Nutritional Intervention in Postviral Chronic Fatigue Syndrome and Fibromyalgia (CFS/FMS). A Unique Porcine Serum Polypeptide Nutritional Supplement Principal Investigators: Jacob Teitelbaum MD* , Gaetano Morello ND**, Sarah Goudie***

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Abstract

Aims: To determine the effectiveness of a unique polypeptide serum extract in improving the symptoms of post viral and other causes of CFS and fibromyalgia (CFS/FMS).

Background: CFS/FMS affects 2.1% of the world's population. An earlier study showed these oral polypeptides to be beneficial in 60% of cases. It is estimated that the current pandemic is triggering postviral CFS/FMS in about 10 to 15% of infections and will likely cause well over 15 million new CFS/FMS cases. This creates a great need for effective supportive options for CFS/FMS.

Objectives: The purpose of this initial pilot study was to further explore the effectiveness of this unique polypeptide nutritional support, including its effectiveness in those with postviral as compared to other causes of CFS and fibromyalgia.

Method: An open-label prospective study of 100 people recruited worldwide from the investigator's (JT) practice and newsletter.

*Inclusion criteria***:** Meeting the CDC diagnostic criteria for CFS or ACR 2010 (amended 2011) diagnostic criteria for fibromyalgia. People were asked if their CFS/FMS began after a viral infection.

Interventions: 100 subjects received the porcine serum polypeptide extract, four 500 mg tablets twice daily for five weeks after an initial five-day loading dose.

Outcome measures: All patients were assessed at baseline and after five weeks of treatment using a Visual Analog Scale (1-10 points) rating energy, sleep, cognitive function, pain, overall well-being, anxiety, and digestive health, as well as the Revised Fibromyalgia Impact Questionnaire (FIQR). The primary outcome measure was the pre- and post-treatment VAS composite score for the first five symptoms. FIQR, individual symptom VAS, and the person's

overall assessment of much worse, worse, no change, better, or much better were assessed as secondary outcome measures.

Results: 100 subject patients completed the treatment trial. 59% of subjects rated themselves as improved, with 13% rating themselves as much better.

In the 59% of subjects who improved, significant improvement was seen in all categories:

1. 79% average increase in energy (p<.001)
2. 84.2% average increase in overall well-being (p<.001)
3. 45.7% average improvement in sleep (p<.001)
4. 52.2% average improvement in mental clarity (p<.001)
5. 22% average decrease in pain (p=.001)
6. 54.4% average composite improvement in the above five domains (p<.001)
7. 35.3% average decrease in anxiety (p<.001)
8. 57.1% average improvement in digestive symptoms (p<.001)
9. FIQR decreased from 61.9 to 39.3. (36.5%) (p<.001)

The intervention was essentially equally effective in the postviral (n=52) versus nonviral (n=48) CFS/FMS group. Looking at the entire participant group of 100, improvements from baseline were also highly significant.

Conclusions: A unique porcine serum polypeptide nutritional supplement (Recovery Factors® by Recovery Nutraceuticals), resulted in markedly improved energy levels, sleep, mental clarity, pain relief, calming, digestion and overall well-being in those with CFS and fibromyalgia. The effect was similar in those with postviral CFS/FMS versus other triggers, suggesting that this intervention may also be effective for persistent post-viral symptoms.

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Keywords: Fibromyalgia, chronic fatigue syndrome, polypeptides, immune deficiency, pain, pain relief, COVID-19, postviral CFS, treatment

Introduction

Fibromyalgia (FMS), which currently affects about 2.1% of adults worldwide and an estimated three to six million Americans[1], and chronic fatigue syndrome (CFS) are two overlapping and disabling

syndromes. CFS affects more than one million people in the United States. There are tens of millions of people with similar fatiguing illnesses who do not fully meet the strict research definition of CFS.[2] Severe persistent fatigue, diffuse migratory pain, cognitive dysfunction, and disordered sleep are common symptoms reported by patients suffering with these syndromes, along with gastrointestinal symptoms and anxiety exacerbated by their illness.

