My Body is Fit and Fabulous at School (MyBFF@school)

Purpose

In order to address and curb the high prevalence of childhood obesity in Malaysia, a school-based intervention program, MyBFF@school is developed for implementation in all schools in the country. The program is specific for overweight and obese students and it is hypothesized that by participating in this program, students will be able to control their body mass index.

Condition

<table>
<thead>
<tr>
<th>Overweight</th>
<th>Obese</th>
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<tbody>
<tr>
<td>Other: MyBFF@school program</td>
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Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: School-based Intervention Program - My Body is Fit and Fabulous

Further study details as provided by Ministry of Health, Malaysia:

Primary Outcome Measures:

- BMI z-score [ Time Frame: 32 weeks of intervention ] [ Designated as safety issue: No ]
  
The primary outcome is reduction in the BMI z-score of participating students.

Secondary Outcome Measures:

- Percentage body fat [ Time Frame: 32 weeks of intervention ] [ Designated as safety issue: No ]
  
  Body fat of all participating students will be measured at baseline, week-16 and week-32 following intervention using Inbody 720 body composition analyzer (GE Healthcare).

Estimated Enrollment: 320
Study Start Date: February 2014
Estimated Study Completion Date: December 2016
Estimated Primary Completion Date: November 2014 (Final data collection date for primary outcome measure)
No Intervention: Control
Equal number of age-matched overweight and obese students will be selected from a control school. There will be no intervention, and students will participate in their usual health and physical education classes plus any other curriculum activities provided by the school.

Experimental: MyBFF@school program
Students will participate in all 3 components of MyFF@school for a total of 32 weeks; 1-hour of SSG thrice weekly plus 30 to 45 minutes of either nutrition or psychology classes once a week. All students including those in the control arm will be assessed at baseline, week-16 and at end of the study. They will undergo anthropometric measurements, body fat assessment, clinical examination and fitness test by modified Harvard step-test.

Other: MyBFF@school program
Students will be required to participate in all 3 components of MyBFF@school (SSG, nutrition and psychology sessions) for 16 weeks under the supervision of trained researchers, then for another 16 weeks supervised by their respective teachers-in-charge of physical education and/or co-curriculum activity. Each SSG session will be for an hour, thrice weekly while the nutrition or psychology session will be for 30-45 minutes once a week.

Detailed Description:
A nationwide Nutrition Survey of Malaysian Children carried out between 2008-2009 among 3542 children aged from 6 months to 12 years showed a prevalence of 9.8% overweight and 11.8% obesity while in a more recent 2011 Global School-based Student Heath Survey showed that the percentage of overweight and obese Malaysian school children age 13-15 years old was 25.4% and 10.9% respectively. If left unchecked, these children will grow up to be obese adults, developed various obesity-related complications such as cardiovascular diseases, diabetes etc. Realising the urgent needs to address the problems, the Ministry of Health Malaysia with the cooperation of the Ministry of Education, proposed to implement MyBFF@school in all schools in Malaysia. Students participating in MyBFF@school will take part in a structured physical activity in the form of small sided football game (SSG), and are to attend intensified and interactive nutrition and psychology classes aimed at improving their knowledge, self-esteem and self-empowerment.

Eligibility
Ages Eligible for Study: 7 Years to 16 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria
Inclusion Criteria:
Classified as overweight and obese based on BMI of 85th percentile and above, according to WHO growth chart.
No medical conditions that could endanger their health when participating in MyBFF@school.
Obtained parental and assent consents.

Exclusion Criteria:
With either physical or mental disability. With medical condition that prevents him/her to participate in moderate-to-vigorous intensity physical activity.
With comorbidities that may interfere with the study such as diagnosed type 2 diabetes mellitus, hypertension, nephritic syndrome, epilepsy, congenital heart disease and skeletal anomalies.
On steroids, on anti-epileptics and on methylphenidate.

Contacts and Locations
Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02212873

Contacts
Contact: Wan Nazaimoon Wan Mohamud, PhD  +60126659633  nazaimoon@gmail.com
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Locations
Malaysia
**Sponsors and Collaborators**

Ministry of Health, Malaysia

**Investigators**

Principal Investigator: Wan Nazaimoon Wan Mohamud, PhD  Institute for Medical Research, Ministry of Health Malaysia

**More Information**

No publications provided

Responsible Party:  Wan Nazaimoon WM, Dr, Ministry of Health, Malaysia

ClinicalTrials.gov Identifier:  NCT02212873  History of Changes

Other Study ID Numbers:  NMRR1343916563

Study First Received:  August 5, 2014

Last Updated:  August 6, 2014

Health Authority:  Malaysia: Ministry of Health

Keywords provided by Ministry of Health, Malaysia:

- school based intervention
- overweight
- obese
- BMI z score
- fat mass

Additional relevant MeSH terms:

- Overweight
- Body Weight
- Signs and Symptoms

ClinicalTrials.gov processed this record on May 21, 2015