www.ijarp.com ISSN 2456-9992 Page: 01-12

International Journal Advanced Research Publications

Review Article

Volume: 02
Issue: 06

ROLE OF NUTRACEUTICALS IN HUMAN HEALTH

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Article Received: 23 April 2026, Article Revised: 13 May 2026, Published on: 02 June 2026

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DOI: https://doi-doi.org/101555/ijarp.5915

1. ABSTRACT

Nutraceuticals are bioactive food-derived compounds—plant (polyphenols, flavonoids, isoflavones), marine (fucoxanthin), animal (omega-3), and microbial (pro/prebiotics)—with potential health benefits. They act via molecular pathways such as Nrf2 (antioxidant), NF-κB (anti-inflammatory), and AMPK (glucose regulation), though many affect multiple pathways simultaneously, influencing glucose homeostasis, hepatic lipogenesis, apoptosis, and more. Proposed applications include metabolic syndrome, cardiovascular disease, neurodegeneration, immune support, and skin aging. Some RCT evidence supports benefits—phytosterols lower LDL, tea polyphenols and citrus bioflavonoids improve endothelial function, and soy products may enhance sperm motility—but trials are limited by heterogeneity, short durations, poor bioavailability, and lack of long-term morbidity or mortality data. Safety concerns include toxicity and drug interactions in susceptible individuals. Regulatory inconsistency across the US, EU, and India (e.g., DSHEA) contributes to variable quality control and financial burdens for manufacturers and researchers. Wider clinical adoption requires validated research, standardized product quality, interdisciplinary collaboration, and more long-term, well-controlled trials focused on clinical endpoints.

KEYWORDS: Nutraceuticals, Bioavailability, Clinical Evidence, Regulatory Framework, Health Effects.

1. INTRODUCTION

Throughout the last few decades, significant advancements have been made in the field of nutraceuticals due to increasing amounts of scientific knowledge regarding the connection between diet and health outcomes [1]. The term "nutraceutical" refers to a type of food-

derived bioactive compound that has a positive impact on one's health or has a medical benefit, in addition to providing basic nutrition [2]. The rise in popularity of nutraceuticals around the world has created great interest and excitement in their ability to assist with disease prevention, health maintenance, and as an adjunct therapy for many different acute and chronic conditions [3]. The rapid expansion of nutraceuticals on the consumer market is an indicator of consumers becoming increasingly aware of and seeking natural alternatives to pharmaceutical products [4].

Historically understood, nutraceuticals have been based on traditional healing systems (e.g., Ayurveda and TCM), but the modern definition of nutraceuticals encompasses a large number and variety of compounds, including but not limited to polyphenols, flavonoids, carotenoids, omega-3 fatty acids, vitamins, minerals, peptides, prebiotics, probiotics, and herbal extracts [5, 6, 7]. Their consumption appears to provide physiological benefit across a number of systems; examples include metabolic regulation, neuroprotection, etc., which make them viable options for integrative healthcare approaches [8, 9, 10].

In spite of the fact that there are numerous preclinical and clinical investigations that show the positive impacts of numerous nutraceuticals on oxidative stress, inflammation, lipid metabolism, immune function, cognitive decline, cancer progression, skin aging, and so forth [11, 12, 13], there continue to be substantial barriers. These include variability in bioavailability and pharmacokinetics [14], lack of standardized regulatory definitions across jurisdictions [15], insufficient high-quality randomized controlled trials (RCTs) for many products [16], potential adverse effects or drug interactions [17], and issues related to quality control [18].

1. Definition and Classification of Nutraceuticals

In 1989, S. DeFelice proposed that nutraceuticals are any food item or component with medical/health benefits beyond normal food nutrition and aid in the prevention and treatment of disease [15,19]. Various categories of nutraceuticals exist based on source (i.e., plant-based or herbal, animal-based, marine-based or derived, or microbial) and nature (i.e., polyphenols, flavonoids, carotenoids, alkaloids, peptides, fatty acids, vitamins or minerals), as well as overall purpose/function (i.e. dietary supplements, functional foods, or medicinal foods) [2,20,21].