Many of the problems seen in CFS/FMS may be associated with a decrease in tissue energy levels and altered energy metabolism. Numerous factors contribute to the energy crisis seen in CFS and fibromyalgia. In the author's (JT) previously published RCT, optimizing energy levels using the S.H.I.N.E.® Protocol, which addresses sleep, hormonal optimization, infections, and nutritional support, resulted in the treatment group improving dramatically. This protocol resulted in an average 90% improvement in quality of life ($p<.0001$ versus placebo).[3]

Another study recently published by our group showed that this porcine serum polypeptide extract used in this current study significantly improved fibromyalgia in 60% of cases, with these showing an average 59% increase in both energy and quality of life. A significant increase in total IgG and IgG 1 – 4 subsets after intervention was also seen.[4]

Since the earlier study was done, we have had the onset of the COVID-19 pandemic. At the time of writing this study report, there have been over 100 million cases worldwide of COVID-19.[5] In one study of people with the virus, more than half of those infected continued to be symptomatic with 41% noting a worse quality of life.[6] It is estimated that 10 to 15% of these will develop persistent disabling symptoms, which has been coined "Long Haulers Syndrome" or Long COVID." [7] Dr. Anthony Fauci of the NIH has correctly noted that this condition has symptoms that are highly suggestive of postviral chronic fatigue syndrome.[8]

it is not surprising that COVID 19 is triggering postviral CFS/FMS, as numerous viruses have been documented to do so. These include SARS, Epstein Barr virus, Ross River virus , enteroviruses, human herpesvirus-6 and numerous others. [7] It is currently suspected that COVID-19 will result in about 10 million new cases of post viral CFS worldwide.[7]

About half of the cases of CFS/FMS are associated with a postviral trigger. This was also found in the current study where 52 of the 100 subjects noted that their symptoms began after a viral infection. This treatment trial was done to further explore the effectiveness of this polypeptide in CFS/FMS in general, and in post viral CFS/FMS in particular.

Materials and Method

Patient Enrollment

The author (JT) invited patients in his practice as well as readers of his newsletter (available at Vitality101.com) to join in this study. 100 participants qualified for the study by meeting diagnostic criteria for CFS or fibromyalgia, being willing to take the supplement, and completing the pre- and post-

study questionnaires. No compensation was given for being in the study, except all participants received the supplement free of charge.

Inclusion Criteria

1. Subjects needed to meet the ACR 2010 (amended 2011) diagnostic criteria for fibromyalgia[9] or the CDC criteria for chronic fatigue syndrome[10].

2. Subjects needed to be over 18 years of age and nonpregnant.

Exclusion Criteria

1. Subjects could not be on the blood thinner Coumadin.

Outcome Measures

Primary outcome measures: A visual analog scale combining effects on energy, sleep, pain, cognitive function and overall well-being. The VAS questions asked were:

Please rate the following on a scale of 1 (near dead) to 10 (excellent)

A) How is your energy?

1 2 3 4 5 6 7 8 9 10

1= near dead and 10= excellent

B) How is your sleep?

1 2 3 4 5 6 7 8 9 10

1= no sleep and 10= 8 hours of sleep a night without waking

C) How severe is your achiness/pain? (1 is worst possible pain)

1 2 3 4 5 6 7 8 9 10

1= very severe pain and 10 = pain free

D) How is your overall sense of well-being?

1 2 3 4 5 6 7 8 9 10

1= near dead and 10= excellent

E) How is your mental clarity?

1 2 3 4 5 6 7 8 9 10

1= brain dead and 10= good clarity

Secondary outcome measures: Visual analog scales looking at:

1. Anxiety and lower digestive symptoms (gas, bloating, diarrhea, constipation). The questions asked were:

A) Rate your level of anxiety:

1 2 3 4 5 6 7 8 9 10

1= severe anxiety and 10= anxiety not a problem

B) Rate the severity of your digestive symptoms (gas, bloating, diarrhea, constipation):

1 2 3 4 5 6 7 8 9 10

1= severe problem and 10= digestion not a problem

2. Each subject's overall subjective feeling after taking the supplement (i.e., much better, somewhat better, no change, somewhat worse, or much worse.

3. Revised Fibromyalgia Impact Questionnaire (FIQR)[11].

Study subjects were also asked to note if they experienced any adverse side effects. They were also asked to note if they had any other health conditions, and if their illness began, or had a major decline, with self-assessed viral-like symptoms.

Study Design

The design (a prospective open, unblinded trial) used outcome measures in the form of the Visual Analog Scale (VAS) questionnaire and FIQR, which were kept simple to improve compliance. All patients gave informed consent, and the study was approved by the Practitioner Alliance Network IRB (ID#: PAN Study RF-2- 2020).

