

**BIOCHEMICAL COMPOSITION AND METHOD FOR SUPPORT OF COGNITIVE
FUNCTION**

PRIORITY UNDER 35 U.S.C Section 119(e) & 37 C.F.R. Section 1.78

[001] This nonprovisional application claims priority based upon the following prior United States Provisional Patent Application entitled: Biochemical Engineered Solution Application No.: 63/079,771 filed September 17, 2020, in the name of Christina Rahm Cook, which is hereby incorporated by reference for all purposes.

FIELD OF THE INVENTION

[002] The present invention relates generally to nutritional based therapies, more specifically but not by way of limitation, a method and composition that is comprised of nutritional based components such as but not limited to vitamins, amino acids and other components wherein the composition of the present invention is operable to treat individuals with cognitive disorders such as but not limited to Alzheimer's, Autism, and dementia as well as sexual function issues.

BACKGROUND

[003] About fifty million people worldwide are living with dementia and other various cognitive issues and it is estimated that in the absence of more effective treatments the number is estimated to triple in the next three decades. Fatalities due to dementias and other issues that are cognitive based illnesses more than doubled over the last decade making these types of fatalities the fifth leading cause of global deaths compared to being the fourteenth leading cause twenty years ago. In the last twenty years billions of dollars have been invested in research and development for medicinal therapies focused on the cure and prevention of cognitive impairing diseases. While pharmaceutical development has been promising there remains other needs for patients dealing with these cognitive impairing disorders.

[004] One of the areas in which a patients needs are currently not being met is a nutritional based composition that is focused on addressing the unique requirements of a patient combatting a cognitive disorder. Studies have shown for many types of diseases and disorders that various vitamins, amino acids and other nutritional elements can have a positive impact on the treatment of the patient and improve their overall health and ability to manage the disease. In some cases, nutritional based approaches have shown to either reverse the course of the disease and even provide complete relief therefrom. Nutritional supplements in a therapeutically effective amounts of various components supporting the immune function of individuals with cognitive disorders or diseases provide relief or reversal of symptoms as research has shown that primary or secondary immune issues heighten the symptoms and activity of cognitive dysfunction. Additionally, it is propped that various nutritional based compositions support an individual's digestive function and glutathione status which has been found to be important to address in individuals with cognitive disorders or diseases. Healthy digestive/gut function has been linked to a healthy immune function. Potential immune modulating effects by specific vitamins, minerals, plants,

seeds, roots, and oils may be the indirect result of the gut flora composition. It has been found that immune support to include gut support from various nutritional based supplements and combinations there are beneficial to the cognitive function of individuals.

[005] Accordingly, there is a need for a composition that is directed towards individuals that have cognitive diseases or disorders as well as other health related matters such as but not limited to sexual function, wherein the composition of the present invention supports immune and gut function in order to improve an individuals overall health.

SUMMARY OF THE INVENTION

[006] It is the object of the present invention to provide a composition that is operable to provide a nutritional therapy for individuals that have cognitive disorders or deficiencies wherein the composition of the present invention includes vitamin D specifically as cholecalciferol) wherein the vitamin D is provided in alternate forms of nanoemulsion and nanoencapsulation.

[007] Another object of the present invention is to provide a therapeutic nutritional composition that is operable to provide improved health for individuals that have cognitive disorders wherein the composition of the present invention includes optional ingredients such as but not limited to cysteine.

[008] A further object of the present invention is to provide a composition that is operable to provide a nutritional therapy for individuals that have cognitive disorders or deficiencies wherein the composition of the present invention further includes one or more polyunsaturated fatty acids and one or more biologically active compounds, in particular milk derived or bone marrow derived compounds.

[009] Still another object of the present invention is to provide a therapeutic nutritional composition that is operable to provide improved health for individuals that have cognitive disorders wherein the composition of the present invention therapeutically effective amount of turmeric curcumin along with a combination of other ingredients selected from a group further discussed herein.

