

Healthy Change: intervention in maternal perception of pre-school child weight

Submission date 25/09/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/10/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/11/2019	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Childhood obesity is a public concern for its effects on health. Mothers might not participate in activities to prevent and treat obesity unless they accurately perceive their child's weight. Studies conducted in different countries indicate that mothers do not accurately perceive their child's weight, which is more remarkable when the child is overweight/obese. Most interventions targeting childhood obesity do not test the mother's perception of her child's weight. The aim of this study is to test the feasibility and effect of the "Healthy Change" intervention on mothers' perception of the weight of their pre-school child.

Who can participate?

Mothers of children aged 3 to 5

What does the study involve?

Mothers and children are randomly allocated to either the intervention group or the control group. The mothers in the intervention group attend four weekly group education sessions about obesity, healthy eating and physical activity. The mothers in the control group attend four weekly group education sessions about hygiene. The children's height, weight and body fat percentage are measured at the start of the study and 6 weeks later, while the mothers answer questionnaires and focus groups are conducted.

What are the possible benefits and risks of participating?

Potential benefits include increased awareness of overweight and obesity in preschoolers and improved knowledge and skills of raising healthy weight children. This study will shed light on developing effective primary obesity prevention strategies for Hispanic mothers in Mexico and USA. This study has no foreseeable risks, discomforts or hazards.

Where is the study run from?

Three centres in three Mexican States (Nuevo Leon, Tamaulipas and Zacatecas), and one centre in San Antonio, Texas (USA)

When is the study starting and how long is it expected to run for?

February 2017 to November 2018

Who is funding the study?

1. The National Council for Science and Technology (Mexico)
2. The Kellogg's Nutrition & Health Institute (Mexico)

Who is the main contact?

Dr Yolanda Flores-Peña

yolandaflores.uanl@gmail.com

Contact information

Type(s)

Public

Contact name

Dr Yolanda Flores-Peña

ORCID ID

<https://orcid.org/0000-0001-6200-6553>

Contact details

Av. Gonzalitos 1500 Nte

Col. Mitras Centro

Monterrey, N. L.

Monterrey Nuevo León

Mexico

64460

+52 (0)81 811 6280 185

yolandaflores.uanl@gmail.com

Additional identifiers

Protocol serial number

I0002 - 247126

Study information

Scientific Title

Intervention in maternal perception of pre-school child weight in Mexican and Mexican-American mothers: a pilot study

Acronym

HC / MPCW

Study objectives

1. Mothers of the HC intervention group will accurately perceive body weight of her child at the end of the intervention
2. Core elements of the HC intervention (maternal feeding styles, self-efficacy, and family nutrition and physical activity) show changes that represent positive scores
3. Reduce or maintain child's body mass index (BMI) and body fat percentage (BFP)

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. University Autonomus of Nuevo Leon / College of Nursing, 02/06/2015, ref: FAEN-P-1144
2. University of Texas at San Antonio, 31/01/2017, ref: 16-203N

Study design

Multicentre two-arm randomized trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Maternal perception of her child's body weight

Interventions

The Healthy Change intervention is a multicentre two-arm randomized trial with four centres, three in Mexico: Nuevo León, Tamaulipas and Zacatecas, and one in USA, San Antonio, Texas. Each center will have an intervention and a control group. A total of 360 mother-child pairs (90 pairs per center) will be randomly and evenly allocated to either the intervention or control group.

Participating mothers in the intervention group will attend four weekly group education sessions related to Healthy Growth, covering the following contents: 1) Understanding excess weight and obesity as a health problem and their current and future health consequences; 2) How is my child's weight? 3) Maternal feeding practices and physical activity, 4) I can do, which includes strategies for management child lifestyle behaviors related to the child's weight.

The mothers in the control group will attend four weekly group education sessions related to Hygiene and Health Promotion, covering the following topics: 1) The mother as her child's hygiene promoter; 2) Hygiene and food safety at home; 3) Safe ways to store food in your kitchen; and 4) Accident prevention at home and surrounding areas.

First week: basal measurements

Four weeks: intervention

Sixth week: final measurements

Intervention Type

Behavioural

Primary outcome(s)

Maternal perception of child weight (MPCW), measured using the questionnaire Perceptions about Physical Appearance and Health, using the question: I feel my child is: underweight, a little underweight, about the right weight, a little overweight, overweight, and body sketches in the age range 2 to 5 years old. Measured at baseline and 6 weeks.

