[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 the use of an effective amount of polar lipids derived from non-human mammalian milk in the manufacture of a composition or medicament for preventing or reducing the risk of gestational diabetes mellitus (GDM) or preventing or reducing the risk of at least one GDM-associated risk or sequela of GDM in a pregnant subject, comprising that the composition or medicament is to be administered to the pregnant subject in need thereof, wherein the polar lipids comprise one or more phospholipids and one or more gangliosides; and the composition or medicament is to be administered at a daily dosage of from 0.1 to 15 g of the polar lipids.

[0008a] In another aspect, the present disclosure relates to the use of an effective amount of polar lipids derived from non-human mammalian milk in the manufacture of a composition or medicament for preventing or reducing the risk of at least one GDM-associated risk or sequela of GDM in a foetal subject, comprising that the composition or medicament is to be administered to the pregnant mother of the foetal subject in need thereof during gestation, wherein the polar lipids comprise one or more phospholipids and one or more gangliosides; and the composition or medicament is to be administered at a daily dosage of from 0.1 to 15 g of the polar lipids.

[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 an effective amount of polar lipids derived from non-human mammalian milk in the manufacture of a composition or medicament for preventing or reducing the risk of gestational diabetes mellitus (GDM) or preventing or reducing the risk of at least one GDM-associated risk or sequela of GDM in a pregnant subject, comprising that the composition or medicament is to be administered to the pregnant subject in need thereof, wherein the polar lipids comprise one or more phospholipids and one or more gangliosides; and

the composition or medicament is to be administered at a daily dosage of from 0.1 to 15 g of the polar lipids.

2. Use of an effective amount of polar lipids derived from non-human mammalian milk in the manufacture of a composition or medicament for preventing or reducing the risk of at least one GDM-associated risk or sequela of GDM in a foetal subject, comprising that the composition or medicament is to be administered to the pregnant mother of the foetal subject in need thereof during gestation, wherein the polar lipids comprise one or more phospholipids and one or more gangliosides; and

the composition or medicament is to be administered at a daily dosage of from 0.1 to 15 g of the polar lipids.

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

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

5. The use of any one of claims 1 to 4 wherein the polar lipids are to be administered in

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

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

a pharmaceutical composition or medicament comprising a pharmaceutically acceptable diluent, adjuvant, carrier or excipient.

6. The use of any one of claims 1 to 4 wherein the polar lipids are to be administered in a composition or medicament that is:

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

b) a supplement or nutritional composition, or

c) a formula, dietetic product or food.

7. The use of any one of claims 1 to 6 wherein the one or more gangliosides comprises GD3, GM3 or a combination thereof.

8. The use of any one of claims 1 or 7 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.

9. The use of any one of claims 1 to 8 wherein the pregnant subject, or the pregnant mother of the foetal 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).

10. The use of any one of claims 1 to 9 wherein the pregnant subject, or the pregnant mother has a BMI of less than 25 or 30 kg/m^2.

11. The use of any one of claims 1 to 10 wherein the pregnant subject, or the pregnant mother has high blood pressure.

12. The use of any one of claims 1 to 11 wherein the pregnant subject, or the pregnant mother has prediabetes.

13. The use of any one of claims 1 to 12 wherein administration of the polar lipids commences after the first trimester of pregnancy, or between 14 – 16 weeks gestation.

14. The use of any one of claims 1 to 13 comprising lowering fasting mean blood glucose levels in the pregnant subject, or the pregnant mother of the foetal child subject, or lowering fasting mean blood glucose levels in the pregnant subject, or the pregnant mother of the foetal subject to less than 4.35 mmol/l.

15. The use of any one of claims 1 to 14 wherein the composition or medicament comprises milk fat globule membrane material comprising the polar lipids; and/or wherein the composition or medicament is formulated for separate, simultaneous, or sequential administration with a probiotic, optionally wherein the probiotic is *Lactobacillus rhamnosus* HN001.

16. The use of any one of claims 1 to 15, wherein preventing or reducing the risk of the at least one GDM-associated risks or sequelae of GDM comprises preventing or reducing the risk of 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.

17. The use of any one of claims 1 to 16, wherein

a) is formulated to be administered at a daily dosage of from 0.1 to 10 g of phospholipids,

b) is formulated to be administered at a daily dosage of from 2 to 20 mg of gangliosides;

c) the composition or medicament comprises

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

(ii) at least 0.2% by weight phospholipids;

d) any combination of any two or more of (a) to (c).