[0010] An additional object of the present invention is to provide a composition that is operable to provide a nutritional therapy for individuals that have cognitive disorders or deficiencies wherein the composition of the present invention includes ten to twenty percent of N-acetyl-L Tyrosine and ten to twenty percent of anhydrous caffeine wherein the caffeine is from natural sources.

[0011] Yet a further object of the present invention is to provide a therapeutic nutritional composition that is operable to provide improved health for individuals that have cognitive disorders wherein the composition of the present invention includes L-Theanine, velvet bean seed powder and pine bark extract wherein the aforementioned ingredients comprise between five to twenty percent of the composition of the present invention.

[0012] Another object of the present invention is to provide a composition that is operable to provide a nutritional therapy for individuals that have cognitive disorders or deficiencies wherein the composition of the present invention can be prepared with five percent of a form of silicon dioxide from zeolites and benzonites.

[0013] Still an additional object of the present invention is to provide a therapeutic nutritional composition that is operable to provide improved health for individuals that have cognitive disorders wherein the composition of the present invention includes five to ten percent of oligosaccharides prepared from sources such as but not limited to pectin, pectate, alginate, chondrotine, hyaluronic acid, heparine, heparane or bacterial carbohydrates.

[0014] Yet another object of the present invention is to provide a composition that is operable to provide a nutritional therapy for individuals

that have cognitive disorders or deficiencies wherein the composition of the present invention includes an optional fat blend of five to ten percent wherein the fat blend may comprise forty percent borage oil and sixty percent fish oil. Furthermore, the n-3/n-6 fatty acid ratio is between twenty to forty and the n-6 is between fifteen and thirty five of the total fatty acid content.

[0015] To the accomplishment of the above and related objects the present invention may be embodied in the form illustrated in the accompanying drawings. Attention is called to the fact that the drawings are illustrative only. Variations are contemplated as being a part of the present invention, limited only by the scope of the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] A more complete understanding of the present invention may be had by reference to the following Detailed Description and appended claims when taken in conjunction with the accompanying Drawings wherein:

[0017] Figure 1 is a diagram of the steps of preparing the composition of the a preferred embodiment of the present invention.

DETAILED DESCRIPTION

[0018] Referring now to the drawings submitted herewith, wherein various elements depicted therein are not necessarily drawn to scale and wherein through the views and figures like elements are referenced with identical reference numerals, there is illustrated a cognitive formulation and method 100 constructed according to the principles of the present invention.

[0019] An embodiment of the present invention is discussed herein with reference to the figures submitted herewith. Those skilled in the art will understand that the detailed description herein with respect to these figures is for explanatory purposes and that it is contemplated within the scope of the present invention that alternative embodiments are plausible. By way of example but not by way of limitation, those having skill in the art in light of the present teachings of the present invention will recognize a plurality of alternate and suitable approaches dependent upon the needs of the particular application to implement the functionality of any given detail described herein, beyond that of the particular implementation choices in the embodiment described herein. Various modifications and embodiments are within the scope of the present invention.

[0020] It is to be further understood that the present invention is not limited to the particular methodology, materials, uses and applications described herein, as these may vary. Furthermore, it is also to be understood that the terminology used herein is used for the purpose of describing particular embodiments only, and is not intended to limit the scope of the present invention. It must be noted that as used herein and in the claims, the singular forms "a", "an" and "the" include the plural reference unless the context clearly dictates otherwise. Thus, for example, a reference to "an element" is a reference to one or more elements and includes equivalents thereof known to those skilled in the art. All conjunctions used are to be understood in the most inclusive sense possible. Thus, the word "or" should be understood as having the definition of a logical "or" rather than that of a logical "exclusive

or” unless the context clearly necessitates otherwise. Structures described herein are to be understood also to refer to functional equivalents of such structures. Language that may be construed to express approximation should be so understood unless the context clearly dictates otherwise.

[0021] References to “one embodiment”, “an embodiment”, “exemplary embodiments”, and the like may indicate that the embodiment(s) of the invention so described may include a particular feature, structure or characteristic, but not every embodiment necessarily includes the particular feature, structure or characteristic.

