

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

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

l.gibson@roehampton.ac.uk

Contact information

Type(s)

Public

Contact name

Dr Leigh Gibson

Contact details

University of Roehampton

Holybourne Ave

London

United Kingdom

SW15 4JD

+44 (0)208 392 3000

l.gibson@roehampton.ac.uk

Type(s)

Scientific

Contact name

Prof Bee Koon Poh

Contact details

Kebangsaan University Malaysia

Kuala Lumpur

Malaysia

50300 Kuala Lumpur

+60 (0)3 8921 5555

pbkoon@ukm.edu.my

Type(s)

Scientific

Contact name

Prof Cecilia Essau

Contact details

University of Roehampton
Holybourne Ave
London
United Kingdom
SW15 4JD
+44 (0)208 392 3000
c.essau@roehampton.ac.uk

Type(s)

Scientific

Contact name

Dr Sue Reeves

Contact details

University of Roehampton
Holybourne Ave
London
United Kingdom
SW15 4JD
+44 (0)208 392 3000
s.reeves@roehampton.ac.uk

Type(s)

Scientific

Contact name

Prof Carolyn Summerbell

Contact details

Durham University
Stockton Road
Durham
United Kingdom
DH1 3LE
+44 (0)1913342000
carolyn.summerbell@durham.ac.uk

Type(s)

Public

Contact name

Dr Whye Lian Cheah

Contact details

Malaysia Sarawak University (UNIMAS)
Kota Samarahan
Malaysia
94300 Kota Samarahan
+60 (0)82 581 000
wlcheah@unimas.my

Type(s)

Public

Contact name

Dr Julia Lee

Contact details

Malaysia Sarawak University (UNIMAS)
Kota Samarahan
Malaysia
94300 Kota Samarahan
+60 (0)82 581 000
aclee@unimas.my

Type(s)

Public

Contact name

Dr Denise Koh

Contact details

National University of Malaysia
Selangor
Malaysia
43600 Bangi
+60 (0)3 8921 5555
denise.koh@ukm.edu.my

Type(s)

Scientific

Contact name

Prof Ruzita Abd Talib

Contact details

Kebangsaan University Malaysia
Kuala Lumpur
Malaysia
50300 Kuala Lumpur
+60 (0)3 8921 5555
rzt@ukm.edu.my

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

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

Jalan Raja Muda Aziz

Kuala Lumpur

Malaysia

50300 Kuala Lumpur

Study participating centre

Universiti Malaysia Sarawak (UNIMAS)

94300 Kota Samarahan

Sarawak

Malaysia

94300 Kota Samarahan

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, 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), 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, 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?
Interim results article	Perspectives of teachers and parents	01/01/2022	05/10/2022	Yes	No
Other publications	FFQ development	27/11/2019	30/01/2020	Yes	No
Other publications	Adaptation of the intervention for online use	20/08/2023	29/08/2023	Yes	No
Other publications	Process evaluation	06/06/2023	29/08/2023	Yes	No
Other publications	Rationale	10/08/2018	29/08/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes