Health Care and Promotion Committee

Research Fund Secretariat, Research Office, Food and Health Bureau
9/F, Rumsey Street Multi-storey Carpark Building, 2 Rumsey Street, Sheung Wan, Hong Kong
Tel: (852) 3150 8978 Fax: (852) 2102 2444 Email: rfs@fhb.gov.hk

Our Ref.: ( ) in FHB/H/41/131
Your Ref.:

Tel: 3150 8962
Fax: 2102 2444

4 April 2018

Dr GAO Yang
Assistant Professor
Department of Physical Education
Hong Kong Baptist University
12/F, Shek Mun Campus, On Muk Street
Shatin, New Territories, Hong Kong

Dear Dr Gao,

Health Care and Promotion Scheme
Application No.: 01170068

I am pleased to inform you that the Health Care and Promotion Committee has approved a grant of HK$334,520 for your application titled "*School-based physical activity intervention for obesity among adolescents with intellectual disability in Hong Kong*". The Agreement has been sent to the research office of your institution. They will liaise with you for signing the Agreement.

I would like to highlight the following for your special attention:

(a) Please complete the enclosed declaration form.
(b) The commencement date of this project should be within 6 months of the date of this letter.
(c) You and your witness are required to sign three copies of the Agreement.
(d) The terms and conditions on reporting requirements, ethical approval, intellectual property rights and administrative issues are summarised at **Annex**.
(e) Please return the signed copies of the Agreement together with the declaration form to the Research Fund Secretariat **via the Research Office** by **18 April 2018**.

In addition, the Principal Applicant and Administering Institution should seek **prior approval** from the Research Fund Secretariat for any change of Principal Applicant, Co-Applicant(s), scope, study design, methodology, sample size, project duration, or approved budget. You may also wish to visit our website for the guidance note and information about submission of the interim and final reports (https://rfs.fhb.gov.hk/).

study duration: 01/07/2018 to 31/12/2019

Hong Kong Baptist University

Informed Consent Statement

[School-based physical activity intervention for obesity among adolescents with intellectual disability in Hong Kong]

You are invited to participate in a research study. The purpose of this study is to implement and evaluate a modified adapted physical activity (APA) programme to reduce overweight and obesity among adolescents with ID (aged 12-18 years old) in Hong Kong.

Information

The study consists of a 9-month intervention. A randomised controlled trail (RCT) with two arms (intervention and control) will be adopted. Sixty-four overweight/obese adolescents with mild and moderate ID (aged 12-18) will be recruited from special schools in Hong Kong and then randomly assigned into equal intervention and control groups (n=32 for each group). The participants in the intervention group will receive a modified APA programme at school for nine months (Figure 1). The APA programme will consist of 72 training sessions of three stages. Each stage will involve simple and fun endurance and strength-building exercises, gradually increasing in duration and intensity, at a frequency of two sessions per week, and last for about three months. The exercises will be carefully designed based on a comprehensive pre-intervention assessment of each participant, and then to address their special needs in learning and adaption. Participants in the control group will be put in a waiting list during the intervention period, i.e. no intervention action will be delivered to them. However, they will receive the same APA programme right after the completion of the intervention.