[0022] Referring in particular to the Figures submitted as a part hereof, the cognitive formulation and method 100 is prepared and manufactured utilizing conventional laboratory equipment. It should be further understood that the present invention could be provided in alternate media and further include nanoencapsulation and/or nanoemulsion as part of the process. The present invention provides a nutritional product for individuals with cognitive, disorders that are not implementing a therapy of alternate active medication. In formulation of the present invention, step 101 employs the utilization of vitamin D3, specifically in the form of cholecalciferol. As the base of the formulation of the present invention cholecalciferol is provided and it is contemplated within the scope of the present invention that the cholecalciferol is provided in alternate forms of nano-emulsions or nanoencapsulations. Additionally, it is contemplated within the scope of the present invention that the vitamin D3 is present within the formulation within a range of ten to twenty percent of the total formulation. In step 103, the creation of the formulation of the present invention continues with the addition of n-acetyl-l tyrosine. It is contemplated within the scope of the present invention that the n-acetyl-l tyrosine can comprise between ten and twenty percent of the formulation of the present invention. Step 105, the addition of anhydrous caffeine is added to the formulation. It is desired that the anhydrous caffeine is obtained from natural sources such as but not

limited to green tea leaves and/or coffee beans, in particular being extracted therefrom.

[0023] In step 107 the ingredient l-theanine is added to the formulation of the present invention. It is contemplated within the scope of the present invention that l-theanine can comprise between five and twenty percent of the formulation. Step 109, mucuna pruriens is mixed with the additional components listed herein above. It should be understood within the scope of the present invention that the mucuna pruriens could comprise five to twenty percent of the formulation of the present invention. It should be understood by those skilled in the art that mucuna pruriens is also known as velvet bean seed powder. In step 111, proanthocyanidins are added to the formulation of the present invention. It is contemplated within the scope of the present invention that the total presence of proanthocyanidins range between five and twenty percent of the formulation of the present invention. Step 113, turmeric root extract is further added to the formulation of the present invention. It should be understood within the scope of the present invention that the turmeric root extract could comprise between five and twenty percent of the formulation of the present invention. In step 115 a combination of all or some of the following are added to the formulation of the present invention. Components consisting of vitamins A, B, E, C, K, and glutathione producing ingredients such as zinc and niacin are added to the formulation. It is contemplated within the scope of the present invention that only one of the aforementioned could be added or a combination of a few as well as all of the components. It is determined that the percentage of the formulation of either a single or combination of the components of step 115 represent two to five percent of the formulation.

[0024] In step 117, the formulation can be prepared with or without five percent of a form of silicon dioxide from zeolites and bentonites. Step 119 an additive group is added to the formulation of the present invention. The additive group consists of resveratrol, black cumin seed oil, raspberry, aloe vera and apple cider vinegar. Wherein the aforementioned are present

separately at a level between five to ten percent of the formulation. The additive group is further provided in combination with or without prebiotics and probiotics ranging between two and five percent, silicas ranging between two to five percent and silver ions ranging from two to five percent. Step 121, oligosaccharides are added to the formulation of the present invention. It is desired within the scope of the present invention that the oligosaccharides are prepared from pectin, pectate, alginate, chondrotine, hyaluronic acid, heparine, heparane, bacterial carbohydrates, sialoglycans, fucoidan, fucooligosachrides or carrageenan or neutral oligosaccharides. It should be understood that oligosaccharides refer to carbohydrate chains of monosaccharide units with a chain length of 1 and 5000 but could have alternate chain lengths for use in the present invention. More specifically but not by way of limitation the chain lengths could be between two and two hundred and fifty, alternatively between two and fifty, and additionally between two and ten with this chain length being most preferred. Step 123, at least one of the following components is added in order to provide stimulation of glutathione. Components to stimulate glutathione are selected from a group comprising of lipoic acid, pyruvate, silicas, oxaloacetate or oxaloaspartate.

