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(54) **COMPOSITIONS METHODS AND KITS FOR ENHANCING IMMUNE RESPONSE TO A RESPIRATORY CONDITION**

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(57) **ABSTRACT**

Disclosed herein are compositions for treating a respiratory condition, preferably by enhancing immune response in a mammal, the compositions including a therapeutic amount of a probiotic strain of bacteria and a therapeutic amount of an additional component. Also included are methods of treating a respiratory condition, preferably by enhancing immune response, in a mammal. Kits containing the compositions, and instructions for applying the methods are also included. The method includes orally administering to the mammal a therapeutic amount of a probiotic strain of bacteria and a therapeutic amount of an additional component.

COMPOSITIONS METHODS AND KITS FOR ENHANCING IMMUNE RESPONSE TO A RESPIRATORY CONDITION

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/063,735, filed Feb. 6, 2008.

FIELD OF THE INVENTION

[0002] The present invention relates to compositions and methods for treating a respiratory condition, preferably by enhancing immune response to a respiratory condition. More particularly, the present invention relates to compositions comprising a therapeutic amount of a probiotic strain of bacteria and a therapeutic amount of an additional component, and methods of using such compositions. Most particularly, the present invention relates to compositions and methods of using a probiotic strain of bacteria for treating a respiratory condition, preferably by enhancing immune response to a respiratory condition.

BACKGROUND OF THE INVENTION

[0003] According to the Centers for Disease Control (CDC), in 2006 an estimated 56% of students aged 5-17 years missed between 1 and 5 days of school due to illness or injury, 10% missed 6 to 10 days, and 5% missed 11 or more days. In addition, it is estimated that 189 million school days are missed annually (an average of nearly 1 day per episode) due to a cold. In addition to children missing school, when children miss school, as a consequence often a parent misses work to stay home and care for the child. Often one or both parents and any siblings also contract the cold from the sick child which results in the siblings missing school and the parent(s) missing additional days of work either due to their own illness or caring for the sick child(ren).

[0004] However, colds are only one type of respiratory condition affecting the population, and respiratory conditions can be or be triggered by any of a variety of sources including allergens and/or pathogens of viral, bacterial or fungal origin. Common respiratory conditions include cold, influenza (flu), respiratory allergies, and asthma. Symptoms of respiratory conditions typically include coughing, sneezing, headaches, congestion, sore throat, stuffy nose, runny nose, fever, and the like.

[0005] Respiratory product types commonly used to treat such symptoms can generally be categorized as liquid elixirs, cough syrups, cold and flu capsules, cold and flu tablets, allergy tablets, effervescent tablets, mouth and nasal sprays, cough drops, and the like.

[0006] The most commonly employed products for treating respiratory conditions are ingested or bucally administered to inhibit and/or treat onset or fully developed respiratory symptoms. The products typically contain one or more actives dissolved or dispersed in a carrier system for ingestion or bucal delivery into the bloodstream. Although many consumers prefer respiratory products in the form of cough drops, liquids, or capsules, respiratory products in the form of powders and effervescent tablets have also met consumer needs in combating respiratory conditions.

[0007] Some compositions and methods for the prevention and anti-inflammatory compounds, treatments using orally administered aminocarboxylic acid compounds; treatment of cough and colds using compositions comprising non-steroidal anti-inflammatory drugs such as NSAIDS with antihistaminically effective materials such as chlorpheniramine; use of ionic zinc such that the ionic zinc contacts the nasal membrane; and use of probiotic strains of bacterial microorganisms which have been shown to have immunomodulatory effects, for example for the treatment of allergies.

[0008] Many different viruses and strains thereof can result in respiratory conditions and symptoms associated with respiratory conditions. The common cold, for example, is a complex syndrome that may be caused by any of over 200 antigenic viruses, among the most important of which is rhinovirus. Although distinct from the cold viruses, influenza viruses can and do produce many of the same symptoms.