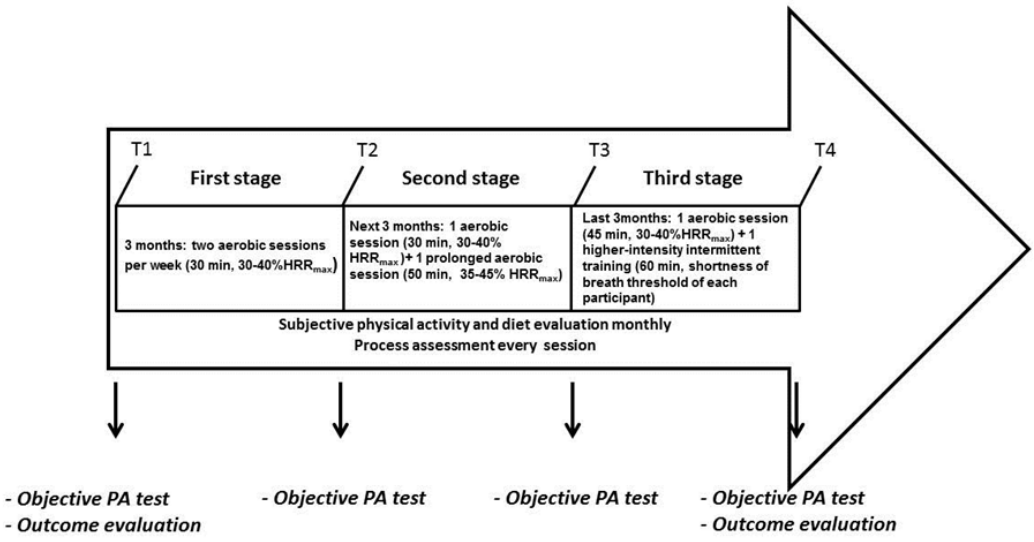

Figure 1 Procedures for intervention delivery and data collection

All participants in the both groups (N=64) will undertake repeated measurements on a set of study outcomes four times at the 0, 3rd, 6th, 9th months during intervention (Table 1). All measurements are non-invasive and no potential consequences are expected. In addition, a questionnaire will be developed to collect each participant's information of socio-demographic characteristics, physical activity level and eating habits at baseline. Those data will be collected by face-to-face interviews or interview calls with the participants and at least one of their parents together (about 15 minutes).

Table 1 Description of outcome measurements

Outcome indicator	Description of measurement	Potential consequences & countermeasures
Height	Portable stadiometer	None
Weight	Tanita TBF-410 Body Composition Analyzer	None
BMI	Calculated from height and weight	None
Waist circumference	Flexible meter ribbon	None
Hip circumference	Flexible meter ribbon	None
Waist-to-hip ratio	Calculated from waist and hip circumference measurements	None
% body fat	Tanita TBF-410 Body Composition Analyzer (foot-to-foot bioelectrical impedance analysis)	
Resting heart rate	Polar T31 Heart Rate Monitor, an electronic device, consists of a heart rate sensor and an elastic strap. It will be worn around the chest to measure heat rate at rest.	None
Physical activity	ActiGraph accelerometer, an electronic device. It will be worn on an elastic belt above the right hip of each adolescent when walking, doing exercise, or sitting, for seven days in a row	None

We will recruit 64 overweight and obese adolescents (aged 12-18 years) from the study schools and randomly assigned them into the intervention group (n=32) and the control group (n=32). Thus, each participant will have the same opportunity in each group. No one will know assignment results in advance.

Benefits

Childhood obesity is a major threat to public health. Children with intellectual disability (ID) are more vulnerable to obesity and metabolic syndrome than general paediatric population. The transition from adolescence to young adulthood is recognised as a particularly high-risk period for weight gain. Interventions to reduce obesity among adolescents with ID are scarce. We expected that findings from the study would make up the knowledge gap and help eliminate existing health inequities among children with ID. It would serve as an example for use of other researchers, policy-makers, and the public to tackle off obesity among children with ID in a global scale. If effective, our programme would be welcomed and adopted by other special schools to reduce obesity among their students in the future. In addition, the effective model can also be extended to reach students with ID in normal schools. We will disseminate our findings by presenting on international conferences, publishing journal articles, and building

up online platforms for learning and sharing to achieve as large benefits as possible. In the long run, we will equip our undergraduates with the effective APA programme and enable them to continue reducing overweight and obesity at their receiving schools for internship and working schools after graduation.

Reasonably foreseeable risks or discomforts

The intervention to the participants in the intervention group is overall safe. However, previous studies reported some rare consequences emerged during interventions, such as sports injury, underweight, and binge eating. We will monitor any consequences closely and prevent them via diverse means (e.g., to inform parents and their children of the possible adverse consequences in advance and provide feasible and practical preventive strategies to them). In addition, parents of the participants in the intervention group can report on any possible consequence during the counselling sessions (once per month) or reach our research team via the hotline. Prompt actions (e.g., proper remedy, suspension of the intervention implementation) will then be exerted if any.

There are no any foreseeable risks or discomforts for the participants in the control group.

