[0006] There remains a need for methods and compositions useful to treat or prevent obesity and related diseases, in particular GDM. There is also a need for methods and compositions for treating or preventing GDM which does not rely changes in dietary modification and counselling. Methods and compositions for the prevention or amelioration of GDM-associated risks or sequelae of GDM are also desirable.

[0007] It is an object of this invention to provide improved or alternative methods and compositions for treating or preventing GDM and/or treating or preventing one or more GDM-associated risks or one or more sequelae of GDM.

SUMMARY

[0008] In one aspect, the present disclosure relates to use of one or more polar lipids in the manufacture of a composition or medicament for ~~treating or~~ preventing or reducing the risk of gestational diabetes mellitus (GDM) or preventing or reducing the risk or severity of at least one GDM-associated risk or sequela~~e~~ of GDM in an adult subject, comprising that the composition or medicament is to be administered to ~~a~~ the adult subject in need thereof, wherein the one or more polar lipids is derived from non-human mammalian milk.

[0008a] In another aspect, the present disclosure relates to use of one or more polar lipids in the manufacture of a composition or medicament for ~~treating or~~ preventing or reducing the risk or severity of at least one GDM-associated risk or sequela~~e~~ of GDM in a foetal, neonatal, infant or child subject, comprising that the composition or medicament is to be administered to the mother of the foetal, neonatal, infant or child subject in need thereof, wherein the one or more polar lipids is derived from non-human mammalian milk.

[0008b] In one example, the disclosure relates to a method of treating or preventing GDM in a subject in need thereof, and/or treating or preventing one or more GDM-associated risks or one or more sequelae of GDM in a subject in need thereof, the method comprising administration of one or more polar lipids to the subject.

[0009] In another example, the disclosure relates to a method of treating or preventing GDM in a subject in need thereof, the method comprising administration of one or more polar lipids to the subject.

[0010] In another example, the disclosure relates to a method of treating or preventing one or more GDM-associated risks or one or more sequelae of GDM in a subject in need thereof, the method comprising administration of one or more polar lipids to the subject.

[0011] In another example, the disclosure relates to a method of treating or preventing at least one GDM-associated risk or sequelae of GDM in a foetal, neonatal,

CLAIMS

1. Use of one or more polar lipids in the manufacture of a composition or medicament for ~~treating or~~ preventing or reducing the risk of gestational diabetes mellitus (GDM) or preventing or reducing the risk or severity of at least one GDM-associated risk or sequela~~e~~ of GDM in an adult subject, comprising that the composition or medicament is to be administered to ~~a~~ the adult subject in need thereof, wherein the one or more polar lipids is derived from non-human mammalian milk.

2. Use of one or more polar lipids in the manufacture of a composition or medicament for ~~treating or~~ preventing or reducing the risk or severity of at least one GDM-associated risk or sequela~~e~~ of GDM in a foetal, neonatal, infant or child subject, comprising that the composition or medicament is to be administered to the mother of the foetal, neonatal, infant or child subject in need thereof, wherein the one or more polar lipids is derived from non-human mammalian milk.

3. The use of claim 1 or 2, wherein the non-human mammalian milk is bovine milk.

~~3~~4. The use of claim 1 or 2 wherein the one or more polar lipids is to be administered in a composition or medicament comprising a physiologically acceptable diluent, adjuvant, carrier or excipient.

~~4~~5. The use of any one of claims 1 to ~~3~~ 4 wherein the one or more polar lipids is to be administered in

a composition comprising, or in the form of, a food, ~~preferably~~

a composition comprising, or in the form of, a food selected from cultured milk, yoghurt, cheese, milk drink and milk powder; or

~~wherein the one or more polar lipids is to be administered in~~ a pharmaceutical composition or medicament comprising a pharmaceutically acceptable diluent, adjuvant, carrier or excipient.

~~5~~6. The use of any one of claims 1 to ~~3~~ 4 wherein the one or more polar lipids is to be administered in ~~at least one of~~ a composition or medicament that is:

a) a maternal formula, or a maternal supplement, or

b) ~~a dietetic product, an infant formula, a follow-on formula, and a growing-up formula.~~ a supplement or nutritional composition, or

c) a formula, dietetic product or food.

~~6. The use of any one of claims 1 to 5 wherein the one or more polar lipids is derived from non-human mammalian milk, preferably bovine milk.~~

7. The use of any one of claims 1 to 6 wherein the one or more polar lipids comprise one or more phospholipids, one or more gangliosides or a combination thereof.

