component for inflammatory diseases. Preferred such diseases are metabolic syndrome related conditions (preferably selected from pre-diabetes, diabetes, cardiovascular disease).

SUMMARY

The present inventors have found that *Lactobacillus fermentum* ME-3, unlike other *Lactobacillus* sp. (Mikelsaar & Zilmer (2009) Microbial Ecology in Health and Disease, 21: 1-27), is a significant inhibitor of pro-inflammatory markers, such as glycated haemoglobin HbA1c, high sensitivity C-reactive protein (hsCRP) and IL-6, and is also capable of stimulating production of the anti-inflammatory and anti-diabetic peptide adiponectin. Consequently, as a result of identifying the underlying mechanism by which the probiotic strain *Lactobacillus fermentum* ME-3 acts, the present inventors have found that it can be used to prevent, alleviate the symptoms of, treat and/or be used as an adjuvant treatment e.g. as an adjuvant component for inflammatory diseases and in particular metabolic syndrome related conditions (preferably selected from pre-diabetes, diabetes, cardiovascular disease). This is particularly surprising, as *Lactobacillus fermentum* ME-3 has previously been reported as an antimicrobial and antioxidative probiotic (EP1401457 & Mikelsaar & Zilmer (2009) Microbial Ecology in Health and Disease, 21: 1-27).

One aspect of the invention relates to the use of a composition comprising Lactobacillus fermentum ME-3 strain DSM 14241 in the manufacture of a medicament for preventing, alleviating the symptoms of or treating, alone or as an adjuvant component, a metabolic syndrome related disorder selected from prediabetes, cardiovascular disease and type 2 diabetes in a subject who is asymptomatic for said metabolic syndrome related disorder and who has a CRP level of 3-10 mg/L.

Another aspect relates to the use of a composition comprising Lactobacillum fermentum ME-3 strain DSM 14241 in the manufacture of a medicament for preventing, alleviating the symptoms of or treating, alone or as an adjuvant component, a metabolic syndrome related disorder selected from prediabetes, cardiovascular disease and type 2 diabetes by simultaneously: a.decreasing the level of glycated haemoglobin HbA1c; b. decreasing or preventing low-grade inflammation on a cellular level; and c. increasing the level of adiponectin, in a subject who is asymptomatic for said metabolic syndrome related disorder and who has a CRP level of 3-10 mg/L.

The disclosure also provides a composition comprising *Lactobacillus fermentum* ME-3, particularly *Lactobacillus fermentum* ME-3 strain DSM 14241 deposited at the Deutsche Sammlung für Mikroorganismen and Zelkulturen GmbH-s on 19/4/2001, for use in preventing, alleviating the symptoms of, treating and/or providing adjuvant treatment, e.g. as an adjuvant component , for an inflammatory disease and in particular metabolic syndrome related conditions. The disclosure also provides a method of preventing, alleviating the symptoms of, treating and/or providing adjuvant treatment, e.g. as an adjuvant component, for an inflammatory disease, and in particular metabolic syndrome related conditions in a subject comprising administering an effective amount of a composition comprising *Lactobacillum fermentum* ME-3 strain DSM 14241 to said subject. The disclosure further provides the use of *Lactobacillum fermentum* ME-3 strain DSM 14241 in the manufacture of a medicament and/or an adjuvant medicament for the prevention, alleviation of the symptoms, treatment and/or adjuvant treatment, e.g. for an inflammatory disease and in particular metabolic syndrome related conditions.

Because of its mechanism of action, *Lactobacillus fermentum* ME-3 is particularly useful in certain subject sub-populations such as asymptomatic subjects, including those with low-grade inflammation, at risk of developing an inflammatory disease, such as cardiovascular disease (CVD), type 2 diabetes or metabolic syndrome; and patients who have suffered a stroke. The present inventors have also discovered that *Lactobacillus fermentum* ME-3 is also particularly beneficial when used in combination with one or more vitamins and/or monocalin K.

The present disclosure therefore also provides a composition comprising *Lactobacillus fermentum* ME-3, for use in preventing, alleviating the symptoms of, treating and/or providing adjuvant treatment (e.g. as an adjuvant

CLAIMS:

1. Use of a composition comprising *Lactobacillus fermentum* ME-3 strain DSM 14241 in the manufacture of a medicament for preventing, alleviating the symptoms of or treating, alone or as an adjuvant component, a metabolic syndrome related disorder selected from prediabetes, cardiovascular disease and type 2 diabetes, in a subject who is asymptomatic for said metabolic syndrome related disorder and who has a CRP level of 3-10 mg/L.

2. Use of a composition comprising *Lactobacillum fermentum* ME-3 strain DSM 14241 in the manufacture of a medicament for preventing, alleviating the symptoms of or treating, alone or as an adjuvant component, a metabolic syndrome related disorder selected from prediabetes, cardiovascular disease and type 2 diabetes by simultaneously:
    a. decreasing the level of glycated haemoglobin HbA1c;
    b. decreasing or preventing low-grade inflammation on a cellular level; and
    c. increasing the level of adiponectin,

    in a subject who is asymptomatic for said metabolic syndrome related disorder and who has a CRP level of 3-10 mg/L.

3. The use of claim 1 or claim 2, wherein ~~the~~ decreased or absent inflammation on a cellular level is measured using the pro-inflammatory marker~~s hsCRP and~~ IL-6.

~~4. The use of any preceding claim, wherein the subject is asymptomatic for said metabolic syndrome related disorder.~~

~~5. The use of claim 4, wherein the asymptomatic subject has a CRP level of ≤ 10 mg/l.~~

~~6. The use of claim 5, wherein the asymptomatic subject has a CRP level of 3-10 mg/l.~~

~~7.~~4. The use of any preceding claim, wherein said composition is a food product, a food supplement or a pharmaceutical composition.

~~8.~~5. The use of claim ~~7~~4, wherein the food product is a medical food product or a functional food product.

~~9.~~6. The use of claim ~~7~~4 or ~~8~~5, wherein the food product is a dairy product such as milk, yogurt, cheese, kefir, or a milk- or whey-based fermented dairy product, or a chocolate product.

~~10.~~7. The use of any preceding claim, wherein said composition is administered prior to, simultaneously with, or subsequently to ~~another active compound, such as~~ an anti-inflammatory composition, one or more vitamins, and/or monacolin K.

~~11.~~8. The use of any preceding claim, wherein said composition further comprises one or more vitamins and/or monacolin K.

~~12.~~9. The use of any preceding claim, wherein said composition comprises *Lactobacillum fermentum* ME-3 strain DSM 14241 in an encapsulated form, in a freeze-dried form, in a coated form, in a capsule, in a tablet or in a powder.

~~13.~~10. The use of any preceding claim, wherein said composition comprises 10^6-10^{11} CFU of *Lactobacillum fermentum* ME-3 strain DSM 14241.