SUMMARY

[0008a] In a first aspect, the present disclosure provides a use of *Lactobacillus rhamnosus* HN001, AGAL deposit number NM97/09514 in the manufacture of a composition or medicament for treatment or prevention of at least one of postnatal depression (PND) and postnatal anxiety (PNA) in a human adult female subject in need thereof.

[0009] In a first example, the disclosure provides a method of treating or preventing of at least one of postnatal depression (PND) and postnatal anxiety (PNA) in a subject, the method comprising administration of *Lactobacillus rhamnosus* HN001, AGAL deposit number NM97/09514 dated 18 August 1997 to a subject in need thereof.

[0010] In one example, the *L. rhamnosus* HN001 is administered in the form of a composition with a physiologically acceptable diluent, adjuvant, carrier or excipient.

[0011] In one example, HN001 is the only probiotic bacteria administered.

[0012] In one example, HN001 is administered with one or more prebiotics.

[0013] In one example, said physiologically acceptable diluent, adjuvant, carrier or excipient is a food. In one example, the food is cultured milk, yoghurt, cheese, milk drink or milk powder.

[0014] Alternatively the composition is a pharmaceutical composition and said excipient or diluent is pharmaceutically acceptable diluent, adjuvant, carrier or excipient.

[0014a] In another aspect, the present disclosure provides a use of *Lactobacillus rhamnosus* HN001, AGAL deposit number NM97/09514 in the manufacture of a composition or medicament for prevention of one or more risks associated with, or sequelae of, at least one of PND and PNA in a neonatal, infant or child subject, wherein the composition or medicament is to be administered to the mother of the neonatal, infant or child subject in need thereof.

[0015] In another example, the disclosure provides a method of treating or preventing one or more risk associated with at least one of PND or PNA, wherein the risk is to an infant born, or to be born to a subject, the method comprising administration of *Lactobacillus rhamnosus* HN001, AGAL deposit number NM97/09514 dated 18 August 1997 to the subject in need thereof.

[0016] In one example, the composition is a maternal formula or a maternal supplement.

[0017] The composition may be a formula, for example a maternal formula, dietetic product, and hypoallergenic examples thereof.

[0018] In preferred examples, the method comprises administering a composition comprising *L. rhamnosus* HN001 to the subject. Preferably, the composition is a supplement, formula, dietetic product or food.

CLAIMS

1. Use of *Lactobacillus rhamnosus* HN001, AGAL deposit number NM97/09514 in the manufacture of a composition or medicament for treatment or prevention of at least one of postnatal depression (PND) and postnatal anxiety (PNA) in a human adult female subject in need thereof.

2. Use of *Lactobacillus rhamnosus* HN001, AGAL deposit number NM97/09514 in the manufacture of a composition or medicament for prevention of one or more risks associated with, or sequelae of, at least one of PND and PNA in a neonatal, infant or child subject, wherein the composition or medicament is to be administered to the mother of the neonatal, infant or child subject in need thereof.

3. The use of claim 1 or 2, wherein the composition or medicament comprises a physiologically acceptable diluent, adjuvant, carrier or excipient.

4. The use of any one of claims 1 to 3, wherein the composition is or comprises a food.

5. The use of claim 4, wherein the food is selected from cultured milk, yoghurt, cheese, milk drink and milk powder.

6. The use of claim 1 or 2, wherein the composition or medicament is a pharmaceutical composition comprising a pharmaceutically acceptable diluent, adjuvant, carrier or excipient.

7. The use of claim 1 or 2, wherein the composition or medicament is:

    a. a maternal formula or a maternal supplement, or
    b. a supplement, formula, dietetic product or food.

8. The use of any one of claims 1 to 7, wherein the *L. rhamnosus* HN001 is in a reproductively viable form.

9. The use of any one of claims 1 to 7, wherein the *L. rhamnosus* HN001 is killed, lysed, fractionated or attenuated.

10. The use of any one of claims 1 to 9, wherein

    a. the composition or medicament is to be administered after the first trimester of pregnancy,
    b. the composition or medicament is to be administered between 14 – 16 weeks gestation,
    c. the composition or medicament is to be administered from 14 to 16 weeks gestation until delivery, or
    d. the composition or medicament is to be administered from 14 to 16 weeks gestation to 6 months post-partum.

11. The use of any one of claims 1 to 10, wherein the composition or medicament is formulated for simultaneous or sequential administration with a prebiotic.

12. The use of claim 11, wherein the prebiotic comprises fructooligosaccharides, galactooligosaccharides, or human milk oligosaccharides, and combinations thereof.

13. The use of any one of claims 1 to 12, wherein the use results in a score of less than 13 in the Edinburgh Postnatal Depression Scale (EPDS) in the human adult female subject, or the mother; and/or a score of less than 15 in the State Trait Anxiety Inventory 6 item version (STAI6) 6 item scale in the human adult female subject, or the mother.

14. The use of any one of claims 2 to 13, wherein the one or more risks associated with, or sequelae of, at least one of PND and PNA in a foetal, neonatal, infant, child or adult subject are selected from emotional problems, behavioural problems, psychiatric diagnoses, and hyperactivity.

15. The use of any one of claims 1 to 14, wherein

    the treatment is prophylactic treatment,

    the treatment is prophylactic treatment of an adult female subject having an expected or established increased risk of at least one of PND or PNA,

the treatment is prophylactic treatment of an adult female subject attempting to become or recently pregnant,

the adult female subject, or the mother, is pregnant,

the adult female subject, or the mother, is pregnant and is 35 years or older,

the adult female subject, or the mother, is pregnant and has a history of at least one of PND and PNA,

the adult female subject, or the mother, is pregnant, is 35 years or older, and has a history of at least one of PND and PNA,

the subject is a neonatal, infant, or child subject, and the composition or medicament is to be administered to the subject's mother, or

the subject is a neonatal, infant or child subject and the composition or medicament is to be administered to the subject's pregnant mother during gestation.

16. The use of any one of claims 1 to 8 or 10 to 15, wherein the composition or medicament is to be administered at a dosage rate of *L. rhamnosus* HN001 of at least 6×10^9 cfu per day.