Key secondary outcome(s)

Measured at baseline and 6 weeks:

1. Maternal feeding styles, assessed using the Caregiver Feeding Style Questionnaire that categorizes the participants in four styles: a) authoritative, b) authoritarian, c) indulgent, and d) uninvolved
2. Maternal perception of influence on her child's health behaviors, assessed using two questions of the Questionnaire Perceptions about Physical Appearance and Health: I can influence my child's food choices and I can influence my child's amount physical activity. Participant with agreement or strong agreement were considered to have self-efficacy for the health behavior. Those with agreement or strong agreement to both statements were considered as affirming high self-efficacy for influencing their child's health behaviors (Eckstein et al., 2006).
3. Obesogenic environment evaluated by the Family and Nutrition and Physical Activity (FNPA) screening tool. The FNPA is a behaviorally based assessment designed to allow parents to evaluate obesogenic environments and practices that may predispose youth to becoming overweight.
4. Child BMI and percentage body fat. The child's weight will be measured by Seca Scale 813 and height by Seca stadimeter 214, the body fat percentage will be measured by bioelectrical impedance by InBody 230. Child BMI will be classified according to the percentile in malnutrition (percentile <3), low weight (≥ 3 and <15), normal weight (≥ 15 and < 85), SP (≥ 85 but < 97) and OB (≥ 97) (WHO, 2012).

Completion date

30/11/2018

Eligibility

Key inclusion criteria

1. Women who are identified as mother of a child aged between 3 to 5 years
2. Child enrolled in one of the institutions selected in Mexico's States
3. Mothers selected from the population that attends the Head Star Center located in San Antonio, Texas, who are Mexican-American

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

1. Mothers who plan to change address
2. Children with special motor limitation or any disease that limits their growth and development

Date of first enrolment

01/03/2017

Date of final enrolment

30/03/2018

Locations**Countries of recruitment**

Mexico

United States of America

Study participating centre

Jardín de Niños Juan Escutia

Monterrey

Mexico

64379

Study participating centre

Jardín de Niños Estefanía Castañeda

Monterrey

Mexico

64330

Study participating centre

Jardín de Niños Melchor Muzquiz

Mexico

66440

Study participating centre

Jardín de Niños Estefanía Castañeda

H. Matamoros

Mexico

87370

Study participating centre

Jardín de Niños Rita Padrón

H. Matamoros

Mexico

87430

Study participating centre

Club 20-30

H. Matamoros

Mexico

87450

Study participating centre

Jardín de Niños Esperanza Tobias Ruiz

H. Matamoros

Mexico

87380

Study participating centre

Kindergarten Víctor Manuel García Ortega

Guadalupe, Zacatecas

Mexico

98615

Study participating centre

Kindergarten María Guadalupe Vega de Luevano

Zacatecas, Zacatecas

Mexico

98040

Study participating centre

Rhapsody Head Start Center 78216

San Antonio, Texas

United States of America

78216

Study participating centre

Pilgrim Head Start Center 78213

San Antonio, Texas

United States of America

78213

Study participating centre

Lackland Head Start Center 78227

San Antonio, Texas

United States of America
78227

Sponsor information

Organisation

Universidad Autónoma de Nuevo León

ROR

<https://ror.org/01fh86n78>

Funder(s)

Funder type

Government

Funder Name

The National Council for Science and Technology (Mexico)

Funder Name

The Kellogg's Nutrition & Health Institute (Mexico)

Results and Publications

Individual participant data (IPD) sharing plan

All data will be stored in a secured laboratory or office facility with access limited to research staff only. All hard copy files will be stored in locked filing cabinets within the laboratory or office and all electronic files will be stored on password protected computers. Only the research staff will have access to files and the link connecting names to the issued identity codes. All the staff will undergo rigorous training on data collection, data entry, and data storage procedures to ensure all participant information is protected.

Research records will not be released without an individual's consent unless required by law or a court order. Records may be viewed by the Institutional Review Board (IRB) of College of Nursing of The University Autonomus of Nuevo Leon and the IRB of The University of Texas at San Antonio, but the confidentiality of all records will be protected to the extent permitted by law. The data resulting from participants may be used in publications and/or presentations but participants' identities will not be disclosed.

To help the trialists to remember the information discussed in the focus group, the discussion session will be audio-taped. Audiotapes will be transcribed by a trained research staff. Transcriptions will be used for analysis. All storage of data will take place on password protected

computers that only research staff have access to. No information identifying individuals or any institution will be reported. Participant identity, comments, as well as all audiotapes and written records will be kept confidential and secure. All data collected from these focus groups will have names removed upon collection, such that names will not be used at any time during the research process, or the publication of findings.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/05/2018	01/07/2019	Yes	No