Patients could continue their currently prescribed drug treatments during the study. They were asked not to make any changes to their current protocol during the study. The study duration was ~ five weeks, preceding by a 5-day loading dose, for a total of 40 days. If the subjects felt better with a lower dose, they were allowed to decrease from the eight pills a day. In that event, they were still instructed to complete the poststudy questionnaire when they had a few of the initial 360 pills left.

Study Intervention

The nutritional intervention (or "The test product") consisted of a unique proprietary polypeptide extract from porcine serum (Recovery Factors® from Recovery Nutraceuticals, www.RecoveryFactors.com). Recovery Factors is a complete profile serum-derived, porcine protein, extracted through proprietary extraction mechanisms targeting all 20 amino acids and iron. No lipids or glucose are extracted.

This has been used for over a decade in hospitals for treating severe malnutrition. Subjects were given the following dosing instructions:

Day 1-3: Take four tablets, three times a day (12 total tablets per day) for three days.

Day 4-5: If energy levels are improved, then continue the same dosage for day four and five. If no energy improvement, increase the dosage to five tablets, three times a day for day 4 and 5 (15 total tablets per day).

Day 6: Drop to four tablets twice per day (eight total tablets per day).

It is recommended to take the doses first thing in the morning on an empty stomach, and at around 3 p.m. in the afternoon.

Each subject was supplied with 360 tablets and instructed to complete the follow-up form when they had a few days of the supplement left (to ensure that they were still on the supplement when they completed the poststudy questionnaire).

Statistical Analysis

All analyses were performed using the Statistical Package for the Social Science (SPSS) version 27.0 (SPSS Inc., IBM Corp., Armonk, USA). Continuous variables were assessed for normality using visual inspection of histograms and qq-plots. T-tests, chi-square tests, and Fisher's exact tests were used to describe differences on demographic and clinical variables between subgroups within the sample. The primary outcome measure was the VAS total score measured pre- and post-treatment. Secondary outcomes were pre- and post-treatment total scores on each of the seven VAS subscales as well as the FIQR total score. A series of mixed model ANOVAs (analysis of variance) was used to assess whether there was an effect of treatment by examining change in the primary and secondary outcomes. Time was entered as a within-subjects factor (i.e, pre- and post-treatment scores) and post-viral illness status entered as a between-subjects factor (yes: n = 52; no: n = 48). The group by time interaction was examined to determine whether the effect of treatment was different for subjects with and without post-viral illness onset. The assumption of equality of variances was assessed with Levene's test. The alpha level was set to .05 for the primary analysis. To adjust for multiple testing in relation to the secondary outcome analyses, a Bonferonni Correction was applied with the alpha level set to .006 (.05/8). Effect sizes are reported as partial eta squared (η^2) and can be interpreted as .01 = small, .06 = medium, and .13 = large.

A supplementary set of analyses was conducted to determine whether treatment effects were different for subjects who self-reported improvement (n = 59, 'better' or 'much better') versus those who reported no improvement (n = 41, 'no change', 'worse', or 'much worse'). Mixed model ANOVAs were conducted for each of the primary and secondary outcomes with improvement status entered as the between-subjects factor along with corresponding group by time interactions. The interactions were used to test group differences in treatment effects. To better understand group differences, follow-up paired samples t-tests were computed to determine examine treatment effects in each group separately. The same alpha levels as described above were applied to these supplementary analyses.

Results

A total of 100 participants completed the study. No missing data were observed on any of the variables. The sample characteristics are summarized for the full sample in Table 1 and by self-reported improvement status in Table 2. Participants who self-reported improvement had a slightly shorter duration ofprestudy CFS or fibromyalgia compared to those who reported no improvement. There were no group differences on age, gender, diagnosis, or presence of comorbid medical conditions.

For the primary analysis, there was a main effect for time indicating a significant improvement in VAS total scores ($F_{1,98} = 172.15$, $p < .001$, $\eta^2 = .637$). There was no main effect of post-viral illness status ($F_{1,98} = 1.19$, $p = .278$, $\eta^2 = .012$) or a group by time interaction ($F_{1,98} = 0.85$, $p = .360$, $\eta^2 = .009$) indicating that there is no difference in the effect of treatment between participants with and without post-viral illness onset. A secondary analysis of the VAS subscale scores and FIQR scores yielded a pattern of results consistent with the above, indicating main effects for time, but no effect for post-viral illness status (all ps > .150). A description of the main treatment effect in the full sample is summarized in Table 3. Full results of the mixed models are reported in Table 4.