1.1 Plant-Derived Nutraceuticals

Examples of plant-derived nutraceuticals include polyphenols (e.g., resveratrol found in grapes), flavonoids (e.g., quercetin found in onions), carotenoids (lycopene from tomatoes), alkaloids (berberine from barberry), saponins (ginsenosides found in ginseng), terpenoids

(limonene from citrus fruits), glucosinolates (sulforaphane from broccoli), and dietary fibers (e.g., beta-glucans found in oats), as well as various extracts sourced from herbs (i.e., curcumin from turmeric), [7,22,23].

1.2 Animal- and Marine-Derived Nutraceuticals

Animal-derived nutraceuticals include peptides/proteins (collagen hydrolysates), omega-3 fatty acids (eicosapentaenoic (EPA)/docosahexaenoic acid (DHA) from fish oils), conjugated linoleic acid (CLA) from sources derived from meat or dairy products [35], and bovine colostrum which is rich in immunoglobulins and lactoferrin [41], among others. Naturally derived nutraceuticals from marine organisms offer a unique variety of bioactive compounds, including fucoxanthin, which can be isolated from brown algae [43], as well as bioactive peptides that have antihypertensive/antioxidant characteristics [20].

1.3 Microbial-Derived Nutraceuticals

Probiotics (live beneficial bacteria) and prebiotics (a type of non-digestible fiber that promotes the growth of beneficial bacteria in the gut) are two important types of nutraceuticals (microbial-derived sources of healthy food) with established roles in gut health and immune regulation [10].

1.4 Functional Foods vs Dietary Supplements

Functional foods are whole foods that have been fortified with additional nutrients or bioactive substances so that they provide specific health benefits beyond just being basic nutrition. Examples of functional foods include fortified cereals and yogurts that contain probiotics/prebiotics/omega-3 fatty acids/vitamins/minerals/etc. [21] By contrast, dietary supplements are concentrated forms of the nutrients and bioactive substances defined above, which can be taken as capsules/tablets/powder/liquid/gels in order to supplement an individual's daily diet [8].

2. Mechanisms of Action: Molecular Pathways Influenced by Nutraceuticals

The effects of nutraceuticals occur via multiple molecular mechanisms, which each target one or more different primary cellular pathways. For example, nutraceuticals regulate many cellular pathways that play key roles in the body, such as the oxidative stress response (Nrf2 pathway), inflammatory response (NFkB pathway), lipid metabolism (inhibition of HMGCoA reductase), and glucose regulation (activation of AMPK pathway and modulation of PPARs), as well as providing neuroprotective effects (via anti-amyloidogenic and antioxidant actions), and modulating the immune system (via cytokine production and

interaction with the gut microbiome), and inducing cell death in cancer cells via the p53 pathway and/or the activation of the caspases pathway [3, 14, 23, 36].

2.1 Antioxidant Activity

Many nutraceuticals act as potent antioxidants by scavenging for ROS and/or increasing the activity of endogenous antioxidant enzymes through the Nrf2 pathway. Examples of nutraceuticals with proven antioxidant properties include polyphenols, such as curcumin/resveratrol and/or chlorogenic acid/sulforaphane/fucoxanthin, Vitamins C and E, carotenoids, flavonoids and food-derived protein peptides [13, 22, 23, 36, 43]

2.2 Anti-inflammatory Effects

The inflammatory response is being reduced by compounds like omega-3 fatty acids, polyphenols, sulforaphane and limonene due to their ability to inhibit pro-inflammatory cytokines through the suppression of NF-kappa B signaling pathways which can help prevent chronic low-grade inflammation as seen in metabolic syndrome and cardiovascular, neurodegenerative diseases and cancer progression. [3, 36,38].

2.3 Lipid-Lowering Actions

Phytosterols, stanols, red yeast rice, berberine, soluble fibers and garlic extracts can also lower cholesterol absorption and synthesis by inhibiting HMG-CoA reductase and NPC1L1 transporter pathways which improve plasma lipid profiles while reducing risk factors of cardiovascular disease as well as helping manage dyslipidemia. [14, 17, 18].

2.4 Glycemic Control & Insulin Sensitivity

Also, compounds such as berberine, polyphenols, fibers, probiotics can increase insulin sensitivity and glucose uptake via AMPK activation, inhibition of gluconeogenesis, enhancing GLP-1 secretion, and modulating gut microbiota composition thus benefiting diabetes and metabolic syndrome management through their combined effects. [26, 42].