[0009] Additionally, allergies are a particularly bothersome respiratory condition. Allergies can be, without limitation by theory, the result of hyper-reactivity of the immune system to foreign or self antigens. Type I allergy, such as allergic rhinitis (e.g., hay fever) or atopic dermatitis, occurs in allergic subjects upon exposure to environmental allergens (e.g., pollens or dust mites), and results in key clinical symptoms, similar to those of cold and flu, such as sore throat, cough, fatigue, sneeze, running nose, nasal drip, stuffy nose, nasal congestion, excessive mucus, sinus pressure, plugged ears, itchy nose, itchy, red, puffy, swollen, irritated and watery eyes.

[0010] In healthy status, the immune system maintains a balance between cytokines produced by different helper T lymphocyte subsets: Th1 and Th2 lymphocytes. In contrast, an allergic subject demonstrates a biased dysfunction of Th2 over Th1 that leads to an elevated IgE antibody production. The elevated production of IgE may be induced by hyper-reactivity of Th2 lymphocytes that secrete cytokines (e.g., IL-4, IL-5). Th1 cytokines (e.g., interferon-gamma, IL-12) may counteract Th2 cytokines and regain a healthy state in murine systems. IgE antibody-bound mast cells interact with allergen, triggering release of chemical mediators (e.g., histamine, leukotriene) and cause vasodilation and hypersecretion in various tissues. Antihistamines or leukotriene antagonists compete with the secreted inflammatory mediators from mast cells and significantly reduce clinical respiratory symptoms. Probiotic strains of bacteria have also been shown to have immunomodulatory effects when used in the treatment of allergies.

[0011] Thus, pinpointing specific causes of respiratory conditions can be difficult because there are a number of factors involved in the manifestation of respiratory conditions that are not fully understood. However, it is generally understood that factors including lowered immunity, stress, lack of sleep, too much exercise, malnutrition, seasonal changes, social activities, age, environmental toxins and even certain medications (i.e. immunosuppressive medications) can increase the risk of, and make individuals more susceptible to, various respiratory conditions.

[0012] Therefore, there remains a need for compositions and methods for enhancing immune response to a respiratory condition, in mammals, including human children. This need is particularly apparent with respect to children because the use of common cold/flu actives for children 12 years of age and under has recently come into question with respect to both efficacy and safety of those actives in children. There-

ity to respiratory conditions, preventing and treating respiratory conditions, and reducing the severity and duration of respiratory conditions, which are safe, effective, palatable and easy to administer and use.

SUMMARY OF THE INVENTION

[0013] The present invention comprises compositions for treating a respiratory condition, preferably by enhancing immune response to a respiratory condition in a mammal, comprising a therapeutic amount of a probiotic strain of bacteria and a therapeutic amount of an additional component. The present invention also includes methods of treating a respiratory condition, preferably by enhancing immune response to a respiratory condition in a mammal, comprising orally administering to the mammal a therapeutic amount of a strain of *Lactobacillus* and a therapeutic amount of an additional component. The present invention also comprises kits containing the compositions. The present compositions and methods can also or alternatively include a strain of *Bifidobacterium* and/or other additional components. The compositions of the present invention can formed as a single composition or separate compositions packaged together in a kit.

DETAILED DESCRIPTION OF THE INVENTION

[0014] Various documents including, for example, publications and patents, are recited throughout this disclosure. All documents are hereby incorporated by reference.

[0015] Referenced herein may be trade names for components including various ingredients utilized in the present invention. The inventors herein do not intend to be limited by materials under a certain trade name. Equivalent materials (e.g., those obtained from a different source under a different name or reference number) to those referenced by trade name may be substituted and utilized in the descriptions herein.

[0016] In the description of the invention various embodiments and/or individual components are disclosed. As will be apparent to the ordinarily skilled practitioner, all combinations of such embodiments and components taught in the disclosure are possible and can result in preferred executions of the present invention.

[0017] All percentages and ratios are calculated by weight unless otherwise indicated. All percentages, parts and ratios are calculated based on the total composition unless otherwise indicated. Weights as they pertain to listed ingredients are based on the specific ingredient level and, therefore, do not include carriers or by-products that may be included in commercially available materials, unless otherwise specified.

[0018] As used herein, the terms "mixture" and "combination" include multiple components or ingredients formed into one resulting component, components that can be separate but contained in a single dosage form, and components that can be administered in the same treatment regimen even if not physically formed into a single component or contained in a single dosage form. As used herein, the terms "mixture" and "combination" may be used interchangeably.

[0019] As used herein, "mammal" includes but is not limited to humans as well as domestic animals including cat, dog, cow, rabbit, and horse.

[0020] As used herein, "respiratory condition" includes susceptibility to, risk of, and onset of symptoms of the conditions piratory tract viral infections, respiratory tract bacterial infections, respiratory tract fungal infections, allergies (for example to pollen, fungi, and environmental allergens), asthma, auto-immune conditions, rhinitis, sinusitis, bronchiolitis, acute respiratory distress syndrome (ARDS), severe acute respiratory syndrome (SARS), respiratory cancer, emphysema, COPD, difficulty breathing, cough, and conditions pursuant to respiratory surgeries (including pre- and post-operative management).

[0021] As used herein, "immune response" includes all of the specific and non-specific processes and mechanisms involved in how the body defends and repairs itself against bacteria, viruses, fungi, allergens and all substances, insults, challenges, biological and/or physical invasions of the body that are harmful to the body.

[0022] As used herein "enhancing immune response" means a change to the immune system which provides a benefit to the mammal. "Enhancing" the immune response also includes prevention, treatment, cure, mitigation amelioration, inhibition and/or alleviation of a respiratory condition and/or symptoms thereof. "Enhancing the immune system" results in benefits including improved quality of life; improved mood and/or reduced stress; improved concentration; better overall health; improved respiratory health; preserving, maintaining and/or restoring normal ability to perform normal daily tasks, including the ability to go to work and/or school; providing, supporting and/or maintaining normal vitality and energy levels; and enhancing sleep including quality of sleep. "Enhancing the immune system" also includes maintaining, supporting and/or strengthening natural defenses, and enhancing wellness and overall immune system health.

[0023] As used herein "cold, influenza and allergy-like symptoms" refers to symptoms typically associated with respiratory conditions as defined herein. These symptoms include, but are not limited to, nasal congestion, chest congestion, sneezing, rhinorrhea, fatigue, malaise, cough, fever, chills, body ache, sore throat, headache, excessive mucus, sinus pressure, nasal drip, runny nose, itchy eyes, watery eyes and other known cold, influenza and allergy-like symptoms.

[0024] As used herein "respiratory viruses" refers to those viruses that are causal agents of respiratory conditions that result in cold and influenza-like symptoms. Non-limiting examples of such viruses include Rhinovirus, Myxovirus (Influenza virus), Paramyxovirus (Parainfluenza virus), Respiratory Syncytial virus, Adenovirus and Coronavirus.

[0025] As used herein "respiratory bacteria" refers to those bacteria that are causal agents of respiratory conditions that result in cold and influenza-like symptoms. Non-limiting examples of such bacteria include *Hemophilus influenzae*, mycobacteria, *pasteurella, Pneumocystis jiroveci, Mycobacterium tuberculosis, Streptococcus pheumoniae*, bacteria pneumonia and *Klebsiella pneumoniae.*

[0026] As used herein "respiratory fungi" refers to those fungi that are causal agents of respiratory conditions that result in cold and influenza-like symptoms. Non-limiting examples of respiratory fungi and fungally caused respiratory conditions include aspergillosis, hisoplasmosis, *Blastomyces*, dermatitidis, *Cryptococcus neoformas, Coccidioidomycosis*, and *Pneumocystis jiroeci.*

