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 treating or preventing 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 treating or preventing one or more risks associated with, or sequelae of, at least one of PND and PNA in a foetal, neonatal, infant or child subject, wherein the composition or medicament is to be administered to the mother of the foetal, 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.

[0019] In certain examples, the *L. rhamnosus* HN001 is in a reproductively viable form, preferably in a reproductively viable form and amount. In other examples, the *L. rhamnosus* HN001 is killed, lysed, fractionated or attenuated.

[0020] The disclosure further provides *L. rhamnosus* HN001 for treating or preventing at least one of PND or PNA, or for treating or preventing one or more risk associated with, or one or more sequelae of, at least one of PND or PNA

[0021] The disclosure further provides *L. rhamnosus* HN001 in the manufacture of a composition for treating or preventing at least one of PND or PNA or for treating or preventing one or more risk associated with, or one or more sequelae of, at least one of PND or PNA. The composition may be a composition such as those as described herein including, for example, a food or medicament.

[0022] It will be appreciated that the disclosure also contemplates the use of *L. rhamnosus* HN001 in the manufacture of a composition of the disclosure, for example a composition for treating or preventing at least one of PND or PNA in a subject.

[0023] In one example the composition is suitable for oral administration. In other examples, the composition is suitable for parenteral administration. In examples relating to preventing one or more risk associated with, or one or more sequelae of, at least one of PND or PNA in a foetal subject, the composition is suitable for oral administration to a pregnant mother during gestation.

[0024] In various examples, the method is a method of treating or preventing at least one of PND or PNA in a subject having an increased risk of at least one of PND or PNA. In one example, the method is a method of treating or preventing at least one of PND or PNA in a subject who has previously suffered at least one of PND or PNA.

[0025] In a further example the subject has suffered from, experienced, has or had, one or more of: prenatal depression or anxiety, a personal or family history of depression, moderate to severe premenstrual symptoms, maternity blues, birth-related psychological trauma, birth-related physical trauma, previous stillbirth or miscarriage, cigarette smoking, low self-esteem, childcare or life stress, low social support, poor marital relationship or single marital status, and low socioeconomic status.

[0026] In one example, the method is a method of preventing recurrence of at least one of PND or PNA in a subject who has previously suffered from at least one of PND or PNA, the method comprising administering an effective amount of HN001 or a derivative thereof to a subject in need thereof.

[0027] In one example, the method comprises beginning administration of HN001 after the first trimester of pregnancy. In one example, administration of HN001 begins between 14 – 16 weeks gestation.

[0028] This disclosure may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this disclosure relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

[0029] The term "comprising" as used in this specification means "consisting at least in part of". When interpreting each statement in this specification that includes the term "comprising", features other than that or those prefaced by the term may also be present. Related terms such as "comprise" and "comprises" are to be interpreted in the same manner.

[0030] In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the disclosure. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] Figure 1 shows the number eligible, recruited and allocated in the PIP Study described in the Example section. *women did not complete the psychological outcomes questionnaire for various reasons including: pregnancy complications, maternal ill health, preterm birth, refusal and could not be contacted.

CLAIMS

1. Use of *Lactobacillus rhamnosus* HN001, AGAL deposit number NM97/09514 in the manufacture of a composition or medicament for treating or preventing 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 treating or preventing one or more risks associated with, or sequelae of, at least one of PND and PNA in a foetal, neonatal, infant or child subject, wherein the composition or medicament is to be administered to the mother of the foetal, 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 higher rates of 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 a subject having an expected or established increased risk of at least one of PND or PNA,

the treatment is prophylactic treatment of a subject attempting to become or recently pregnant,

the treatment is prophylactic treatment of a foetal subject by administration of the composition to the foetal subject's mother,

the treatment is prophylactic treatment of a neonatal, infant or child subject by administration of the composition to the subject's breastfeeding mother,

the treatment is therapeutic treatment of a neonatal, infant or child subject by administration of the composition to the subject's mother,

the subject is pregnant,

the subject is pregnant and is 35 years or older,

the subject is pregnant and has a history of at least one of PND and PNA,

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

the subject is a foetal 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 mother.

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.