ISRCTN11347525 https://doi.org/10.1186/ISRCTN11347525

The 3 Healthy Study for obesity prevention among vulnerable children

Submission date
25/07/2019

Recruitment status
No longer recruiting

Registration date
30/07/2019

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Few studies have used an ecological perspective for childhood obesity prevention among socioeconomically vulnerable children. An ecological perspective emphasizes the influences of multi-level environments on human behaviors, and has been effectively applied in the reduction of health inequalities. In the present study, the Healthy Lifestyle Intervention was designed based on an ecological perspective to prevent obesity among socioeconomically vulnerable children in the public welfare system setting, via the adoption of the various components of healthy lifestyle behaviours. The aim of this study is to examine the effects of the Healthy Lifestyle Intervention on healthy lifestyle behaviours and obesity status in socioeconomically vulnerable children in a community child centre setting. The researchers hypothesised that an intervention group who received the Healthy Lifestyle Program would have significant improvements in healthy lifestyle behaviours and significant reduction in obesity status, compared to a control group after 12 weeks.

Who can participate?
Children and parents enrolled in eight community child centres in Seongbuk municipal county, Seoul. In the present study, socioeconomically vulnerable children were defined as those registered in the public welfare system of community child centres, which serve children from: 1) families receiving benefits from the National Basic Livelihood Security System and 2) non-traditional families including grandparent-grandchild and single-parent families (Ministry of Health and Welfare, 2019).
Eligibility criteria for child participants were: 1) in primary 3–6 grade schools and 2) no mental and physical disabilities. Eligibility criteria for parent participants were: 1) mothers, fathers, or legal representatives of the children who agreed to participate, 2) living with the children, and 3) no mental and physical disabilities.

What does the study involve?
Eight community child centers are randomly allocated to an intervention group (four centers) and a control group (four centers). The intervention group receive a 12-week Healthy Lifestyle Intervention, while the control group receive usual care provided in the Community Child Center (CCC) program. The Healthy Lifestyle Intervention was designed based on an ecological perspective to prevent obesity among socioeconomically vulnerable children in the public

welfare system setting, through the adoption of various healthy lifestyle behaviors. The Healthy Lifestyle Intervention had child-level, parent-level, and center-level strategies. The child-level strategies comprised weekly educational session for healthy eating and activity for 12 weeks. The parent-level strategies comprised one group teaching, two home visits, three telephone counselling, and 12 times text messaging. The center-level strategies comprised one education sessions for directors and cooks, one workshop with researchers, parents, and center directors, and one walking festival with researchers, parents, and center directors as wells as building policy changes and curriculum development.

What are the possible benefits and risks of participating?
With regard to the benefits of participating in the study, the intervention group receive two types of incentives: goods and money. The goods included a cookery book, T-shirts, eco-bag, and cooking utensils, and money amounting to $50 for the children and $300 for the parents. The control group receive two types of incentives: education material (a booklet) and $20 for children and $50 for the parents. With regard to risks of participating, it was assumed that there are no risks regarding irreversible physical injuries. However, there may be some discomforts regarding completing questionnaires and physical examinations (measurement of body weight and height). The researchers made efforts to minimize the discomfort by providing a 20-minute break time, supportive environments, and keeping privacy.

Where is the study run from?
College of Nursing, Korea University, Seongbuk-Gu, Seoul, South Korea

When is the study starting and how long is it expected to run for?
November 2014 to October 2017

Who is funding the study?
National Research Foundation of Korea grant funded by the South Korean government

Who is the main contact?
Prof. Jina Choo
jinachoo@gmail.com/jinachoo@korea.ac.kr

Contact information

Type(s)
Scientific

Contact name
Prof Jina Choo

ORCID ID
https://orcid.org/0000-0001-9271-3689

Contact details
145 Anam-ro Seongbuk-gu
Seoul
Korea, South
02741
+82 (0)2 3290 4925
jinachoo@gmail.com

Additional identifiers

Protocol serial number
NRF-2014R1A2A1A11050974

Study information

Scientific Title
Development and effects of the healthy children, healthy families, healthy communities program for obesity prevention among vulnerable children: using the ecological perspective

Acronym
The 3 Healthy Study

Study objectives
The study hypothesis was whether the Healthy Lifestyle Intervention would be associated with the improvements in healthy lifestyle behaviours and obesity status in socioeconomically vulnerable children in the public welfare system setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/10/2017, Korea University institutional review board (Anam-Dong, Seongbuk-Gu, Research Ethics Center, Office of Research Management, Korea University, Seoul 136-713, South Korea; Tel: +82 (0)2-3290-1137/1139; Email: kuirb@korea.ac.kr), No. 1040548-KU-IRB-17-82-A-2

Primary study design
Interventional

Study design
Cluster randomised trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Childhood obesity

Interventions
The present study was conducted in public welfare system settings (i.e., community child centers). Eight community child centers recruited for the present study were randomly allocated to an intervention group (four centers) and a control group (four centers). After then participant recruitment was conducted from each of intervention and control groups.

Of 26 community child centers in Seongbuk county, Seoul, South Korea, eight centers agreed to participate, which had a total of 261 children, and then were randomly allocated to the intervention group (four centers) and the control group (four centers). The centers had 121 children eligible for the study (i.e., 63 in the intervention group and 58 in the control group). Of

the 121 eligible children, 52 children (and 29 parents) of the intervention group were enrolled, while 55 children (and 32 parents) of the control group were enrolled in the study.

