

CHRONOMICS TRIAL: REPORT OF A 3-MONTH PILOT STUDY

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The Chronomics Trial will test-validate the evolutionary diet/tissue hypothesis (De Meester, 2009), i.e., that a return to the original balanced (1:1) ratio of polyunsaturated fatty acids (PUFAs) and/or to a corresponding 25% proportion of ω 6 highly unsaturated fatty acids (HUFAs) in plasma/serum total lipids (ω 6: ω 3 PUFAs = 1:1 and/or % ω 6 in HUFAs = 25) (www.columbus-concept.com) can possibly reduce the risk of developing chronic degenerative diseases to zero at population level. The longitudinal study will be conducted in three different age groups of healthy subjects living in Southern Poland (adolescents, adults, elderly), with focus on biomarkers and clinical/psychological symptoms of development of cardiovascular and psychological diseases.

The heretofore reported non-trivial 3-m pilot study was carried out on 5 family-related subjects + 4 family-acquainted subjects (external references) to test the protocol designed for the 4-y-long psychosomatic intervention trial involving 90 subjects distributed evenly over 3 subgroups of 30 adolescents, 30 adults & 30 elderly (Chronomics Trial, EU FP7-259825-1). The pilot study has been completed and shows promising results in terms of real potential for the "titration" of tissue fatty acid composition (Omega-6 Status, Ω 6S, % ω 6-HUFAs in total blood fatty acids) back to their envisaged evolutionary standards (Columbus Hypothesis: ω 6: ω 3-PUFAs = 1:1 and/or % ω 6-HUFAs = 25) in subgroups of modern Western human populations. The main observation was that: (i) age & gender, (ii) body mass composition & index, and (iii) metabolic rate & lifestyle do not appear to substantially influence the:

" $\Delta\Omega$ 6S = -7.5 units/g ω -3 HUFA/day"

response of modern Western blood/tissue fatty acid composition to ω -3 HUFA (PUR3) supplementation in the presence of an agent for reducing epigenetic-genomic effects (a "blunter")(LIPISTASE). Within the 3-m pilot study, all subjects in the adolescent & elderly subgroups on the 6 pills a day (2.7g ω -3 HUFA (PUR3)/day), in association with 2 tablets LIPISTASE/day, have had their Ω 6S reduced by some 20%, with no reduction in blood concentration of ω -6 HUFA. In the adult group, the three individuals were on a 1.0, 3.6 & 4.5g ω -3 HUFA (PUR3)/day intervention program. They respectively had their Ω 6S decreased and/or stabilized at 67.5, 48.0 & 41.0, thus confirming the generality of the blood/tissue titration method observed in the adolescent & elderly groups. All subjects reported subjective mind- and body-wise (cognition, concentration, communication, breathing, general feeling, relief of dizziness and pain) health improvements. The first adult subject reported slight improvement in the annual episode of seasonal allergy whereas the next two reported feelings of rejuvenation in all senses. Medical, biochemical & socio-psychological analyses do confirm those self-assessed subjective improvements. In all three subgroups, prolonged ω -3 HUFA (PUR3) intake appears to maintain the new status, not to further reduce it. The results of the 3-m Pilot Chronomics Study not only refine the size of the problem in terms of the daily intake of ω -3 HUFA (PUR3) needed to reverse the Omega-6 Status (Ω 6S) from 75 to 50 (3.35g ω -3 HUFA (PUR3)/day) and then from 50 to 25 (3.35g ω -3 HUFA (PUR3)/day) in the blood-tissue of a modern Western population, but also provides clear indication as to the benefit of promoting the approach and of doing so in the presence of a "blunter" (LIPISTASE) of inter-individual genotypic variance.

Obviously, a reduction in daily intake of omega-6 fatty acids from plant & animal origins would help a long way in reducing the currently requested daily intake of ω -3 HUFA (PUR3) needed to continue with, and/or to maintain post-intervention, the evolutionary selected blood/tissue balance. In this respect, foods responding to the Columbus Concept (Wild Foods for HealthTM; www.columbus-concept.com) appear to be ideally designed. In a general sense, the efficacy and safety of the Chronomics Trial protocol are adjudged satisfactory.