

Official Title:

Whether Probiotics Use in Neonate and Infant
Improve Their Mother's Life Quality?

NCT number:

Not available

Document Date:

January 29, 2021

Title

Whether Probiotics Use in Neonate and Infant Improve Their Mother's Life Quality?

Sponsor/Collaborators

Sponsor: Buddhist Tzu Chi General Hospital

Responsible Party: Principal Investigator

Investigator: Yu-Chao Hsiao

Affiliation: Buddhist Tzu Chi General Hospital

Human Subjects Review

Board Status: Approved **Approval Number:** IRB109-247-A

Board Name: Research Ethics Committee, Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation

Board Affiliation:

Research Ethics Committee, Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation

Phone: 886-3-8561825 Ext: 13272 Email: IRB@tzuchi.com.tw

Address: 707, Sec.3, Chung-Yang Rd., Hualien, 97002, Taiwan

Study description

Postpartum depression and poor quality of life during postpartum were an vital issue in recent years. Infant's health condition was thought to be a possible reasons related mother's postpartum quality of life, and functional gastrointestinal disorders such as infantile colic and regurgitation were common problem during infant period. Previous study revealed that probiotics may improve the infant's discomfort caused by functional gastrointestinal disorders. Thus, our study aimed to investigate whether probiotics use in neonate and infant improve their mother's life quality?

Study design

Study Type: Interventional **Primary Purpose:** Prevention

Study Phase: N/A **Interventional Study Model:** Parallel Assignment

Number of Arms: 2

Experimental: Probiotics group

Will give Probiotics with Vitamin D3 one drop per day for 90 days

Placebo Comparator: Non-probiotics group

Will give Vitamin D3 as placebo five drops per day for 90 days

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 220

We use G-power (edition 3.1.9.7) to calculate case numbers with type I error:5% , type II error:20%, and dropout rate: 10%. Each group will be 110 participants (total 220 participants).

Outcome measures:

Primary Outcome Measure:

1. Maternal quality of life

Maternal quality of life assessed by

The Pittsburgh Sleep Quality Index (PSQI): a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. In scoring the PSQI, there are seven component scores with each scored 0 (no difficulty) to 3 (severe difficulty). The component scores are summed to produce total score (range 0 to 21). Higher scores indicate worse sleep quality.

World Health Organization Quality of Life (WHOQOL) questionnaire - Brief, Taiwan version: a questionnaire including 28 items with each score 0-4. Higher score indicate better quality of life.

Edinburgh Postnatal Depression Scale: a set of 10 screening questions with each score 0 to 3 that can indicate whether a parent has symptoms that are common in women with depression and anxiety during pregnancy and in the year following the birth of a child. Higher score indicate higher risk of postnatal depression.

[Time Frame: at their child birth]

2. Maternal quality of life

Maternal quality of life assessed by

The Pittsburgh Sleep Quality Index (PSQI): a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. In scoring the PSQI, there are seven component scores with each scored 0 (no difficulty) to 3 (severe difficulty). The component scores are summed to produce total score (range 0 to 21). Higher scores indicate worse sleep quality.

World Health Organization Quality of Life (WHOQOL) questionnaire - Brief, Taiwan version: a questionnaire including 28 items with each score 0-4. Higher score indicate better quality of life.

Edinburgh Postnatal Depression Scale: a set of 10 screening questions with each score 0 to 3 that can indicate whether a parent has symptoms that are common in women with depression and anxiety during pregnancy and in the year following the birth of a child. Higher score indicate higher risk of postnatal depression.

[Time Frame: at their child 1-month-old]

3. Maternal quality of life

Maternal quality of life assessed by

The Pittsburgh Sleep Quality Index (PSQI): a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. In scoring the PSQI, there are seven component scores with each scored 0 (no difficulty) to 3 (severe difficulty). The component scores are summed to produce total score (range 0 to 21). Higher scores indicate worse sleep quality.

World Health Organization Quality of Life (WHOQOL) questionnaire - Brief, Taiwan version: a questionnaire including 28 items with each score 0-4. Higher score indicate better quality of life.

Edinburgh Postnatal Depression Scale: a set of 10 screening questions with each score 0 to 3 that can indicate whether a parent has symptoms that are common in women with depression and anxiety during pregnancy and in the year following the birth of a child. Higher score indicate higher risk of postnatal depression.

