

# Toybox Study Malaysia: improving healthy energy balance behaviours in pre-schoolers

<b>Submission date</b> 18/06/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/06/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/08/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

In Malaysia, levels of childhood obesity have risen considerably over the last two decades. As such strategies to treat and prevent obesity are needed urgently and it is now considered a public health priority. In particular the preschool years are an important time for establishing healthy eating and physical activity behaviours. The aim of this study is to assess the practicalities of adapting the existing European ToyBox Study intervention programme to the Malaysian kindergarten setting. The ToyBox Study Malaysia will specifically target kindergartens funded by Jabatan Kemajuan Masyarakat (KEMAS), the Community Development Department under the Ministry of Rural and Regional Development in Malaysia in two key areas: Kuala Lumpur and Sarawak on the Island of Borneo. The specific aims of the study are to: adapt the ToyBox Study programme for use in Malaysia, including translation into Bahasa Malaysia and adapting the modules to local cultures; evaluate the feasibility of the intervention by assessing the acceptability of the ToyBox Study programme to parents and kindergarten teachers; and evaluate the adapted ToyBox Study programme by comparing the effects of the Toybox Study programme to usual care in kindergartens on physical activity and healthrelated behaviours and outcomes.

### Who can participate?

All children in the participating kindergartens between the age of 3 and 5 years will be invited to participate in the intervention

### What does the study involve?

Kindergartens are randomly allocated to deliver the Toybox Study programme or usual care. The intervention will run for 24 weeks across an entire kindergarten school year and focuses on four-targeted behaviours (drinking, snacking, physical activity, sedentary behavior) which are integrated with a lot of engagement into the daily life of the kindergarten. The ToyBox material includes newsletters, tip-cards and posters specifically designed to support parents at home too. These include information and ideas on how parents can actively and enthusiastically support their children to adopt these behaviours but also adopt them themselves and benefit the whole family.

What are the possible benefits and risks of participating?

The intervention poses no risk and it is hoped that it will benefit young children and their families achieve healthier energy balance-related behaviours that will benefit their long-term health.

Where is the study run from?

1. Universiti Kebangsaan Malaysia
2. Universiti Malaysia Sarawak (UNIMAS)

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

January 2017 to September 2019

Who is funding the study?

Medical Research Council Newton-Ungku Omar Fund

Who is the main contact?

Dr Leigh Gibson

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**Additional identifiers**

## Clinical Trials Information System (CTIS)

Nil known

## Protocol serial number

Nil known

# Study information

## Scientific Title

Improving healthy energy balance-related behaviours among preschoolers in Malaysia: feasibility of adapting the ToyBox Study

## Acronym

ToyBox

## Study objectives

The Toybox study programme will improve four energy balance-related behaviours (water drinking, snacking, physical activity and sedentary behaviour) which impact on obesity risk in children attending kindergartens in the intervention arm of the study compared to children attending kindergartens in the usual care arm of the study.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Approved 10/01/2017, ethics committee, Faculty of Medicine and Health Sciences, University Malaysia Sarawak (94300 Kota Samarahan, Sarawak Malaysia; Tel: +60 (0)82 581 000), ref: UNIMAS/NC-21.02/03-02Jld.2(68) B
2. Approved 08/11/2017, UKM Research Ethics Committee (Level 1, Clinical Block, Chancellor Tuanku Muhriz Hospital, UKM Medical Centre, Jalan Yaacob Latif, Bandar Tun Razak, 5600 Cheras, Kuala Lumpur Malaysia; Tel: +603 (0)9145 5046; Email: sepukm@ukm.edu.my), ref: UKM PPI/111/8/JEP-2017-658

## Study design

Pilot randomised control trial

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Obesity

## Interventions

The original ToyBox study is an evidence-based intervention that has previously been conducted in six European countries. The ToyBox study was designed to improve four energy balanced related behaviours which impact on risk of obesity in kindergarten children, namely: drinking water, healthy meals and snacks, physical activity and sedentary behaviour. Materials from the

original ToyBox study have been made available for this study to test the feasibility of this intervention in Malaysia. The ToyBox Study Malaysia intervention includes lesson plans, newsletters and age-appropriate equipment (including stories, toys, mats and colourful cups and plates) to target the four key energy balance-related behaviours.

Kindergartens will be randomly assigned to the intervention or control arm of the study. The intervention will be run in 22 KEMAS (the Community Development Department under the Ministry of Rural and Regional Development) run kindergartens: 15 in Peninsular Malaysia and 7 in Sarawak with 18 and 8 control kindergartens respectively, following usual care. The intervention will run over a period of 24 weeks and measures of the four target behaviours will be made pre and post intervention.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Feasibility assessed using:

1. Recruitment of participating kindergartens and families
2. Level of retention/drop out
3. Acceptability of the intervention and the outcome measures for stakeholders at a stakeholders workshop
4. Evaluation of the process of intention and intervention adherence; qualitative interviews and ToyBox questionnaire data

### **Key secondary outcome(s)**

1. Food and drink intakes assessed using a food frequency questionnaire pre and post intervention
2. Behaviour outcomes assessed using a questionnaire pre and post intervention
3. Sedentary behaviour and physical activity assessed using accelerometers pre and post intervention
4. Height, weight and waist circumferences measured using standard World Health Organisation anthropometric protocols pre and post intervention

### **Completion date**

01/09/2019

## **Eligibility**

### **Key inclusion criteria**

All children in the participating kindergartens between the age of 3 and 5 years will be invited to participate in the intervention

### **Participant type(s)**

All

### **Healthy volunteers allowed**

No

### **Age group**

Child

**Lower age limit**

3 years

**Upper age limit**

5 years

**Sex**

All

**Total final enrolment**

987

**Key exclusion criteria**

Data from children whose parents are unable to provide informed consent will be excluded from the study

**Date of first enrolment**

01/01/2018

**Date of final enrolment**

01/03/2018

**Locations****Countries of recruitment**

Malaysia

**Study participating centre****Universiti Kebangsaan Malaysia**

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**Study participating centre****Universiti Malaysia Sarawak (UNIMAS)**

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**Sponsor information**

## Organisation

University of Roehampton

## ROR

<https://ror.org/043071f54>

## Funder(s)

### Funder type

Research council

### Funder Name

Medical Research Council Newton-Ungku Omar Fund

### Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Leigh Gibson ([l.gibson@roehampton.ac.uk](mailto:l.gibson@roehampton.ac.uk)), all data collected should become available 01/01/2021 and for an unlimited time. Requests for any analysis should be sent to [ResearchOffice@roehampton.ac.uk](mailto:ResearchOffice@roehampton.ac.uk), for any analyses, data will be in an anonymised secure password protected format, consent was obtained for the current study but not for other subsequent studies. The researchers will endeavour to work in line with the good practice principles from the MRC data sharing policy set out here: <http://www.methodologyhubs.mrc.ac.uk/files/7114/3682/3831/Datasharingguidance2015.pdf>

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Interim results article</a>	Perspectives of teachers and parents	01/01/2022	05/10/2022	Yes	No
<a href="#">Other publications</a>	FFQ development	27/11/2019	30/01/2020	Yes	No
<a href="#">Other publications</a>	Adaptation of the intervention for online use	20/08/2023	29/08/2023	Yes	No
<a href="#">Other publications</a>	Process evaluation	06/06/2023	29/08/2023	Yes	No
<a href="#">Other publications</a>	Rationale	10/08/2018	29/08/2023	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes