

A clinical study:

Evaluation of quality of life in persons with Chronic Fatigue Syndrome /Myalgic Encephalomyelitis CFS/ME before and after administration of food supplements designed to reduce free radical activity.

Carried out at IFM-kliniken, Falun, Sweden



Major problems

for CFS/ME patients

- Lack of effective treatment
- They've been sick since their original symptoms started
- Symptoms were caused by a known stressor
- Followed by a chronic condition
- Often life-long (Reeves et al 2003)

We undertook a clinical study

with 9 participants previously diagnosed with CFS/ME (CDC)

- They had taken part in a previous clinical study
- Had tried many other treatments
- Had been sick for many years.



Pall 2002 (1, 2, 3); 2007

- Pall suggests free radical biochemistry as the perpetuating cause of CFS/ME
- The classical symptoms can be generated by plausible mechanisms involving nitric oxide (NO), peroxynitrite (ONOO⁻) and superoxide.

The aim of this study

- To investigate the relevance of nutrients previously demonstrated to reduce the free radical activity of NO, ONOO⁻ and superoxide as an effective therapy to restore quality of life in subjects with Chronic Fatigue Syndrome/Myalgic Encephalomyelitis.

Assessment of life quality

We used four products designed to affect free radical activity

And assessed if 8 weeks application lessened the symptoms/improved the quality of life in persons diagnosed with CFS/ME

Assessment of free radical activity was beyond the scope of this study.

4 food supplements

in addition to previous health support program



Research approach

To discover whether or not the supplements have an effect on the physical and/or mental quality of life in persons with CFS/ME.



The MOS 36-item (SF-36) Short-Form Health Survey

- SF-36 is a well-validated psychometric instrument
 - One of the tools recommended in the measurement of CFS/ME (Reeves 2003)
 - Can be compared to well-validated norms.
- It addresses
- Physical/social activity
 - Vitality
 - Bodily pain
 - Physical/Mental role
 - Social functioning
 - Perception of general health

SF-36 cont'd

- These 8 multi-item scales are weighted, summed up, standardised and transformed
- They make up score indices:
 - Physical Component Score (PCS)
 - Mental Component Score (MCS).
- The scale for the indices of the general population is between 0-75, with a score of 50 representing the norm (Sullivan et al 2002).

PCS and MCS

statistical and clinical significance

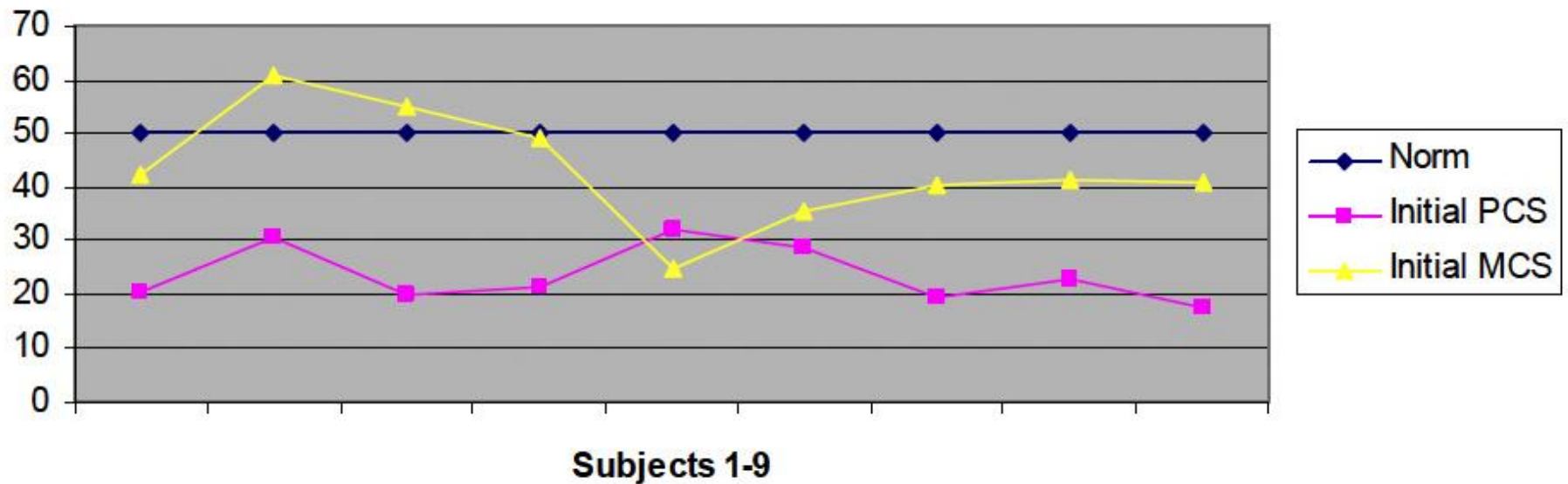
- The PCS and MCS are more compressed than the 8 multi-item scales
- Small changes are of statistical and clinical significance (Sullivan et al 2002).

