

**Effects of intermittent caloric restriction in youth with
cardiometabolic risk: a randomized controlled pilot study**

Supplementary Research Ethics Board Approval

NCT number: NCT04011995

September 20, 2019

**Effects of intermittent caloric restriction in youth with cardiometabolic risk:
a randomized controlled pilot study**

Supplementary Research ethics board approval

This is a randomized controlled pilot study to evaluate the effects of intermittent caloric restriction compared with low carbohydrate diet in youth with cardiometabolic risk. Total trial duration for individual subject is one month consisting of a 14-day intervention phase and a 14-day self-maintenance phase.

In the previous study protocol, the eligible subjects were defined as pre-diabetic youth aged 13 to 30 years old which were high risk population for cardiometabolic diseases. The study was approved by the Research Ethics Committee of the Children's Hospital of Fudan University (CHFU 2017 No. 228) in December 2017.

In 2019, we adjusted the inclusion criteria and expanded the age range of the eligible subjects after discussion by the study team.

The adjusted inclusion criteria are as follows:

- (1) Aged 9-30 years old;
- (2) With at least one of the following cardiometabolic risk:
 - Overweight or obesity (central obesity or general obesity);
 - Prediabetes: impaired fasting glucose and/or impaired glucose tolerance;
 - Dyslipidemia;
 - Elevated blood pressure.

The previous subjects and the adjusted subjects were from the same population, and previous subjects were part of the adjusted study subjects. The protocol after adjusting the subjects was also approved by the Research Ethics Committee of the Children's Hospital of Fudan University (CHFU 2019 No. 216) in June 2019.

RESEARCH ETHICS BOARD APPROVAL

PROTOCOL TITLE: Effects of Intermittent Caloric Restriction on Glucose Regulation and Related Gene Methylation in Youth Pre-diabetic Youth

PRIMARY INVESTIGATORS: Weili Yan PROTOCOL TYPE: Lifestyle intervention study

APPLICATION INSTITUTIONS: Children's Hospital of Fudan University

STARTING AND ENDING DATES: 2018.1—2020.12

NAME LIST OF RESEARCH ETHICS BOARD: Zhu qi-rong; Zhou wen-hao; Xiao xian-min; Lu yi-qun; Qiu zi-long; Xing qing-he; Kan hai-dong; Qian li-ling; Shi xiao-hua; Yin yin

THE FOLLOWING ITEMS ARE COMPLETED BY RESEARCH ETHICS BOARD:

DOCUMENTS: (CLICK ✓ BEFORE OPINION)

(✓) protocol
(✓) application form
(✓) informed and consent form
() relevant approvals
() other informations

RESEARCH ETHICS BOARD'S OPINION (CLICK ✓ BEFORE OPINION)

() approval
(✓) to be re-investigated in case of supplying supplementary documents
() disapproval

REMARKS:

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CHAIRMAN'S SIGNATURE:

Liliy Qian



DATE:

2017-12-16

RESEARCH ETHICS BOARD APPROVAL

PROTOCOL TITLE: Effects of intermittent caloric restriction in youth with cardiometabolic risk: a randomized controlled clinical trial

PRIMARY INVESTIGATORS: Weili Yan | PROTOCOL TYPE: Lifestyle intervention study

APPLICATION INSTITUTIONS: Children's Hospital of Fudan University

STARTING AND ENDING DATES: 2019.7—2022.12 (Protocol ID: ICR_2019_2.0)

NAME LIST OF RESEARCH ETHICS BOARD:: Zhu qi-rong; Zhou wen-hao; Xiao xian-min; Lu yi-qun; Qiu zi-long; Xing qing-he; Kan hai-dong; Qian li-ling; Shi xiao-hua; Yin yin

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REMARKS:

CHAIRMAN'S SIGNATURE:

Liling Qian

DATE: _____

2019-6-13