A supplementary analysis examining change in VAS total scores by improvement status revealed a main effect for time ($F_{1,98} = 212.15$, $p < .001$). There was a significant group by time interaction ($F_{1,98} = 51.91$, $p < .001$, $\eta^2 = .364$) indicating that the treatment effects were larger for those who self-reported improvement versus no improvement (see Figure 1). Additional analyses of VAS subscales revealed significant group by time interactions, with greater change for the improvement group noted for all VAS subscale scores except for pain and anxiety, the latter of which did not survive a Bonferroni correction. This can be taken to mean that treatment effects for pain and anxiety were similar across groups. For the FIQR, a significant group by time interaction indicated a greater effect for treatment among those who self-reported improvement. Full results of the mixed model ANOVAs are reported in Table 5.

Given the interesting finding that the effect of treatment differs between those who self-reported improvement versus no improvement, subsequent analyses were conducted separately for each group to gain further insight into who responds to the polypeptide treatment. Paired samples t-tests revealed that those who self-reported improvement showed large improvements across all symptom scales. A description of these effects is included in Table 3. In contrast, those who self-reported no improvement showed more selective symptom changes, with no significant improvement noted on subscales measuring pain ($p = .256$), anxiety ($p = .074$), and cognition ($p = .011$, did not survive a Bonferroni correction).

Table 1. Sample Descriptive Statistics

Variable	Full Sample (n = 100)
Age in years, mean (SD)	55.77 (11.99)
Gender, male %	15
Duration of illness in years, mean (SD)	18.97 (11.28)
Diagnosis of CFS, %	99
Diagnosis of FMS, %	92
Diagnosis of CFS + FMS,	91

Comorbid medical condition, %	90
Self-reported feeling post-treatment, %	
Much worse	1
Worse	6
No change	34
Better	46
Much better	13

Note. CFS = chronic fatigue syndrome ; FMS = fibromyalgia syndrome.

Table 2. Sample Descriptive Statistics by Self-Reported Improvement Status

Variable	Improvement (n = 59)	No improvement (n = 41)	Group comparison Test statistic (p-value)
Age in years, mean (SD)	55.66 (1.54)	55.93 (12.39	t = .11 (.914)
Gender, male % (n)	10 (6)	22 (9)	X^2 = 2.62 (.105)
Duration of illness (years), mean (SD)	17.06 (1.43)	21.73 (1.77)	t = 2.07 (.041)
Diagnosis of CFS, % (n)	100 (59)	98 (40)	Fisher's exact p = .410
Diagnosis of FMS, % (n)	95 (56)	88 (36)	Fisher's exact p = .267
Diagnosis of CFS + FMS, % (n)	95 (56)	85 (35)	Fisher's exact p = .155
Comorbid medical condition, % (n)	90 (53)	90 (37)	Fisher's exact p = 1.00

Note. CFS = chronic fatigue syndrome ; FMS = fibromyalgia syndrome.

Table 3. Average VAS and FIQR Scores and Percent Change from Baseline.

Domain (VAS 1-10)	Full sample (N = 100)				59% of subjects who improved			
	Pre Rx, mean (SD)	Post Rx, mean (SD)	% Improvement	p-value	Pre Rx, mean (SD)	Post Rx, mean (SD)	% Improvement	p-value
1. Energy	3.6 (1.2)	5.7 (2.0)	58.3	<.001	3.8 (1.2)	6.8 (1.4)	79.0	<.001
2. Sleep	4.4 (1.5)	6.1 (1.9)	38.6	<.001	4.6 (1.5)	6.7 (1.8)	45.7	<.001
3. Pain	5.1 (1.8)	5.9 (1.9)	15.7	.001	5.0 (1.7)	6.1 (1.9)	22.0	.001
4. Well-being	3.7 (1.1)	6.0 (1.9)	62.2	<.001	3.8 (1.0)	7.0 (1.5)	84.2	<.001
5. Cognition	4.4 (1.4)	6.1 (1.9)	38.6	<.001	4.6 (1.3)	7.0 (1.5)	52.2	<.001
6. Total 1-5	21.2 (4.3)	29.8 (7.5)	40.6	<.001	21.7 (4.0)	33.5 (5.8)	54.4	<.001
7. Calmness	5.3 (1.9)	6.7 (2.2)	26.4	<.001	5.1 (1.7)	6.9 (2.0)	35.3	<.001
8. Digestion	4.1 (2.0)	5.9 (2.3)	43.9	<.001	4.2 (1.8)	6.6 (2.2)	57.1	<.001
9. FIQR total	61.5 (12.8)	44.5 (15.7)	27.6	<.001	61.9 (12.8)	39.3 (15.8)	36.5	<.001

Note. VAS = Visual analog scale (1-10); FIQR = Revised fibromyalgia impact questionnaire. The p-values for full sample represent results of the mixed model ANOVA indicating a main effect of time. The p-values for the subjects who improved represent results from the paired samples t-tests.