[0027] As used herein, a "probiotic" microorganism or strain of microorganism confers beneficial functions and/or

amount. As used herein "probiotic" microorganism includes bacteria, bacterial homogenates, ground bacterial cells, bacterial proteins, bacterial extracts, bacterial ferment supernatants, and mixtures thereof "Probiotic" microorganisms also include natural and/or genetically modified microorganisms, viable or dead; processed compositions of microorganisms; their constituents and components such as proteins and carbohydrates, extracts, distillates, isolates, purified fractions, and mixtures thereof of bacterial ferments that beneficially affect a host. Although a use of probiotic microorganisms herein can be in the form of viable cells, use can be extended to non-viable cells such as killed cultures, or compositions containing beneficial factors expressed by the probiotic microorganism. Killed cultures may include thermally killed microorganisms, or microorganisms killed by exposure to altered pH or subjected to pressure. "Probiotic" microorganism is further intended to include metabolites generated by the microorganisms during fermentation, if such metabolites are not separately indicated. These metabolites may be released to the medium of fermentation, or they may be stored within the microorganism.

[0028] The abbreviation CFU (referring to "colony-forming unit") as used herein designates the number of bacterial cells revealed by microbiological counts on agar plates, as will be commonly understood in the art.

[0029] The term "pharmaceutically acceptable carrier" refers to any solid, liquid or gas combined with components of the compositions of the present invention to deliver the components to the user. These vehicles are generally regarded as safe for use in humans, and are also known as carriers or carrier systems.

[0030] The term "therapeutic amount" of a component, composition, or like material as used herein refers to a concentration or amount of any active defined herein that is ingested, including ingestion by buccal administration, that is effective to provide the desired effect or benefit to a host animal without undue adverse side effects (such as toxicity, irritation, or allergic response), commensurate with a reasonable benefit/risk ratio when used in the manner of this invention. In the present invention, desired effects and/or benefits include enhancement of the immune system including treatment, prevention or resistance of respiratory conditions in a mammal. The specific "therapeutic amount" will, obviously, vary with such factors as the particular condition being treated, the particular composition to be used, the physical condition of the treated mammal, the size and weight of the treated mammal, the duration of treatment, the nature of concurrent therapy (if any), the specific dosage form to be used, other components present in a given dosed composition, and the dosage regimen desired for the component or composition.

[0031] Additional definitions are provided as necessary herein as they occur.

[0032] The compositions and methods of the present invention can comprise, consist of, or consist essentially of the elements and limitations of the invention described herein, as well as any of the additional or optional ingredients, components, limitations, or steps described herein.

Compositions

[0033] The present invention comprises compositions comprising a therapeutic amount of a probiotic strain of bacteria defined herein. The present invention also can comprise kits containing the compositions, with the compositions formed as single compositions or as separate compositions packaged together in a kit.

[0034] In one embodiment, the probiotic strain of bacteria herein is able to maintain viability following transit through the gastrointestinal tract. This is desirable in order for live cultures of the bacteria to be taken orally, and for colonization to occur in the intestines and bowel following transit through the esophagus and stomach. Colonization of the intestine and bowel by the probiotic strain of bacteria is desirable for long term probiotic benefits to be delivered to the host. Oral administration of non-viable cells or purified isolates thereof can induce temporary benefits. However, if the bacteria are not viable, they are not able to grow, and are more limited in ability to continuously deliver a probiotic effect. As a result, this may require the host to be dosed regularly in order to maintain the health benefits. In contrast, viable cells that are able to survive gastric transit in viable form, and subsequently colonize by adhering to and proliferating on the gut mucosa, are better able to deliver probiotic effects continuously.

[0035] The compositions utilized in the compositions and methods herein comprise a probiotic strain of bacteria. Non-limiting examples of bacteria suitable for use herein include strains of *Streptococcus lactis, Streptococcus cremoris, Streptococcus diacetylactis, Streptococcus thermophilus, Lactobacillus bulgaricus, Lactobacillus acidophilus, Lactobacillus helveticus, Lactobacillus bifidus, Lactobacillus casei, Lactobacillus lactis, Lactobacillus plantarum, Lactobacillus rhamnosus, Lactobacillus delbruekii, Lactobacillus thermophilus, Lactobacillus fermentii, Lactobacillus salivarius, Lactobacillus reuteri, Lactobacillus brevis, Lactobacillus paracasei, Lactobacillus gasseri, Pediococcus cerevisiae, Bifidobacterium longum, Bifidobacterium infantis, Bifidobacterium adolescentis, Bifidobacterium bifidum, Bifidobacterium animalis, Bifidobacterium pseudolongum, Bifidobacterium thermophilum, Bifidobacterium lactis, Bifidobacterium bulgaricus, Bifidobacterium breve, Bifidobacterium subtilis, Escherichia coli* and strains of the genera including *Bacillus, Bacteroides, Enterococcus* (e.g., *Enterococcus faecium*) and *Leuconostoc*, and mixtures and/or combinations thereof.

