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# Comparing methods for weight gain in premature infants

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 07/03/2023 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 23/03/2023 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 29/03/2023 | Pregnancy and Childbirth | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
In developing countries, high rates of premature birth and slow growth of the unborn baby (intrauterine growth retardation) result in a high incidence of low birth weight. The causes are unknown and there are likely to be many, limiting the effects of interventions before birth (prenatal). Interventions after birth (postnatal) in neonatal intensive care units (NICUs) that facilitate growth and positive contact with parents such as kangaroo mother care (KMC) and infant massage have been independently observed to improve weight gain in preterm infants. The objective of this study is to compare weight gain and length of hospital stay in premature infants receiving Vimala massage, KMC, or both.

Who can participate?
Preterm infants 30-35 weeks of gestational age who were clinically stable, tolerating enteral feeds and had a parent able to provide the intervention.

What does the study involve?
Newborns were randomized into three groups: KMC, Vimala massage, or mixed KMC and massage. The results from each group will be compared with historical controls who received none of the interventions (Control Group). Weight gains over 10 days will be compared.

What are the possible benefits and risks of participating?
KMC ideally paired with exclusive breastfeeding, (ideally) results in early discharge, weight gain and arousing the interest of mothers towards their children. Early contact with the premature baby helps parents to accept their baby's condition more quickly and gradually take over the baby’s care. Numerous studies have shown that preterm infants who receive massage gain weight faster. The mechanism of weight gain through massages is not clear, but it is thought to improve the uptake of nutrients, reduce the effects of stress, decreased basal metabolism and improved metabolic efficiency with subsequent weight gain. No possible associated risks have been described.

Where is the study run from?
Hospital UMAE No. 48 of the Mexican Social Security Institute (Mexico)

When is the study starting and how long is it expected to run for?
March 2008 to January 2009

Who is funding the study?
Mexican Social Security Institute (Mexico)

Who is the main contact?
González, Alma Patricia, MD (Neonatologist, Department of Neonatology), patipili999@hotmail.com (Mexico)

# Contact information

### Type(s)
Principal investigator


### Contact name
Dr Alma Patricia González

### ORCID ID
https://orcid.org/0000-0002-3401-7519

### Contact details
Avenida Mexico e Insurgentes S/N
León, Guanajuato
Mexico
37328
+52 477 132 91 26
alma.gonzalezx@imss.gob.mx


### Type(s)
Scientific


### Contact name
Dr Alma Patricia González

### Contact details
Avenida Mexico e Insurgentes S/N
León, Guanajuato
Mexico
37328
+52 477 132 91 26
patipili999@hotmail.com


### Type(s)
Scientific


### Contact name
Dr Gloria-Patricia Sosa-Bustamante

### ORCID ID

https://orcid.org/0000-0002-8460-4965

**Contact details**
Avenida Mexico e Insurgentes S/N
León, Guanajuato
Mexico
37328
None provided
gloria.sosa@imss.gob.mx

# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**Protocol serial number**
Nil known

# Study information

**Scientific Title**
Weight gain in premature infants receiving kangaroo mother care, Vimala massage or both: a randomized clinical trial

**Study objectives**
Weight gain and length of hospital stay are similar or different in premature infants receiving a massage program, kangaroo mother program, or both.

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
Approved 31/05/2008, Hospital Ethics Research Board Neonatal Intensive Care Unit of the Hospital UMAE No. 48 of the Mexican Social Security Institute (Avenida Mexico e Insurgentes S /N, Leon Guanajuato, Mexico 37160; +52 477 717 48 00 ext 32 814; 10028hgp48@gmail.com ), ref: R-2008-1002-11

**Study design**
Single-blind randomized study

**Primary study design**
Interventional

**Study type(s)**
Treatment

**Health condition(s) or problem(s) studied**
Weight gain in premature infants

**Interventions**

Infants were randomized with a random number table, to a Kangaroo Mother Care Group, Vimala Massage Group, or a Mixed Group (MG) with both manoeuvres and weight gain monitored daily for 10 days. They were compared to a historical control group (HC) of 21 newborns who received usual nursery care and none of the interventions in a previous study.

The study groups are as follows:
1. Kangaroo mother care
2. Vimala massage
3. Both (kangaroo mother care and Vimala massage)

Infant's weight, head circumference and caloric intake will be recorded daily between 8 and 9:00 AM during the 10 days of the study. The weight will be monitored by means of a Seca digital scale model 3741321009 and the head circumference will be measured with a flexible millimeter tape. All infants will receive breast milk supplemented by formula (preNAN Nestlé ® 0.8 cal/ml). The incubators in use are ISSOLETE model C-86 brand Nafarrete.
Descriptive statistics and percentages for weight, gestational age, head circumference, type of food and caloric intake will be presented. Student t-tests, X2 and ANOVA will be used to compare groups, and repeated measures ANOVA or Kruskal Wallis test for the comparison of the trends over 10 days. Two-sided p-values <0.05 will be considered statistically significant. The NCSS version 97 statistical program will be used for all calculations.

### Intervention Type
Mixed

### Primary outcome(s)
The infant's weight measured using a Seca digital scale daily between 8:00 and 9:00 AM during the 10 days of the study

### Key secondary outcome(s))
Hospital stay measured using patient medical notes in days from birth to hospital discharge

### Completion date
31/01/2009

## Eligibility

### Key inclusion criteria
We included neonates with a corrected gestational age of 30 to 35 weeks (according to the Ballard scale), who were clinically stable (required no supplemental oxygen or any additional intervention, other than nutrition and incubator) and receiving orogastric tube feeding.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Neonate

### Sex

All

### Total final enrolment
79

### Key exclusion criteria
1. Congenital anomalies
2. Known cardiovascular or abdominal pathologies that could impact weight gain
3. History of maternal drug abuse, or who were experiencing seizures or receiving central nervous system depressor medications or parenteral nutrition
4. Newborns with inadequate caloric intakes
5. Who fasted for more than 6 hours because they had gastric residue
6. Receiving specific visual, auditory, tactile, or kinesthetic stimulation

### Date of first enrolment
01/06/2008

### Date of final enrolment
21/01/2009

## Locations

### Countries of recruitment
Mexico

### Study participating centre
**Hospital UMAE No. 48 of the Mexican Social Security Institute**
Avenida Mexico e Insurgentes S/N
León, Guanajuato
Mexico
37328

## Sponsor information

### Organisation
Mexican Social Security Institute

### ROR
https://ror.org/03xddgg98

## Funder(s)

### Funder type

Government

**Funder Name**
Instituto Mexicano del Seguro Social

**Alternative Name(s)**
Mexican Social Security Institute, IMSS

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
Mexico

## Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

**IPD sharing plan summary**
Published as a supplement to the results publication