Assessment

- The SF-36 data was analysed and compared at the outset to Swedish norms
- To assess whether or not physical function, general health or vitality varies
- Comparing the physical and mental indices of persons with CFS/ME and the population at large.

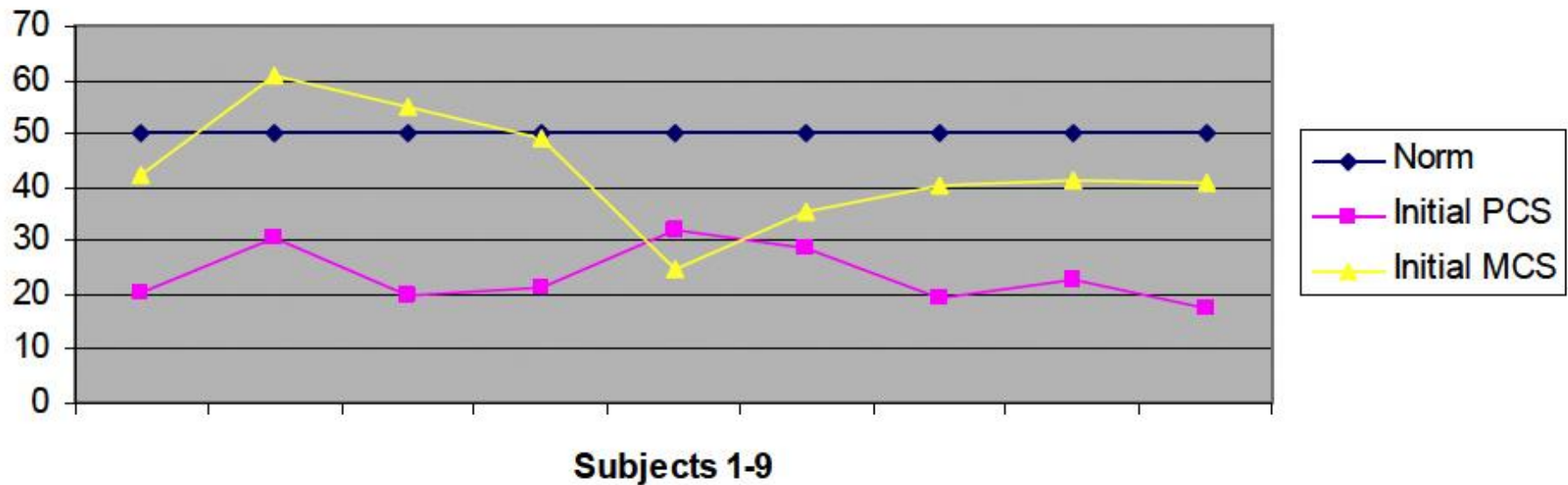
Perception of quality of life varied greatly at the onset compared to SE norm

Fig A: Initial PCS and MCS compared to Swedish norm



The Mental Component Score was higher than the PCS

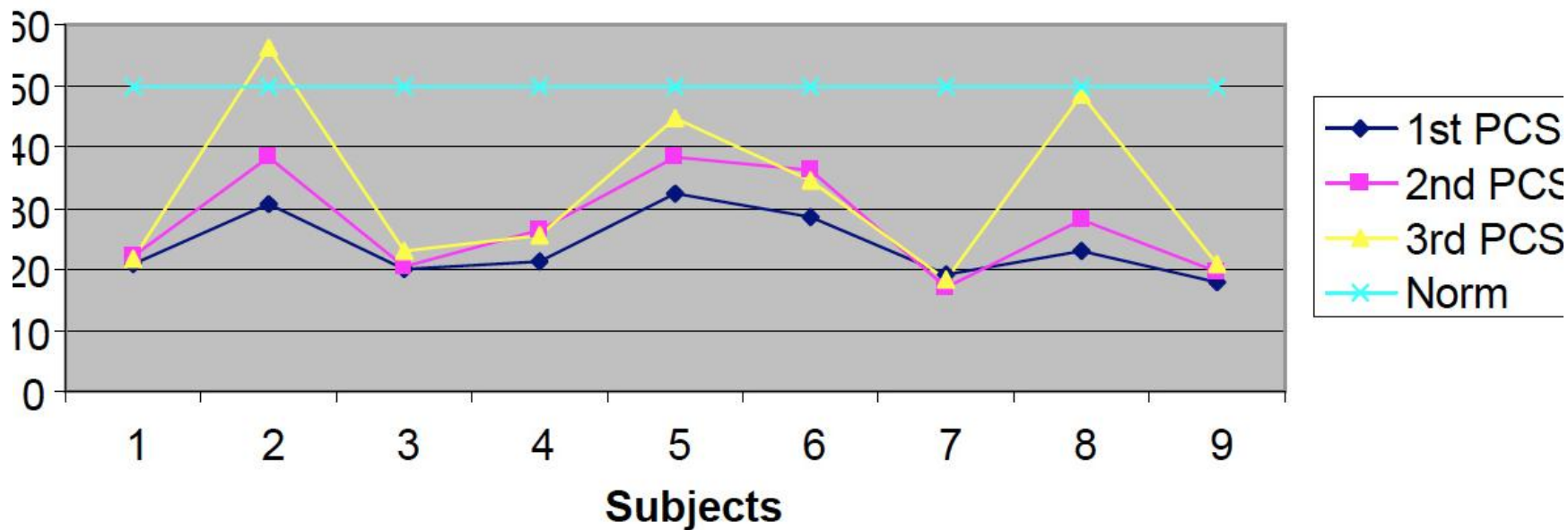
Fig A: Initial PCS and MCS compared to Swedish norm