Emergency medical treatment

In the unlikely event of physical injury resulting from your participation in this study, emergency medical treatment will be provided at no cost to you. Be certain that you immediately notify the researcher if you are injured. If you require additional medical treatment you will be responsible for the cost. No other compensation will be provided if you are injured in this research.

Confidentiality

We will strictly keep your data collected for the study confidential through the following means: (1) all paper copies will be completed data entry and stored in a cabinet with a lock within 3 months after data collection. Only the PI can access the cabinet; (2) we will build up two datasets of the digital copies: the first dataset consists of your name, contact information (if any), study school and a number assigned to you as an identifier, which will be kept in a separate USB and requires a password access. In addition, only the PI can access the dataset; the second dataset consists of the identifier and other information (excluding your name, contact information, and study school), which will NOT be stored in the USB with the first dataset. The second dataset will be used for data analysis; (3) we will destroy all of your data collected for this study within 5 years after completion of the study (including both paper data and digital data); (4) all reports/manuscripts generated from the study will be in aggregate terms and no individual response will be described and identified. Collectively, your data collected for this study will be kept confidentiality strictly.

Compensation and insurance

For participating in this study you will receive the following compensations: (1) A token compensation (a $100 coupon) will be given to you if your child completes the whole study. You will not receive the compensation if your child withdraws before the end of the study. You will also not receive the compensation if your child cannot attend 80% of all sessions (58 out of the 72 training sessions) without acceptable reasons; (2) Stationery (e.g. pens, erasers) will be rewarded to your child if s/he fulfills the attendance rate of 80% (58 sessions). Otherwise, no reward will be given to your child if his/her attendance rate is below than 80%; (3) Rewards (e.g. stickers) will be given to your child if s/he satisfactorily completes each exercise session. Otherwise, no reward will be given to your child if s/he is absent from any session.

Contact

If you have questions at any time about the study or the procedures, you may contact the researcher, Dr. GAO, Yang , at Department of Physical Education, Hong Kong Baptist University, and 3411 3082 . If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact the Committee on the Use of Human and Animal Subjects in Teaching and Research by email at hasc@hkbu.edu.hk or by mail to Graduate School, Hong Kong Baptist University, Kowloon Tong, Hong Kong.

Participation

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at any time by contacting the researcher, Dr. GAO, Yang , at Department of Physical Education, Hong Kong Baptist University, and 3411 3082 , without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed.

Your participation is important for success of the study. Thank you for your cooperation.

Consent

I have read and understand the above information. I have received a copy of this form. I agree to participate in this study.

Signature of the Subject _____ Date _____

Signature of the Parent(s)/Guardian(s) _____ Date _____

Signature of the Investigator _____ Date _____

香 港 浸 會 大 學

同意聲明書

[School-based physical activity intervention for obesity among adolescents with intellectual disability in Hong Kong]

你接受邀請參與這項研究。這項研究目的是實施和評估一項旨在減少香港智障青少年肥胖問題的適應體育運動（adapted physical activity, APA）干預研究。

資訊

這項研究包括一個為期 9 個月的適應體育運動干預措施。我們將邀請 64 位超重或肥胖的輕中度智障青少年（12-18 歲）參與本次研究。參加者將被平均且隨機地分派到干預組和對照組（每組 32 人）。干預組的參加者將首先參加是項為期 9 個月適應體育運動干預，它分為三個階段合共提供 72 次的運動課程（見圖 1）。每個階段為期 3 個月，每週 2 次運動課，每次運動課都包含力量訓練和耐力訓練。這些訓練是研究人員和 PE 老師針對參加者的自身情況共同編制的簡單但又有趣的練習，運動強度逐步增加。在這 9 個月的干預期內，對照組的參加者將被暫時列在候補名單內，不接受任何干預措施。干預完成之後，他們將接受與干預組一樣的干預措施。

