
ESR (mm/hr)	14.83	12.73	12	13.33	12.84	9	0.8654	19.64	22.23	11	0.8311	15.00	10.89	9	0.9937	19.64	18.16	11	0.7348	32.43
TNF- α (pg/mL)	0.78	0.32	12	0.98	0.24	11	0.3835	0.97	0.21	11	0.3242	1.09	0.31	9	0.1679	0.88	0.26	12	0.6527	12.82

Table 4: Percentage of Participants Answering “Yes” To Product Satisfaction Questions.

Question	% Yes
Would you continue using this product?	83.33%
Would you recommend this product to other people with rheumatoid arthritis?	91.67%

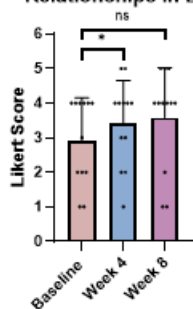


Figure 1. Visual Representation of Individual Questionnaire Data. Data is graphed as group means, and standard deviation and individual data points are shown. ns = $P > 0.05$, * = $P \leq 0.05$, ** = $P < 0.01$. Baseline, $n = 12$; Week 4, $n = 12$; Week 8, $n = 12$. An increase indicates an improvement.

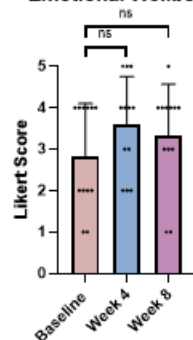




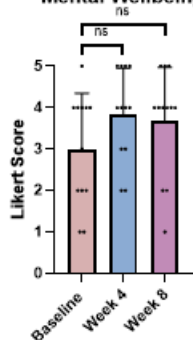
Ability to Enjoy the Relationships in Life



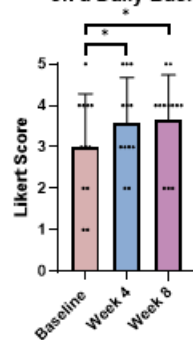
Emotional Wellbeing



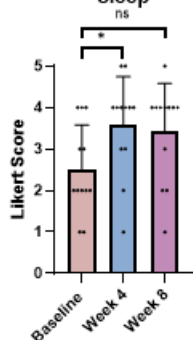
Mental Wellbeing



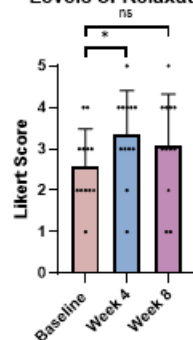
Ability to Enjoy Life on a Daily Basis



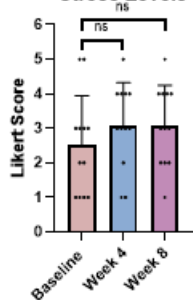
Sleep



Levels of Relaxation



Improvement in Stress Levels



Improvement in Morning Stiffness

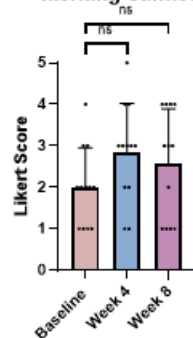




Figure 2. Visual Representation of DAS28 Questionnaire Data. Data is graphed as group means, and standard deviation and individual data points are shown. * = $P \leq 0.05$. Baseline, $n = 12$; Week 4, $n = 12$; Week 8, $n = 12$. A decrease indicates an improvement.

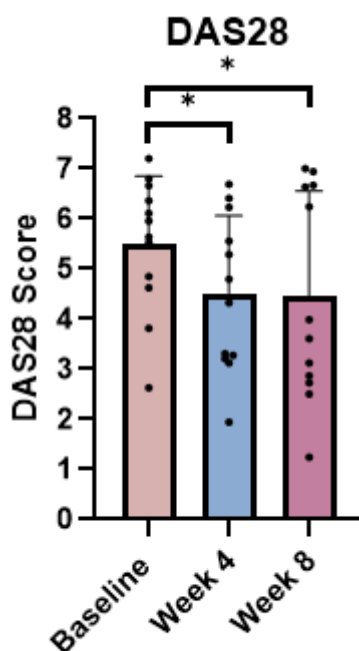


Figure 3. Visual Representation of Blood Biomarker Levels. Data is graphed as group means, and standard deviation and individual data points are shown. ns = $P > 0.05$. A decrease indicates an improvement.



Appendix A: Data Interpretation

(Please consult an attorney before using any claims – these are just example claims from the data that could be used)

*The following information is provided for educational and informational purposes only. Claim examples by Citruslabs are not intended as legal advice or guidance. Citruslabs does not endorse any specific claims made by its clients and cannot guarantee the accuracy, reliability, or completeness of the information provided. The information contained herein is not a substitute for professional legal advice. Anyone seeking to make marketing claims based on the results of a clinical study should consult a qualified attorney to discuss the legal and regulatory requirements governing such claims. Citruslabs shall not be liable for any damages or losses arising from using this information or any reliance on the accuracy or completeness thereof.

By Week 4, Raphael's formula significantly improved:

- Pain levels.
- The ability to live life to the fullest.
- The ability to pursue passions and hobbies.
- The ability to enjoy relationships.
- The ability to enjoy daily life.
- Sleep rating.
- Relaxation rating.
- DAS28 score.

Raphael's formula improved DAS28 scores from high disease activity to moderate disease severity by Week 4, which was maintained through Week 8.

By Week 8, Raphael's formula significantly improved:

- Quality of life.
- Overall wellbeing.
- The ability to live life to the fullest.
- The ability to enjoy daily life.
- DAS28 Score.

By Week 8:

- 83.33% of participants agreed that they would continue using the product.
- 91.67% of participants agreed that they would recommend the product to other people with RA.