

1 April 2019

Ms Rtuh Leach
Via email: ed.lab4215@gmail.com

Dear Ms Leach,

Re: HREC/17/SCHN/164 - Fast Track to Health: The alternate day fasting diet in adolescents with obesity: a randomised controlled trial

The Sydney Children's Hospitals Network Human Research Ethics Committee (the Committee) refers to your complaint received on 23 February 2019 regarding the abovementioned clinical trial.

The Committee has reviewed the material you have provided and the concerns you have raised in your complaint. It had also received a complaint in November 2018 raising concerns regarding the trial's merit and integrity, safety profile and weight bias. A review of that complaint was conducted in accordance with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) (the National Statement), the Australian Code for the Responsible Conduct of Research 2018 (the Code), and local HREC and institutional policies. This review included a response from the study investigators to the complaint and advice from an independent advisory panel. The panel comprised highly experienced experts who are nationally and internationally recognised for their expertise in the areas of eating disorders and mental health, chronic disease, weight management and research ethics. Subject to a number of suggestions to improve the study and which have now been adopted, the panel saw no reason why the study should not proceed from both a scientific and ethical perspective.

The investigation thus concluded with the Committee requesting, amongst other things, additional safeguards to strengthen the study's existing risk management plan. The research team has responded to these and other issues raised in further consultation with key community and professional eating disorder organisations including the Butterfly Foundation and the ANZ Academy of Eating Disorders. A revised version of the study protocol and other relevant study documentation are currently under ethical review.

Having carefully reviewed your complaint, the Committee considers the concerns raised by you have been fully addressed as part of its investigation of the initial complaint mentioned above. In these circumstances, the Committee is of the view that no further action with respect to your complaint is required.

Thank you for your patience during the review of your complaint. If you are not satisfied with this outcome, you can refer your complaint to the SCHN Chief Executive as per the SCHN HREC's Standard Operating Procedures.

Yours Faithfully,
Asra Gholami on behalf of the SCHN Human Research Ethics Committee

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