[0036] Embodiments of the compositions and methods of the present invention comprise strains of lactic acid bacteria selected from the genera *Lactobacillus* and *Bifidobacterium*, such as *Lactobacillus acidophilus, Lactobacillus fermentum* and *Bifidobacterium lactis*, and combinations and/or mixtures thereof. In one embodiment, the methods herein comprise administration of a composition comprising a therapeutic amount of the lactic acid bacteria.

[0037] Non-limiting examples of *Lactobacillus* suitable for use herein include strains of *Lactobacillus bulgaricus, Lactobacillus acidophilus, Lactobacillus helveticus, Lactobacillus bifidus, Lactobacillus casei, Lactobacillus lactis, Lactobacillus plantarum, Lactobacillus rhamnosus, Lactobacillus delbruekii, Lactobacillus thermophilus, Lactobacillus fermentii, Lactobacillus salivarius, Lactobacillus reuteri, Lactobacillus brevis, Lactobacillus paracasei, Lactobacillus gasseri*, and combinations thereof.

[0038] A non-limiting example of a *Lactobacillus* strain suitable for use herein includes the *Lactobacillus acidophilus* strain identified as LAFTI® L10 deposited under accession

[0039] In one embodiment herein, the compositions can comprise at least about 10^4 CFU of *Lactobacillus*, alternatively from about 10^4 to about 10^{14} CFU of *Lactobacillus*, in another embodiment from about 10^6 to about 10^{12} CFU of *Lactobacillus*, in another embodiment from about from about 10^8 to about 10^{11} CFU of *Lactobacillus*, per unit dose of the composition.

[0040] Other non-limiting examples of a *Lactobacillus* strains suitable for use herein include the *Lactobacillus acidophilus* strain identified as CL-92 deposited in Japan at International Patent Organism Depository, FERM BP-4981, the *Lactobacillus acidophilus* strain identified as CL0062 deposited in Japan at International Patent Organism Depository, FERM BP4980, and the *Lactobacillus fermentum* strain identified as CP34 and deposited in Japan at International Patent Organism Depository, FERM BP-8383. These organisms, have been shown, as described in US Patent Application Publication Number US 2005/0214270, to provide anti-allergic effects by suppressing IgE levels in mice, and by reducing allergy symptoms and decreasing IgE titer in the blood in humans.

[0041] In one embodiment, the compositions can comprise at least about 1×10^4, alternatively at least about 1×10^9, alternatively at least about 1×10^{10}, and alternatively at least about 5×10^{10} cells per day of the probiotic strain of bacteria, which can be administered in a single dose, or in a plurality of doses.

[0042] In one embodiment, the methods herein comprise administration of a composition comprising a therapeutic amount a strain of *Bifidobacterium*, which can be mammalian, in addition to, or in alternative to, a *Lactobacillus* as described herein. The mammal treated and a mammalian source of *Bifidobacterium* isolation may be, but need not be, independent.

[0043] Non-limiting examples of *Bifidobacterium* suitable for use herein include strains of *Bifidobacterium longum, Bifidobacterium infantis, Bifidobacterium adolescentis, Bifidobacterium bifidum, Bifidobacterium animalis, Bifidobacterium pseudolongum, Bifidobacterium thermophilum, Bifidobacterium lactis, Bifidobacterium bulgaricus, Bifidobacterium breve, Bifidobacterium subtilis*, and mixtures and/or combinations thereof.