The intervention group received a 12-week Healthy Lifestyle Intervention, while the control group received usual care provided in the Community Child Center (CCC) program. The Healthy Lifestyle Intervention was designed based on an ecological perspective to prevent obesity among socioeconomically vulnerable children in the public welfare system setting, via the adoption of the various components of healthy lifestyle behaviours. The 12-week intervention comprised ecological, multi-level intervention strategies: child-level educational strategies, parenting strategies, and centre-level organisational strategies for obesity prevention among vulnerable children.

The child-level strategies comprised weekly educational session for healthy eating and activity for 12 weeks. The parent-level strategies comprised one group teaching, two home visits, three telephone counselling, and 12 times text messaging. The center-level strategies comprised one education sessions for directors and cooks, one workshop with researchers, parents, and center directors, and one walking festival with researchers, parents, and center directors as wells as building policy changes and curriculum development.

Intervention Type
Behavioural

Primary outcome(s)
BMI z-scores were obtained from AnthroPlus (World Health Organization, 2007). Additionally, children's obesity status was defined as ≥ 85th percentile of BMI calculated using body weight and height (kg/m2). According to the 2007 sex-specific BMI-for-age Korean National Growth Charts (Korea Centers for Disease Control and Prevention, 2012), children were categorized as normal weight (BMI < 85th percentile), overweight (85th percentile ≤ BMI < 95th percentile), or obese (BMI ≥ 95th percentile or BMI ≥ 25 kg/m2). BMI measurement was performed at pre-test (at baseline) and post-test (after 12 weeks).

Key secondary outcome(s)
1. Children's healthy lifestyle behaviour knowledge measured using an 18-item questionnaire (10 for eating and eight for activities) developed by the principal investigator based on inquiries regarding children's awareness of the daily recommended levels for healthy eating and activities. Children responded to each item as 'yes' (correct response coded as 1) or 'no' (incorrect response coded as 0). Coded scores were summed (range 0–18). A higher score indicated a higher knowledge level. It was measured at pre-test (at baseline) and post-test (after 12 weeks)
2. Healthy lifestyle behaviors measured at pre-test (at baseline) and post-test (after 12 weeks).:
2.1. Children's eating behaviours assessed by self-report of a single behaviour, that is, breakfast, fruits, vegetable, milk, sugar-sweetened beverage, and fast food consumption, as well as family mealtimes, in response to the question, 'How many times did you eat breakfast (or other single behaviour) per week on average during the past three months?' They were reported as none per week, one–two times per week, three–four times per week, five–six times per week, once per day, twice per day, or thrice or greater per day. The daily recommended levels of healthy eating behaviours were as follows: daily breakfast; fruit consumption ≥ 2 times; vegetable consumption ≥ 3 times; total milk consumption as either fluid milk or dairy products ≥ 1 time; no sugar-sweetened beverages and fast food; ≥ 1 family mealtime.
2.2. Children's activity behaviours were assessed by self-reports of physical activity and non-sedentary behaviour. Physical activity was assessed as number of days per week with the

question, ‘How many days a week did you exercise moderately or vigorously for 60 minutes on average during the past three months?’ Accordingly, days of sufficient physical activity (indicating moderate or vigorous exercise for 60 minutes per bout) were measured as a continuous variable. The recommended level of sufficient physical activity was defined as 60 minutes of moderate or vigorous activity seven days a week (Centres for Disease Control and Prevention, 2008). Non-sedentary behaviour was assessed as number of hours per day spent on watching television, smartphone use, or computer games. The recommended level of non-sedentary behaviour was < 2 hours per day (Tremblay et al., 2011).
3. Parenting behaviours, specifically those related to obesity, assessed using the Family Nutrition and Physical Activity (FNPA) scale (Ihmels et al., 2009). The FNPA scale is a behavioural assessment designed to allow parents to evaluate obesogenic environments and practices that may predispose children to becoming overweight (The FNPA User Group, 2009), consisting of 10 factors: family meal patterns, family eating habits, food choices, beverage choices, restriction /reward, screen time behaviour and monitoring, healthy environment, family activity involvement, child activity involvement, and family routine. It contains 20 items (two items per factor) measured on a four-point Likert scale (1 = almost never, 2 = sometimes, 3 = usually, and 4 = almost always; possible total scores range from 20–80). There are six negatively worded items (3, 4, 5, 7, 10, and 13), which are reverse scored. It was measured at pre-test (at baseline) and post-test (after 12 weeks).

Completion date
31/10/2017

Eligibility

Key inclusion criteria
Children (N = 104) and parents (N = 59), enrolled in eight CCCs in Seongbuk municipal county, Seoul

In the present study, socioeconomically vulnerable children were defined as those registered in the public welfare system of CCCs, which serve children from:
1. Families receiving benefits from the National Basic Livelihood Security System
2. Non-traditional families including grandparent-grandchild and single-parent families (Ministry of Health and Welfare, 2019)

Inclusion criteria for children:
1. In primary 3–6 grade schools
2. No mental and physical disabilities

Inclusion criteria for parents:
1. Mothers, fathers, or legal representatives of the children who agreed to participate
2. Living with the children
3. No mental and physical disabilities

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Mixed

Sex
All

Total final enrolment
104

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
12/06/2017

Date of final enrolment
28/06/2017

Locations

Countries of recruitment
Korea, South

Study participating centre
Korea University College of Nursing
145 Anam-ro, Seongbuk-gu
Seoul
Korea, South
02841

Sponsor information

Organisation
National Research Foundation

ROR
https://ror.org/013aysd81

Funder(s)

Funder type
Government

Funder Name
National Research Foundation of Korea grant funded by the Korean government (MSIP) (No. NRF-2014R1A2A1A11050974).

Alternative Name(s)
, National Research Foundation (South Korea), NRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Korea, South

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Jina Choo (jinachoo@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/04/2020	23/10/2020	Yes	No