Table 4. Results of Mixed Model ANOVAs Examining Change in Primary and Secondary Outcome by Post-Viral Illness Status (N = 100)

Domain (VAS 1-10)	F-statistic (p-value)	Effect size η^2
1. Energy	Time: 158.57 (<.001) Time*Group: 1.73 (.191)	.618 ---
2. Sleep	Time: 100.08 (<.001) Time*Group: 0.69 (.409)	.505 ---
3. Pain	Time: 11.87 (.001) Time*Group: 0.03 (.856)	.108 ---
4. Well-being	Time: 278.17 (<.001) Time*Group: 2.06 (.154)	.626 ---
5. Cognition	Time: 90.17 (<.001) Time*Group: 0.12 (.726)	.479 ---
6. Total (1-5)	Time: 172.15 (<.001) Time* Group: 0.85 (.360)	.637 ---
7. Calmness	Time: 39.57 (<.001) Time*Group: 0.09 (.768)	.288 ---
8. Digestion	Time: 65.68 (<.001) Time*Group: 0.04 (.852)	.401 ---
9. FIQR total	Time: 149.70 (<.001) Time*Group: 0.11 (.744)	.604 ---

Note. VAS = Visual analog scale (1-10); FIQR = Revised fibromyalgia impact questionnaire.
Group: Post-viral illness - yes (n = 52); Post-viral illness - no (n = 48)

Table 5. Supplementary Mixed Model ANOVAs Examining Change in Primary and Secondary Outcomes by Improvement Status (N = 100)

Domain VAS (1-10)	F-statistic (p-value)	Effect size η^2
1. Energy	Time: 197.97 (<.001) Time*Group: 58.05 (<.001)	--- .372
2. Sleep	Time: 96.04 (<.001) Time*Group: 14.71 (<.001)	--- .130
3. Pain	Time: 9.97 (.002) Time*Group: 2.15 (.145)	--- .021
4. Well-being	Time: 192.38 (<.001) Time*Group: 46.50 (<.001)	--- .322
5. Cognition	Time: 93.69 (<.001) Time*Group: 28.91 (<.001)	--- .228
6. Total (1-5)	Time: 212.15 (<.001) Time*Group: 51.91 (<.001)	--- .364
7. Calmness	Time: 35.32 (<.001) Time*Group: 7.03 (.009)	--- .067
8. Digestion	Time: 61.38 (<.001) Time*Group: 13.14 (<.001)	--- .118
9. FIQR total	Time: 164.24 (<.001) Time*Group: 31.56 (<.001)	--- .244

Note. VAS = Visual analog scale (1-10); FIQR = Revised fibromyalgia impact questionnaire. Group: Improvement (n = 59); No improvement (n = 41).