55% improvement

experienced after 8 weeks supplementation

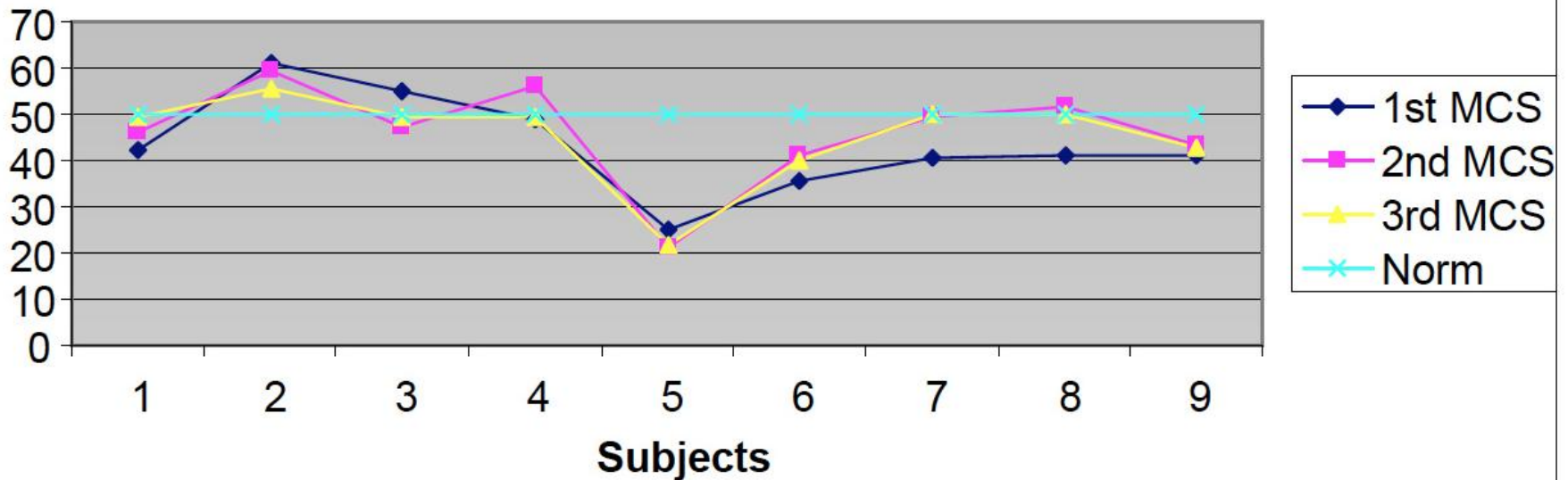
Fig B: PCS before, during and after supplementation



MCS improved in 5 subjects

3 had low MCS throughout vs norm

Fig C: MCS, before, during and after supplementation



Conclusions

These results should be viewed in contrast to the lack of successful therapeutic methods available for persons with CFS/ME (Reeves et al 2003, Franzon 2007).

After two months supplementation 55% improvement in physical wellbeing.

Conclusions cont'd

- This result is of great value and should be investigated further in conjunction with other therapies, in order to develop guidelines for combinations of successful therapies.

Later clinical correlation between supplement intake and reduced free radical activity

- Electro Interstitial Scanner – EIS
- This measures interstitial fluid and is on a par with EKG and EEG measurements
- We frequently find symptom reduction, after taking the products used in this study
- This correlates with less or no interstitial nitric oxide (NO), peroxynitrite (ONOO-) and/or superoxide activity as measured by EIS.

Many CFS/ME patients are regularly treated with this protocol

- Since this study was carried out (2009) these supplements continue to be an important part of the CFS/ME protocol at IFM-kliniken
- Patients may stop them for a while but always return to them if symptoms recur
- It is only the price that stops them taking them all the time.

Taking advantage of the new situation

- Initial health improvements level out after taking these products
- We find that the playing field has changed
- Now is the chance to include other therapies that were previously not tolerated
- Sauna, exercise, Qi gong or Tai chi.

IFM-kliniken's

8 steps to restore health

- Remove pathogens and allergens
- Repair the gut
- Restore the intestinal flora
- Provide enzyme supplements
- Support healthy organ function/muscles/bones
- Reduce stress and risk factors
- Provide nutrition
- Suggest lifestyle changes (sauna, exercise)

CSF/ME is still a life-long challenge

- Although the products in this study provide important nutritional support
- Health gains are not permanent
- This condition still requires life-long support
- Further solutions are needed
- The cost is too high for the average CFS/ME patient
- These solutions need to become part of mainstream medical treatment for CFS/ME.