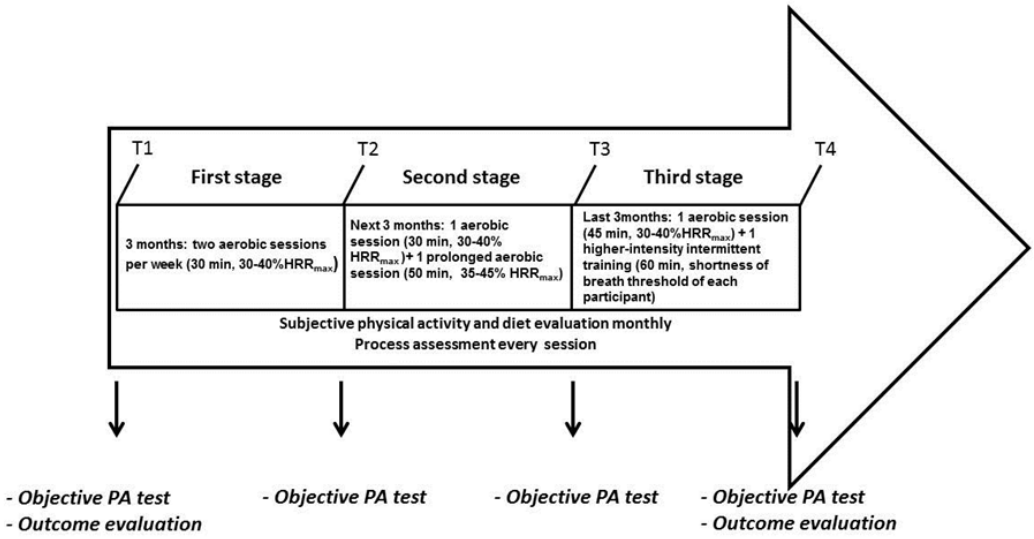

Figure 1 適應體育運動干預措施和效果評估流程圖

每位參加者都要接受表 1 列出的評估項目。這些評估都是安全可靠的非入侵性評估項目。每個項目將在干預期的第 0、3、6、及 9 個月進行評估測量（共 4 次）。此外，我們還會以問卷調查的方式收集每位參加者的人口社會學資料、體能活動情況和飲食習慣（大約 15 分鐘）。問卷調查將以面對面訪談或電話訪談的形式進行，訪談對象包括參加的學生以及至少一位他們的家長。

參與者簽名_____ 家長/監護人簽名_____

表 1 評估測量項目的描述

評估項目	描述	可能造成的損傷或後果
兒童身高	測高儀	無
兒童體重	Tanita TBF-410 Body Composition Analyzer	無
兒童 BMI	由身高、體重計算而得	無
兒童腰圍	軟尺	無
兒童臀圍	軟尺	無
兒童腰臀比	由腰圍、臀圍計算而得	無
兒童體脂百分比	Tanita TBF-410 Body Composition Analyzer (foot-to-foot bioelectrical impedance analysis)	無
兒童靜息心率	Polar T31 Heart Rate Monitor。用一條彈力帶把 Polar 佩戴在兒童胸部位置，測量兒童靜息心率。	無
兒童體能活動	ActiGraph accelerometer。用一條彈力帶把 Accelerometer 佩戴在兒童的右臀，用以測量兒童每天的體能活動和靜態行為，共連續佩戴 7 天。	無

我們將從香港特殊學校（輕、中度智障兒童的學校）中邀請 64 位超重或肥胖的輕中度智障青少年（12-18 歲）參與本次研究。參加者將被平均且隨機地分派到干預組和對照組（每組 32 人）。每位參加者進入干預組或對照組的機會是均等的。沒有人事先知道分派結果。

<u>益處</u>

兒童肥胖是一個重大的公共衛生課題。智障兒童尤其容易出現肥胖和其他代謝性疾病。青少年是一個控制體重增加和減少其他代謝性疾病風險的一個重要過度時期。然而針對智障青少年減重的干預研究證據很少。本研究的結果將填補這一項知識空白，有助消除當前智障兒童所面臨的健康不均等性。本研究可以在全球範圍內為其他相關研究者、政策制定者和公眾提供一個範例，以減少智障青少年的肥胖和其他代謝性疾病的風險。如果研究結果顯示干預有效，我們將在其他特殊學校推廣是項干預。同時，我們也會把它推廣至在普通學校里就讀的智障兒童。我們將在國際會議上呈報我們的研究結果，在國際雜誌上發表相關論文，并建立和維護一個網路平台以提供有效的範例與有需要的人士（如智障兒童家長或學校老師），幫助智障兒童保持健康體重。此外，我們會把這個成功的干預引入教學，教授給我們的本科生，讓他們在實習學校或畢業后的工作學校里繼續推廣，進一步對抗香港智障青少年的肥胖問題。

