Clinical Trial Protocol
Iranian Registry of Clinical Trials
19 Apr 2022

KidChen Study: Randomized-controlled trial of experiential healthy meal preparation among children in improving nutritional outcomes

Protocol summary

Study aim
To evaluate the effectiveness of a hands-on healthy meal preparation intervention on changes of psychosocial factors, home food environment and anthropometric measures among children.

Design
Parallel, single-blind, school-based randomized-controlled trial with target sample size of 96 children.

Settings and conduct
Study will be conducted in schools in Kuala Lumpur, Malaysia. Stratified random sampling will be used in which one out of the total of three zones in Kuala Lumpur, Malaysia will be randomly selected. Then simple random sampling will be used whereby two primary schools will be randomly selected from the randomly selected zone. Both schools will then be randomly assigned to either intervention or control group. Finally, we will randomly select 48 children from each school. Participants will not know if there are in the intervention or control group.

Participants/Inclusion and exclusion criteria

Intervention groups
Hands-on healthy meal preparation focusing on various food groups.

Main outcome variables
Knowledge, attitude, practice and self-efficacy of healthy meal preparation. Home food availability. Anthropometric measures (BMI z-score, waist circumference, body fat %).

General information

Reason for update

Acronym
KidChen (Kids in Kitchen)

IRCT registration information
IRCT registration number: IRCT20190626044024N1
Registration date: 2019-08-05, 1398/05/14
Registration timing: prospective

Last update: 2019-08-05, 1398/05/14
Update count: 0

Registrant information
Name
Choon Ming Ng
Name of organization / entity
UCSI University
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-26, 1398/06/04
Expected recruitment end date
2019-09-02, 1398/06/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
KidChen Study: Randomized-controlled trial of experiential healthy meal preparation among children in improving nutritional outcomes
Public title
Hands-on healthy meal preparation in improving children’s nutritional outcomes

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Malaysian children aged 9-11. Able to read, write and understand English/Malay language. Children that voluntarily participate, with their parent’s consent.

Exclusion criteria:
Children with food allergies (eg: wheat/gluten, dairy, or peanuts) Children with any serious co-morbidity/learning disabilities

Age
From 10 years old to 11 years old

Gender
Both

Phase
N/A

Groups that have been masked
- Participant

Sample size
Target sample size: 96

Randomization (investigator’s opinion)
Randomized

Randomization description
Stratified random sampling will be used in which one out of the total of three zones in Kuala Lumpur, Malaysia will be randomly selected. Then simple random sampling will be used whereby two primary schools will be randomly selected from the randomly selected zone. Both schools will then be randomly assigned to either intervention or control group. Finally, we will randomly select 48 children from each school. For randomization, we will use the Research Randomizer.

Blinding (investigator’s opinion)
Single blinded

Blinding description
Participants will be blinded in the study. Children will not know whether they are in intervention or control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Medical Research and Ethics Committee (MREC), Malaysia

Street address
Kompleks Institut Kesihatan Negara Blok A, No 1, Jalan Setia Murni U13/52, Seksyen U13, Bandar Setia Alam, 40170 Shah Alam, Selangor.

City
Selangor

Postal code
40170

Approval date
2018-05-04, 1397/02/14

Ethics committee reference number
NMRR-18-725-41268, KKM/NIHSEC/P18-815 (11)

Health conditions studied

1
Description of health condition studied
Knowledge, attitude, practice and self-efficacy for healthy meal preparation, food consumption pattern and body composition

ICD-10 code

ICD-10 code description

Primary outcomes

1
Description
Knowledge, attitude, practice and self-efficacy for healthy meal preparation

Timepoint
2 weeks before intervention, 2 weeks after intervention and a 3-month follow-up

Method of measurement
Reliable and valid questionnaire

2
Description
Food consumption pattern

Timepoint
2 weeks before intervention, 2 weeks after intervention and a 3-month follow-up

Method of measurement
Reliable and validated questionnaire

3
Description
Home food availability

Timepoint
2 weeks before intervention, 2 weeks after intervention and a 3-month follow-up

Method of measurement
Reliable and valid questionnaire

4
Description
Body composition

Timepoint
2 weeks before intervention, 2 weeks after intervention
Method of measurement
BMI z-score: Tanita SC-330 for weight and stadiometer
Seca 203 for height; waist circumference: measuring tape; body fat percent: Tanita SC-330

Secondary outcomes
empty

Intervention groups
1
Description
Intervention group:
Category
Lifestyle

2
Description
Control group:
Category
N/A

Recruitment centers
1
Recruitment center
Name of recruitment center
Primary school selected
Full name of responsible person
Ng Choon Ming
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Sponsors / Funding sources
1
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Name of organization / entity
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Full name of responsible person
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Grant name
Centre of Excellence for Research, Value Innovation and Entrepreneurship
Grant code / Reference number
Proj-In-FAS-058
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
UCSI University
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Domestic
Type of organization providing the funding
Academic
Person responsible for general inquiries
Contact
Name of organization / entity
UCSI University
Full name of responsible person
Ng Choon Ming
Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available