[0025] In step 125, probiotics and prebiotics selected from micro-organisms suitable for human consumption which are able to improve the microbial balance of the intestine are added to the formulation of the present invention. It should be understood within the scope of the present invention that live, dead or bacterial fragments could be utilized. Step 127, an optional fat blend could be added to the formulation of the present invention wherein the fat blend can comprise between five and ten percent of the formulation when present. The preferred fat blend consists of borage oil and fish oil and having a n-3/n-6 fatty acid ratio between twenty and forty. Furthermore, the total fatty acid content is between fifteen and thirty-five. In step 129, active molecules including growth factors, immunoglobulins and/or colostrum are added to the formulation. The aforementioned is a representation of the

formulation of the present invention. It should be further understood within the scope of the present invention that the formulation of the present invention can include some or all of the following preparation techniques. Vitamins and minerals of the components produced in host cells, Nanomaterial scaffolds, nano emulsions or nanoencapsulations.

[0026] Additional embodiments of the formulation are contemplated within the scope of the present invention. A formulation comprising of a combination of the components listed herein in steps 101 through step 113 without any of the additional components is contemplated within the scope of the present invention. The formulation of the present invention having only the components from steps 101 through 113 demonstrated a reduction symptoms associated with cognitive functioning. Additional input of the components from steps 115 through 127 further enhanced results. Another alternative embodiment the present invention relates to the use of the components listed herein and optional ingredients including but not limited to cysteine and/or source of cysteine. During the manufacture of the formulation of the present invention using various forms of nano-emulsions and nano-encapsulations of the immediately aforementioned. The present invention having a therapeutically effective amount of the components from steps 101 through 113 were shown to support the subject's immune function due to impact on immune system where it is known that issues in the immune system heighten the symptoms and activity of cognitive dysfunction. Furthermore, when various combinations of the components listed in steps 101 through 125 were used there was an improved effect on additional symptoms that can cause worsened effects on various cognitive issues such as gut dysfunction and/or glutathione related issues. The formulation of the present invention optionally comprises bacteria of the genus *Lactobacillus* and/or *Bifidobacterium*. Preferably the formulation of the present invention comprises a *Bifidobacterium* selected from the group consisting of *B. longum*, *B. breve* and *B. bifidum* and/or *Lactobacillus* selected from the group of *L. casei*, *L. paracasei*, *L. rhamnosius*, *L. acidophilus*, and *L. plamtarium*. A

preferred alternative embodiment of the formulation of the present invention comprises *Bifidobacterium breve* and/or *Lactobacillus paracasei*.

[0027] In the preceding detailed description, reference has been made to the accompanying drawings that form a part hereof, and in which are shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments, and certain variants thereof, have been described in sufficient detail to enable those skilled in the art to practice the invention. It is to be understood that other suitable embodiments may be utilized and that logical changes may be made without departing from the spirit or scope of the invention. The description may omit certain information known to those skilled in the art. The preceding detailed description is, therefore, not intended to be limited to the specific forms set forth herein, but on the contrary, it is intended to cover such alternatives, modifications, and equivalents, as can be reasonably included within the spirit and scope of the appended claims.

WHAT IS CLAIMED IS:

1. A formulation targeted towards individuals with cognitive disorders wherein the formulation comprises:

Vitamin D as cholecalciferol, wherein the cholecalciferol comprises between ten and twenty percent of a total of the formulation;

N-acetyl-L Tyrosine, wherein the N-acetyl-L Tyrosine is present within a range of ten to twenty percent of the total of the formulation;

Anhydrous caffeine, wherein the anhydrous caffeine is present in the total of the formulation between an range of ten to twenty percent;

L-Theanine, wherein the L-Theanine is present within a range of five to twenty percent of the total of the formulation;

Mucuna Pruriens, wherein said mucuna pruriens comprising between five and twenty percent of the total of the formulation;

Proanthocyanidin, wherein said proanthocyanidin is present in the total of the formulation between a range of five and twenty percent;

Turmeric root extract, wherein the turmeric root extract is present in the formulation between a range of five to twenty percent.

2. The formulation targeted towards individuals with cognitive disorders as recited in claim 1, wherein the formulation further includes at least one component selected from a group consisting of: vitamin A, B, E, C, K, Zinc or Niacin.