8. The use of claim 7 wherein the one or more gangliosides comprises GD3, GM3 or a combination thereof.

9. The use of claim 7 or 8 wherein the one or more phospholipids comprises one or more phosphatidylcholines, one or more phosphatidylinositols, one or more phosphatidylserines, one or more lysophospholipids, one or more phosphatidylethanolamines, one or more sphingomyelins, one or more dihydrosphingomyelins, one or more glycerolphospholipids, phosphatidylglycerol, or a combination of any two or more thereof.

10. The use of any one of claims 1 to 9 wherein the adult subject, or the mother of the foetal, neonatal, infant or child subject~~,~~:

a) has an increased risk of GDM~~,~~,

b) has previously suffered GDM,

c) is over the age of 30 years,

d) has previously been pregnant,

e) has a BMI greater than 25,

f) has prediabetes, or

g) any combination of any two or more of (a) to (f).

~~11. The use of claim 10 wherein the subject, or mother, has previously suffered GDM.~~

~~12. The use of claim 10 or 11 wherein the subject, or mother, over the age of 35 years.~~

~~13. The use of any one of claims 10 to 12 wherein the subject, or mother, has previously been pregnant.~~

~~14~~11. The use of any one of claims 1 to ~~9~~ 10 wherein the adult subject, or the mother, is a woman, a woman who has had one or more previous pregnancies, or a pregnant woman, ~~or a breast-feeding woman,~~ with a BMI of less than 25 or 30 kg/m^2.

~~15~~12. The use of any one of claims 1 to ~~9~~ 10 wherein the adult subject, or the mother, is a woman, a woman who has had one or more previous pregnancies, or a pregnant woman, ~~or a breast-feeding woman,~~ with a BMI of greater than 25 or 30 kg/m^2.

~~16~~13. The use of any one of claims 1 to ~~15~~ 12 wherein the adult subject, or the mother, is a woman, a woman who has had one or more previous pregnancies, or a pregnant woman, ~~or a breast-feeding woman,~~ with high blood pressure.

~~17~~14. The use of any one of claims 1 to ~~16~~ 13 wherein the adult subject, or the mother, is a woman, a woman who has had one or more previous pregnancies, or a pregnant woman, ~~or a breast-feeding woman,~~ with prediabetes.

~~18~~15. The use of any one of claims 1 to ~~17~~ 14 ~~in~~ wherein administration of the one or more polar lipids commences after the first trimester of pregnancy, ~~preferably wherein administration commences~~ or between 14 – 16 weeks gestation.

~~19~~16. The use of any one of claims 1 to ~~18~~ 15 comprising lowering fasting mean blood glucose levels in the adult subject, or the mother of the foetal, neonatal, infant or child subject, ~~preferably~~ or lowering fasting mean blood glucose levels in the adult subject, or the mother of the foetal, neonatal, infant or child subject to less than about 4.35 mmol/l.

~~20~~17. The use of any one of claims 1 to ~~19~~ 16 wherein the ~~treating or preventing comprises administration of~~ composition or medicament comprises milk fat globule membrane material comprising the one or more polar lipids; and/or wherein the composition or medicament is formulated for ~~treating or preventing further comprises~~ separate, simultaneous, or sequential administration ~~of~~ with a probiotic, ~~preferably~~ optionally wherein the probiotic is *Lactobacillus rhamnosus* HN001.

18. The use of any one of claims 1 to 17, wherein preventing or reducing the risk or severity of the at least one GDM-associated risks or sequelae of GDM comprises preventing or reducing one or more of excessive birth weight, preterm birth, unwanted induced labour, suboptimal APGAR score at birth, infant hypoglycaemia, and infant respiratory distress syndrome at birth.

19. The use of any one of claims 1 to 18, wherein the composition or medicament

a) is formulated to administer from about 0.1 to about 15 g of the one or more polar lipids per day,

b) is formulated to administer at least about 0.13 g polar lipids per day,

c) is formulated to administer at least about 0.12 g phospholipids per day,

d) is formulated to administer at least about 0.078 g gangliosides per day;

e) the composition or medicament comprises

(i) at least about 0.2% by weight polar lipids, and/or

(ii) at least about 0.2% by weight phospholipids;

f) any combination of any two or more of (a) to (e).