[0044] A non-limiting example of a *Bifidobacterium* strain suitable for use herein includes *Bifidobacterium lactis* identified as LAFTI® 94 deposited under accession number CBS 118529 that can be purchased from DSM Corporation. Other examples of useful *Bifidobacterium* strains include *Bifidobacterium longum* strain identified as BB-536 (Morinaga & Co., LTD, Japan)

[0045] In one embodiment herein, the compositions used in the methods herein comprise at least about 10^4 CFU of *Bifidobacterium*, alternatively from about 10^4 to about 10^{14} CFU of *Bifidobacterium*, in another embodiment from about 10^6 to about 10^{12} CFU of *Bifidobacterium*, in another embodiment from about from about 10^8 to about 10^{11} CFU of the *Bifidobacterium*, per unit dose of the composition.

[0046] In one embodiment, the probiotic strain of bacteria, can comprise a freeze-dried powder (as would be understood by one of skill in the art) can comprise from about 1% to about 50%, alternatively from about 1% to about 40%, alternatively from about 1% to about 30%, and alternatively from about 2% to about 20%, by weight of the composition.

Additional Components

[0047] The compositions of the present invention can, by way of non-limiting example, an additional probiotic strain of bacteria; one or more of prebiotics and/or fiber; vitamins; minerals, metals and elements; plant-derived components; fungal-derived components; carotenoids; anti-oxidants; and mixtures/combinations thereof can be used.

[0048] The compositions of the present invention can comprise, by way of non-limiting example, one or more probiotic strains of bacteria plus one or more of an additional probiotic strain of bacteria, a prebiotic, a fiber, vitamins, minerals, elements, plant-derived components, fungal-derived components, carotenoids, and antioxidants. Non-limiting examples of some additional components are provided below.

Prebiotics/Fiber

[0049] The compositions of the present invention comprising the probiotic used herein can comprise a prebiotic and/or a fiber.

[0050] As used herein, the term "prebiotic" includes substances or compounds that beneficially affect the host mammal by selectively promoting the growth and/or activity of one or more probiotic bacteria in the gastro-intestinal tract of the host mammal, thus maintaining normal health or improving health of the host. Typically, prebiotics are carbohydrates, (such as oligosaccharides), but the term "prebiotic" as used herein does not preclude non-carbohydrates. Many forms of "fiber" exhibit some level of prebiotic effect. Thus, there is considerable overlap between substances that can be classified as "prebiotics" and those that can be classified as "fibers".

[0051] Non-limiting examples of prebiotics suitable for use in the compositions and methods include psyllium, fructo-oligosaccharides, inulin, oligofructose, galacto-oligosaccharides, isomalto-oligosaccharides xylo-oligosaccharides, soy-oligosaccharides, gluco-oligosaccharides, mannan-oligosaccharides, arabinogalactan, arabinxylan, lactosucrose, gluconannan, lactulose, polydextrose, oligo-dextran, gentioligosaccharide, pectic oligosaccharide, xanthan gum, gum arabic, hemicellulose, resistant starch and its derivatives, and mixtures and/or combinations thereof.

[0052] When present, the compositions can comprise from about 100 mg to about 100 g, alternatively from about 500 mg to about 50 g, and alternatively from about 1 g to about 40 g, of prebiotic, per daily dose of the composition.

Fiber

[0053] As used herein, the term "fiber" means carbohydrate polymers including those naturally occurring in food as consumed, those having been obtained from food raw material by physical, enzymatic or chemical means, and synthetic carbohydrate polymers, which are resistant to digestion and absorption in the small intestine and have partial fermentation in the large intestine.

[0054] Non-limiting examples of fiber and analogous carbohydrate polymers suitable for use in the compositions and methods of the present invention include pectins, psyllium, guar gum, xanthan gum, alginates, gum arabic, fructo-oligosaccharides, inulin, agar, beta-glucans, chitins, dextrins, lignin, celluloses, non-starch polysaccharides, carrageenan, and mixtures and/or combinations thereof.

[0055] In one embodiment, the fiber is glucose polymers, preferably those which have branched chains. Among such suitable fibers is one marketed under the tradename "Fiber-

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