3. The formulation targeted towards individuals with cognitive disorders as recited in claim 2, wherein the formulation of the present invention further includes glutathione producing ingredients.

4. The formulation targeted towards individuals with cognitive disorders as recited in claim 3, wherein the glutathione producing ingredients are selected from a group consisting of: lipoic acid, pyruvate, silicas, oxaloacetate and oxaloaspartate.

Patent Application
Docket No.: Ccook-04

5. The formulation targeted towards individuals with cognitive disorders as recited in claim 4, Resveratrol, 5-10% Black Cumin Seed oil, 5-10% Raspberry, 5-10% Resveratrol, 5-10% Aloe Vera, 5-10% Apple Cider Vinegar 5-10%

6. The formulation targeted towards individuals with cognitive disorders as recited in claim 5, Prebiotics and Probiotics 2-5%

7. The formulation targeted towards individuals with cognitive disorders as recited in claim 6, silicas 2-5% and silver ions

8. The formulation targeted towards individuals with cognitive disorders as recited in claim 7, wherein the formulation further includes silicon dioxide having a percentage range of the total formulation of the present range up to five percent and wherein the silicon dioxide is derived from zeolites and benzonites.

9. The formulation targeted towards individuals with cognitive disorders as recited in claim 8, wherein said formulation further includes a fat blend, said fat blend being comprised of borage oil and fish oil, said fat blend comprising between five and ten percent of the total of the formulation.

10. The formulation targeted towards individuals with cognitive disorders as recited in claim 9, wherein said formulation further includes cysteine or source of cysteine.

11. The formulation targeted towards individuals with cognitive disorders as recited in claim 10, wherein the formulation further includes a bacteria group, said bacteria group consisting of one or more of the following group of bacteria: Lactobacillus or Bifidobacterium, and wherein said Bifidobacterium is selected from a group consisting of B. longum, B. breve and B. bifidum, and wherein said Lactobacillus is selected from the group of L. casei, L. paracasei, L. rhamnosus, L. acidophilus, and L. plantarium.

12. The formulation targeted towards individuals with cognitive disorders as recited in claim 11, wherein said bacteria group present in the formulation includes *Bifidobacterium breve* or *Lactobacillus paracasei*.

13. The formulation targeted towards individuals with cognitive disorders as recited in claim 12, wherein said formulation further includes one or more biologically active molecules.

14. The formulation targeted towards individuals with cognitive disorders as recited in claim 13, wherein said biologically active molecules of the formulation consist of a group consisting of one of the following biologically active molecules: growth factors, immunoglobulins, milk products or milk derived components.

15. The formulation targeted towards individuals with cognitive disorders as recited in claim 14, wherein said formulation further includes an oligosaccharide, said oligosaccharide comprising between five and ten percent of the total of the formulation.

16. The formulation targeted towards individuals with cognitive disorders as recited in claim 15, wherein said oligosaccharides are prepared from a group consisting of one of the following: prepared from pectin, pectate, alginate, chondrotine, hyaluronic acid, heparine, heparane, bacterial carbohydrates, sialoglycans, fucoidan, fucooligosachrides, carrageenan or neutral oligosaccharides.

ABSTRACT OF THE DISCLOSURE

The present investigation relates to a nutritional based formulation for individuals with cognitive disorders such as but not limited to Alzheimer's and Dementia as well as sexual dysfunction. The formulation of the present invention further is focused on providing nutritional therapy to potentially treat other conditions such as but not limited to abnormal hormone function and sexual dysfunction. The formulation is produced utilizing various techniques to include but not be limited to nano-emulsions and nano-encapsulation. The formulation of the present invention includes varying percentages of the following and additional components: Turmeric root extract, Cholecalciferol, N-acetyl-L tyrosine, Caffeine, L-Theanine, Mucuna Pruriens. It is further contemplated within the scope of the present invention that an additional vitamin group could be added having a range of two to five percent of the total of the formulation. Additionally, an optional fat blend could further be incorporated into the formulation of the present invention.