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

Submission date
25/09/2017

Recruitment status
No longer recruiting

Registration date
04/10/2017

Overall study status
Completed

Last Edited
06/11/2019

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 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 measure
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.

Secondary outcome measures
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).

Overall study start date
01/02/2017

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

Age group
Mixed

Sex
Both

Target number of participants
360 mother-child pairs (90 pairs per center)

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

Sponsor details
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Sponsor type
University/education

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http://investigacion.uanl.mx/contacto-2/

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

Publication and dissemination plan
Findings will be published in peer-reviewed journals and communicated to key audiences, including personnel of participant centres:
1. The protocol will be published immediately after registration
2. The results from the Mexican States will be published in December 2019 and the complete report (USA and Mexico) in August 2020

Intention to publish date
01/12/2019

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