2.5 Neuroprotective Mechanisms

Neuroprotective effects occur with curcumin, resveratrol, quercetin, omega-3 fatty acids, saffron, ginkgo biloba, and polyphenol-rich extracts via their anti-inflammatory and antioxidant properties, inhibiting amyloid beta aggregation, enhancing synaptic plasticity and regulation of neurotransmitter systems thus potentially reducing cognitive decline risk associated with dementia, neurodegenerative diseases such as Alzheimer's, Parkinson's, Huntington's, and mild cognitive impairment and supporting stroke recovery. [6, 19, 28, 32].

2.6 Immune Modulation & Antimicrobial Effects

Polysaccharides, fatty acids, labdanes, probiotics, prebiotics, and bovine colostrum affect both innate and adaptive immunity by modulating T-cell, B-cell activity, gut barrier integrity,

and the balance of microbes in one's gut thus promoting infection resistance, mitigating allergies, and managing inflammatory disorders. [10, 41].

2.7 Anticancer Properties

Polyphenols such as those found in neem extracts and other natural sources (fucoxanthin, chlorogenic acid, sulforaphane) can induce apoptosis/inhibit cell growth/block angiogenesis/modulate epigenetic regulators/reduce the toxicity of chemotherapy, demonstrating the potential as a chemopreventive/adjuvant against a variety of cancers. [16, 24, 43].

3. Clinical Applications Across Major Disease Domains

3.1 Metabolic Disorders: Obesity & Diabetes Mellitus

Nutraceutical interventions aimed at obesity/type 2 diabetes/metabolic syndrome are focused on using polyunsaturated fatty acids/polyphenols/fibers/probiotics/prebiotics/chlorogenic acid/moringa leaves/barberry extracts, all of which have been shown to improve glycemic control/lipid profile/body weight/inflammatory markers using multiple mechanisms. [26, 27, 42]. However, little data is known about the clinical effectiveness of these interventions due to the heterogeneity of the studies (design, dosage, population, and outcomes). [26].

3.2 Cardiovascular diseases & Dyslipidemia

The top causes of morbidity and mortality around the world are cardiovascular disease. The efficacy and tolerability of many lipid-lowering nutraceuticals including red yeast rice, phytosterols, soluble fibres, berberine, artichoke extract, bergamot polyphenol, garlic extract and green tea spirulina are supported by numerous RCT/meta-analyses. [17 With doses of plant sterols (≥1 grams/day), there is a reduction in LDL-C of approximately 12mg/dL [18]; omega-3 fatty acids may decrease triglycerides/blood pressure/inflammation [29]; coenzyme Q10 can improve endothelial function/blood pressure; and aged-garlic extract can reduce the risk of hypertension. In spite of the above surrogate marker results, data on long-term morbidity/mortality are still insufficient. [18].

3.3 Neurodegenerative Diseases & Cognitive Decline

The potential benefits of curcumin/resveratrol/quercetin/diet high in flavonoids/ polyunsaturated fats/probiotic supplementation on neuroprotective mechanisms against Alzheimer's disease/Parkinson's disease/Huntington's disease/cognitive decline and depressive/anxious symptoms could also be associated with their anti-inflammatory/antioxidant/neurotrophic actions. [6, 19, 28]. There has yet to be solid evidence backing the use of these therapies on a routine basis because of the low number of subjects

studied in trials, the absence of standardization and the large variance between different groups [32, 39, 34, 38, 31, 28, 19, 6].

3.4 Immune System Modulation & Infectious Disease Prevention

Plant extracts, polysaccharides/fatty acids/labdanes, and other supplements such as(probiotics)/Prebiotics /Vitamin D/C/Zinc /Melatonin and bovine colostrum stimulate the immune system to help decrease the incidence of infection, alter inflammatory processes, improve vaccine efficacy, and facilitate the management of COVID-19 [10, 37, 41]. Clinical trials have produced inconsistent results due in many cases to limitations in the method of the trial and the lack of standardization in the applications.

3.5 Cancer Prevention & Therapy Support

Polyphenolic-rich extracts, such as neem, fucoxanthin, chlorogenic acid, suforaphane, have all been shown to exhibit anticancer properties through apoptosis, inhibition of the cell cycle, inhibiting angiogenesis, and reducing the toxicity associated with chemotherapy, providing adjunctive support in people being treated with conventional regimens [16, 24, 43]. Clinical translation is slowed by the limited biological availability and great variability in the pharmacokinetics and inter-individual variability associated with these compounds.