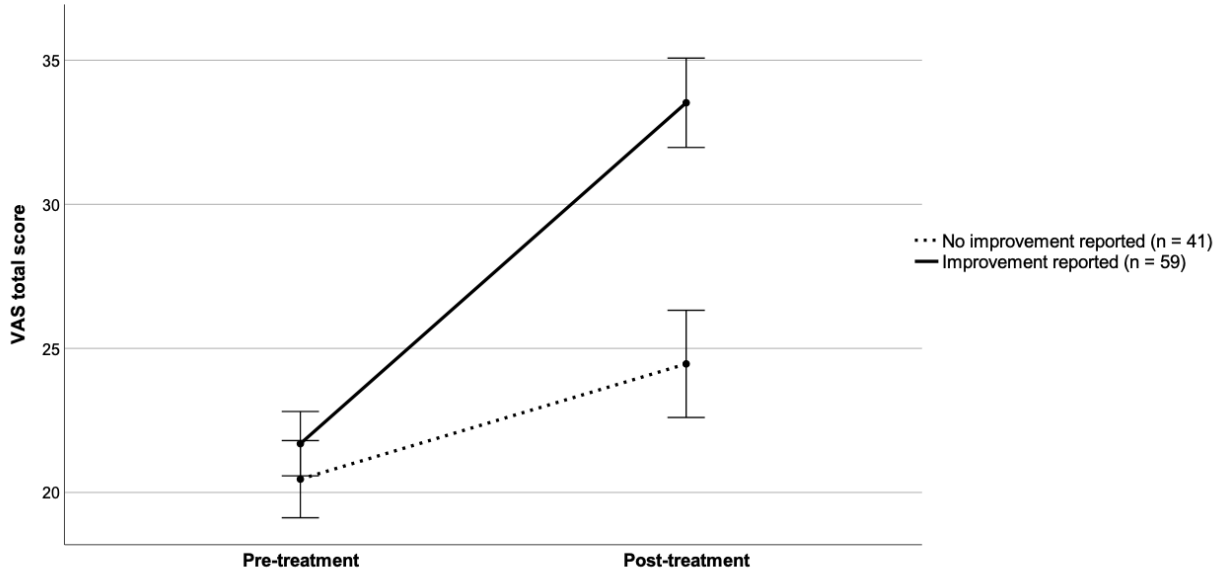

Figure 1. Mean change in VAS total scores by improvement status. Errors represent 95% confidence intervals.

Adverse Effects

Overall, the polypeptide extract was well tolerated. Asked about side effects, 28 subjects noted predominantly minimal and transient ones, which usually resolved with time, lowering the dose, or changing the time of day the supplement was taken. One person however did note severe arthralgias.

The side effects were:

1 – mild digestive symptoms in 12 (resolved in 4 by lowering the dose, and transient in most)

2 – feeling over energized in 11 (resolved in 8 by simply lowering the dose).

Also, under side effects, one person noted transient stuffy nose and weird mood. Two people noted tissue dryness/ increased thirst. And one person noted “feeling happier.”

Discussion

This study provides preliminary data on a potentially effective nutritional intervention for addressing energy deficits and other health conditions in people with chronic fatigue syndrome

and fibromyalgia, including following viral infections. It is very promising that this safe and low-cost intervention was able to significantly improve patients' clinical outcomes, with subjects in the overall group reporting an average 62 % increase in overall well-being. This increased to an average 84% improvement in overall well-being in the 60% of subjects who improved with treatment. Having treated countless thousands of people with fibromyalgia in their respective clinical practices, the authors find this to be remarkable for a single agent response.

The mechanism of action is still unclear. Our recently published earlier study also looked at the effects of the supplement on protective antibodies in those whose pre-study levels were low. These showed an average 14% increase in total IgG antibodies along with improvements in IgG 1 – 4 subsets.[4]

Yet, this is a situation that we often find in medicine. Where the clinical observation of efficacy is made, before understanding the mechanism. And that is what is occurring here.

So what do we know?

1. Clinical experience with tens of thousands of people suffering from severe malnutrition has shown the supplement resulted in marked improvement.
2. That the supplement contains a mix of polypeptides. But that the effect is far greater than simply giving a similar amount of amino acids.
3. that this unique polypeptide mixture results in significant clinical improvement in people with CFS and fibromyalgia including those with symptoms following a viral illness.
4. Our analysis did not find obvious variables that predict who will respond and who will not.

There are several factors that we need to be looking at in the research going forward.

Although "protein" is a general term given to everything made from polypeptide structures, each is quite different in effect. By way of analogy, amino acids are like random words. This unique mix is like a book written from these words. How they are combined makes all the difference.

Decades of experience using this nutritional supplement for malnutrition has shown that it quite safely and effectively helps people regain energy, suggesting a significant anabolic affect.

As research continues, we are left with an observation made by the late Dr. Janet Travell. First see what is, and then try to understand it.

Fortunately, research has now advanced to the point where fatigue and other health conditions associated with CFS and fibromyalgia can be significantly improved with nutritional intervention. For example, ribose was shown to be associated with an average 61% increase in

energy and a highly significant 37% increase in overall well-being.[12] An RCT looking at the SHINE Protocol, Optimizing Sleep, Hormones, Immunity, Nutrition, and Exercise as able resulted in an average 90% increase in quality of life.[3] This study using the Recovery Factors polypeptide mix adds one more uniquely effective approach to optimizing function in this very ill population.

This study has a number of weaknesses, the key ones being the lack of a placebo control group. Now that we have completed the initial two studies, an RCT is planned for the future.

Conclusions: A unique porcine serum polypeptide nutritional supplement (Recovery Factors® by Recovery Nutraceuticals), resulted in markedly improved energy levels, sleep, mental clarity, pain relief, calming, digestive symptom improvement and overall well-being in those with CFS and fibromyalgia, including those with postviral CFS/FMS.

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