Clinical abstract – reference list.


Clinical Research Update
Double X

Effects of Daily Multi-Supplementation on Nutrient Status and Risk Factors in Healthy Adults

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Clinical abstract.

Most people do not eat enough fruits and vegetables and thus have less than optimal levels of the vitamins, minerals, and phytochemicals that have been associated with healthy longevity.\(^1\)\(^2\) Because of this, medical authorities recommend that all healthy adults consume a daily serving of a multivitamin.\(^3\)\(^4\)\(^5\) However, more research is needed to verify whether findings from test tube or population studies also apply to people actually consuming a given multisupplement as intended – information that can only be gathered by means of clinical trials.\(^7\)

The challenge of clinical research on dietary supplements is there’s no disease to treat, cure, or prevent: How can one hope to find an improvement if everybody’s already healthy to begin with? But health now, of course, doesn’t necessarily reflect health in the future. Between any two people of apparently equivalent good health, there may be unsuspected differences in risk factors.

With this background, the DOUBLE X\(^\circledast\) 2005 reformulation study was designed to test the benefits of consuming the recommended daily serving of DOUBLE X on two levels: first, by analyzing the levels in the bloodstream of the health-promoting nutrients contained in DOUBLE X; second, by analyzing the levels of selected risk factors.

For this Independent Review Board-approved study, 120 healthy men and women were recruited, gave their written informed consent to participate in the clinical trial, and had a medical exam by the physician Principal Investigator. All subjects then gave blood samples before and after consuming either DOUBLE X or placebo (three tablets, twice a day) for six weeks. At week six, these samples were analyzed for nutrients and risk factors.

In the realm of nutrient levels, as expected, plasma levels of vitamins B6, B12, and folate increased significantly in the DOUBLE X group but showed no change in the placebo group. These three nutrients are important factors in the recycling of homocysteine, a harmful by-product of protein metabolism.\(^8\)\(^9\)\(^10\)

Beta-carotene, which can be converted to vitamin A in the body,\(^11\) and vitamin E, another important antioxidant,\(^12\) were both also significantly increased in the DOUBLE X\(^\circledast\) group but not in the placebo group. In the realm of risk factors, homocysteine reduced to a large extent in the DOUBLE X group relative to the placebo group. Homocysteine is the by-product of protein metabolism via methionine; it is known to induce DNA strand breakage, oxidative stress, and apoptosis (cell death). Insufficient recycling of homocysteine into cysteine by B6 or back into methionine by folic acid and B6 leads to elevated plasma homocysteine levels and increased risk for age-related health issues.

Last in this list of positive outcomes from this study, but perhaps first in importance, the Micronucleus Assay, a measure of DNA damage in dividing cells, showed significantly reduced DNA damage in subjects who had consumed DOUBLE X for six weeks, but no significant change in subjects who had consumed placebo. DNA damage, as indicated by the Micronucleus Assay, is believed to be a sensitive early marker of risk of chronic health conditions.

This controlled clinical study thus demonstrates beneficial nutrients in DOUBLE X are absorbed by the body, and that functional benefits – in lowered homocysteine levels, and protected DNA – are detectable in healthy adults, which suggests that DOUBLE X helps maintain healthy aging.