<u>合理可預見風險或不適</u>

本研究中的干預措施對參加者是安全的。但是，之前的相似研究曾報道一些罕見風險或不適， 包括：運動傷害、體重過輕、暴食症等。我們將密切監測任何不良風險或不適，通過多種手段預防任何風險或不適的發生（包括：讓參加者和父母了解所有不良風險或不適的可能性以及早期症狀；為他們提供可能預防的方法和緊急處理的方法等）。另外，我們設立一條熱線電話，

參加者的父母可以隨時通過電話匯報個案或獲得咨詢。任何風險或不適一旦發生，我們會立即採取相應措施（包括：適當的解決方案、立即終止干預等）。對照組中的參加者未見任何可預見風險或不適。

緊急醫療

如因參與這項研究而造成人身傷害時，緊急醫療治療將會被提供，你無需承擔任何成本。如在研究過程受傷，請緊記立即通知研究員。如果你需要額外的醫療處理，所需成本將自行負責。如果你在這項研究中受傷，將不會有任何其他補償。

保密性條例

我們將採取以下措施對你的所有資料嚴格保密：（1）所有紙質數據資料將在收集后 3 個月內完成數據輸入，并存放于有鎖的文件櫃里。只有本研究的項目負責人可以接觸這些紙質數據資料；（2）我們將建立兩個電子數據庫：第一個僅包括你的姓名、聯絡方式、所在學校和一個分配給個人的獨立編號（用以把所有個人資料連接到一起）。第一個數據庫將會單獨存放在一個 USB 中，並且需要通過密碼才能打開。第二個數據庫包括這個獨立編號和其他研究資料，但不包括第一個數據庫中的個人信息。第二個數據庫不會跟第一個數據庫存放在一起，且只用於分析資料；（3）本研究所收集的所有資料（包括紙質的和電子的）將於本研究完成後 5 年內銷毀；（4）所有參與者的身份及其對本研究的反應都不會在報告中被識別。

補償及保險

因參與此次研究項目，參與者將得到以下補償：（1）每位完成本次干預研究的學生，其家長將獲得價值$100 的獎券乙份。如果你的孩子在中途退出本項干預研究，你則不能獲得這項補償（即價值$100 的獎券乙份）。此外，如果你的孩子在沒有合理理由的情況下缺席本次研究達 20%【即缺席 14 次或以上的 APA 鍛煉計劃（總共 72 次）】，你也不能獲得這項補償（即價值$100 的獎券乙份）；(2) 干預組學生的運動參加率達到 80%或以上的同學將獲得學習用品（例如：鉛筆、擦膠）做為獎勵（例如：至少參加了 58 次的 APA 鍛煉計劃）；（3）干預組中的學生，每完成一次 APA 鍛煉計劃將獲得一份小禮品（如：精美貼紙乙張）。缺席者則不能獲得這份小禮品。

聯絡方式

如參與者對研究或過程有任何問題，可聯絡研究員: 高楊 ，地址是 香港浸會大學體育學系 ，聯絡電話是 3411 3082 。 如果參與者認為沒有得到「同意聲明書」中的所描述的待遇，或作爲研究的參與者，其權利受到侵害， 你可以通過發送郵件至: hasc@hkbu.edu.hk 或郵寄到:香港九龍塘香港浸會大學研究院聯絡 HASC。

參與

參與者是自願參與這項研究，參與者可以拒絕參加而不會產生任何處罰。如果決定參加，參與者有權在任何時候退出研究，而不會產生任何罰款，或利益損失；如果參與者在研究資料收集完成後退出，參與者的資料將被退還給參與者或銷毀。如果決定退出研究，你可以聯絡研

參與者簽名_____ 家長/監護人簽名_____

究員: 高楊 ，地址是 香港浸會大學體育學系 ，聯絡電話是 3411 3082 。

同意聲明

我已經閱讀並瞭解上述聲明。我已收到此表格的副本。我同意參加這項研究。

參與者簽名_____簽名日期_____

家長/監護人簽名_____簽名日期_____

研究員簽名_____簽名日期_____