[Time Frame: at their child 3-month-old]

4. Maternal quality of life

Maternal quality of life assessed by

The Pittsburgh Sleep Quality Index (PSQI): a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. In scoring the PSQI, there are seven component scores with each scored 0 (no difficulty) to 3 (severe difficulty). The component scores are summed to produce total score (range 0 to 21). Higher scores indicate worse sleep quality.

World Health Organization Quality of Life (WHOQOL) questionnaire - Brief, Taiwan version: a questionnaire including 28 items with each score 0-4. Higher score indicate better quality of life.

Edinburgh Postnatal Depression Scale: a set of 10 screening questions with each score 0 to 3 that can indicate whether a parent has symptoms that are common in women with depression and anxiety during pregnancy and in the year following the birth of a child. Higher score indicate higher risk of postnatal depression.

[Time Frame: at their child 6-month-old]

Secondary Outcome Measures:

Neonate and infant' health condition

Neonate and infant' health conditions including functional gastrointestinal disorders, diaper dermatitis, and atopic dermatitis.

Functional Gastrointestinal Disorders in Infancy including infantile colic and regurgitation: use questionnaires according to ROME-IV criteria, and higher score indicate worse condition of functional gastrointestinal disorders in infancy.

Diaper dermatitis: use a self-rated questionnaire to determine the condition of diaper dermatitis

Atopic dermatitis: use a self-rated questionnaire to determine the condition of atopic dermatitis

[Time Frame: at baby's 1-month-old]

Neonate and infant' health condition

Neonate and infant' health conditions including functional gastrointestinal disorders, diaper dermatitis, and atopic dermatitis.

Functional Gastrointestinal Disorders in Infancy including infantile colic and regurgitation: use questionnaires according to ROME-IV criteria, and higher score indicate worse condition of functional gastrointestinal disorders in infancy.

Diaper dermatitis: use a self-rated questionnaire to determine the condition of diaper dermatitis

Atopic dermatitis: use a self-rated questionnaire to determine the condition of atopic dermatitis

[Time Frame: at baby's 3-month-old]

Neonate and infant' health condition

Neonate and infant' health conditions including functional gastrointestinal disorders, diaper dermatitis, and atopic dermatitis.

Functional Gastrointestinal Disorders in Infancy including infantile colic and regurgitation: use questionnaires according to ROME-IV criteria, and higher score indicate worse condition of functional gastrointestinal disorders in infancy.

Diaper dermatitis: use a self-rated questionnaire to determine the condition of diaper dermatitis

Atopic dermatitis: use a self-rated questionnaire to determine the condition of atopic dermatitis

[Time Frame: at baby's 6-month-old]

Eligibility

Baby's Age: 1-day-old to 7-day-old

Mother's Age: 20 to 50-year-old

Baby's Sex: All

Criteria:

<Participants of neonates>

Inclusion Criteria :

-Gestational age more than 37 to less than 41 weeks

-Age less than 1 week on entry into the study

-Birth weight adequate for gestational age

-Apgar score of more than 8 at 10 minutes

Exclusion Criteria:

-Congenital disorders and/or clinical or physical alterations at clinical examination

-Antibiotic or probiotic administration before inclusion

-Admission to ICU

<Participants of neonates' mother>

Inclusion Criteria:

(1) Aged between 20-50 and baby included in our study

Exclusion Criteria:

(1) Diagnosed as psychiatric disease during antepartum period or before pregnancy

Study protocol

Infant participants who meet the inclusion criteria will be included, and they will be categorized randomly into experimental group or placebo group. Experimental group will be given experimental agent including vitamin D3 and probiotics for total 90 days. Placebo group will be given placebo agent including vitamin D3 for total 90 days. We will also record infant's birth record at the same time. For both groups, we will ask infant participant's mother about baby's health condition and maternal quality of life by using PSQI, WHOQOL, and Edinburgh Postnatal Depression Scale at the timing of their baby's birth, at baby's 1-month-old, baby's 3-month-old, and baby's 6-month-old.

Statistical analysis

Demographic data, maternal life quality, and infant's health condition will be presented as mean \pm standard deviation, median, or percentile. Independent-Sample t test and hi-square test was performed to evaluate the associations between probiotics use and maternal life quality and infant's health condition. Statistical significance was defined as p value <0.05 . All statistical analyses were performed with Statistical Analysis System, Statistical Package for the Social Sciences or Statistics with R.