3.6 Skin Health & Aging Prevention

Substantial improvements to the skin barrier function, reduction in both photoaging and wound healing, as well as reduction of inflammatory conditions, hyperpigmentation, and reduction in severity of acne occur with the supplementation of bioactive peptides, polyphenols, carotenoids, vitamins and polyunsaturated fatty acids shown to lead to improved skin quality based on observational studies; however, further observational studies with greater size and better statistical evaluation will be required before any recommendations can be made prior to being recommended [15].

4. Safety Concerns & Adverse Effects

Though nutraceuticals are relatively safe under regulated diet intake/following good manufacturing practices/adhering to regulatory rules-injudicious application may result in hepatotoxicity/pulmonary toxicity/cytotoxicity/carcinogenicity/nephrotoxicity/hematotoxicity/cardiac toxicity/drug-nutrient interaction especially for fragile individuals (children, elderly, patients with liver and/or renal failure, those of high-risk, polypharmacy) [8, 33]. Unfortunately, there is still little long-term safety data for most of these products in light of absence of any long-term large scale randomized controlled trials and follow-up studies.

5. Regulatory Framework & Quality Control

There is no universally accepted definition/regulatory framework for nutraceutical products across countries/jurisdictions leading to inconsistencies regarding product labeling/compositional standards/evidence requirements/safety monitoring/post-marketing surveillance [5]. In the US/FDA regulates dietary supplements under DSHEA (1994); EU applies food supplement directives but lacks harmonized standards for claims/evidence requirements/product registration compared with pharmaceuticals [5]. India introduced Food Safety Standards Act (2006) specifically regulating the industry while other countries rely on varying degrees oversight depending on product claims/intended use/local legislation [25]. Strict regulation is essential to curb uncontrolled use/prevent undesirable side effects/improve consumer confidence/promote scientific innovation.

6. CONCLUSION

Nutraceuticals refer to an ever-evolving field of nutrition and pharmaceutical innovation, which holds great potential for aiding in the prevention, treatment and support of many chronic diseases that affect the body; i.e. physiological, metabolic, cardiovascular, neurodegenerative, immunological, cancer-related and others. [1,43] The integration of nutraceuticals into the health-care delivery system presents a significant challenge that requires careful scientific validation of the efficacy, safety and bioavailability of nutraceuticals prior to being integrated into conventional medicine. Additionally, there needs to be education and collaboration between many different professions who would use nutraceuticals, i.e., clinicians, nutritionists, toxicologists, regulatory officials, scientists, manufacturers and policy makers, in order for nutraceuticals to become part of standard practices. [5] Some nutraceuticals have established health benefits when providing additional support in combination with lifestyle changes and conventional medical treatment (e.g., Red Yeast Rice, Phytosterols, Coenzyme Q10, Probiotic supplementation, Polyunsaturated fatty acids and Polyphenol extracts). While the potential exists for nutraceuticals to provide significant benefits to patients when combined with conventional health care, the field of nutraceuticals has encountered many challenges such as a lack of homogeneity between studies, faulty research designs, adverse effects associated with use, regulatory gaps, and the absence of adequately powered long-term prospective randomized control trials linking the use of nutraceuticals to clinical end points (i.e., mortality/MI/stroke). [17,18,29,33,40,43] Continued research, standardization of products, education, and cooperation among the

various disciplines responsible for providing care for patients will be necessary in order to integrate nutraceuticals into the main stream health care delivery system. [5]

7. ACKNOWLEDGMENTS

The authors are thankful to the principal and administration of the Global College of Pharmacy, Kahanpur Khui, Anandpur Sahib, for providing the academic support, resources, and encouraging environment necessary to carry out this extensive review. We also thank our faculty colleagues and peer reviewers, whose insightful discussions helped shape the direction of this manuscript. This particular review did not involve field assistants or direct community participation, but we remain grateful to the broader academic and local community in Punjab for their continued moral support throughout this process.

This research was not supported by any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. The main author has self-funded and agrees to bear all costs associated with the research, literature retrieval and preparation of this manuscript. The authors declare no competing financial interests, affiliations or personal relationships that could have appeared to influence the work, findings or conclusions reported in this paper.

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