

Executive Officer, Research Ethics
Ms Asra Gholami
Sydney Children's Hospital Network
Human Research Ethics Committee

5th November 2018

Dear Ms Gholami,

I wish to lodge a formal complaint to the Sydney Children's Hospital Human Research Ethics Committee regarding the "Fast Track to Health" trial, approval number HREC/17/SCHN/164. I am writing this complaint on behalf of myself, as a clinical psychologist with 20 years experience working primarily with people suffering from disordered eating, eating disorders, weight struggles, and chronic dieting. The complaint is also endorsed by the undersigned health professionals, representing a diverse group of professions, all of whom have significant clinical experience with people suffering from these conditions. In addition, this complaint has been endorsed by two organisations, the Association for Size Diversity & Health (ASDAH), and the National Association for the Advancement of Fat Acceptance (NAAFA).

Collectively, we have witnessed first hand the toll that dieting can take on mental and physical health. The "Fast Track to Health" trial is of great concern to us. We believe that this trial poses a risk of considerable harm to the adolescent participants. We respectfully ask that the ethics committee urgently review this study and either discontinue the trial, or modify the study design by removing the intermittent fasting arm and replacing it with a lower risk experimental condition.

The ethics complaint is framed around three areas of concern: 1. The integrity of the justifications and assumptions underpinning the research, 2. Risk of harm to study participants, and 3. Implicit weight bias.

1. Integrity of the Research Justifications and Assumptions:

According to the Fast Track study's home page,

“While short-term weight loss is possible, keeping the weight off long term is difficult. Modified alternate day fasting (MADF), has shown success in adults.”

There is robust research evidence to show that weight loss dieting can lead to short term weight reduction. However, in the vast majority of cases, such reductions are usually marginal and followed by regain. Over time, dieting is a strong predictor of weight gain, not loss (Siahpush, Tibbits, Raees, Singh, Kessler & Huang, 2015). The NH&MRC (2013) list evidence at Level “A” that weight loss following lifestyle interventions is maximal at 6-12 months, after which weight regain occurs. This report states that most weight is regained by 2 years post diet, and by 5 years the majority of people are at their pre-intervention weight. The Royal Australian College of Physicians (RACP) (2018) also acknowledge that “weight loss is rarely sustained and may come with negative consequences such as a reinforced sense of failure and metabolic re-setting towards promoting weight gain”(p.4). The RACP are now advocating to help people optimise their health, regardless of their weight status.

The American Academy of Paediatrics (2016) have emphasised that in adolescent populations, there is a need to stop focusing on weight and pursuing weight loss, and focus instead on helping young people of all sizes to look after themselves with health supporting behaviours (Golden et al, 2016). Their recommendations state that clinicians should:

“Discourage dieting, skipping of meals, or the use of diet pills; instead, encourage and support the implementation of healthy eating and physical activity behaviors that can be maintained on an ongoing basis. The focus should be on healthy living and healthy habits rather than on weight (E6).”

The assertion that MADF has shown ‘success’ in long-term weight loss in adults is not substantiated, particularly when the NH&MRC (2013) definition of long term as 2 to 5 years post-diet is used. Research on MADF and Intermittent Fasting (IF) in human adults is very much in its infancy. A systematic review of intermittent fasting trials by Headland et al (2016) identified just 6 studies with a follow up period of 12 months or longer. Of these, 3 are actually investigations of the use of intermittent Very Low Calorie Diet (VLCD) regimes lasting one to several weeks, thus they do not reflect a MADF regime (Arguin et al, 2012, Lantz et al, 2003, Wing et al, 1994). Another of the studies included examined the efficacy of taking ‘breaks’ from dieting during behavioural weight loss, which obviously is not reflective of a MADF intervention (Wing et al, 2003).

There were only 2 interventions with follow up periods of 12 months or longer in Headland et al's (2016) review which could be viewed as similar to a MADF regime, and the results were not glowing. Keogh et al (2014) reported an intervention on older females (average age of 60), in which participants undertook either an IER regime where they restricted for 1 week and then ate normally the following week, and compared them to continuous energy restriction (CER) group. 40% of the study participants had dropped out by the 8 week mark, indicating that the regimes were difficult to adhere to. Only 36 finished the 12 month period, and of these, just 11 (7 in the IER and 4 in the CER) people reported continued adherence to the diets. The trial reported only modest weight losses at 12 months (@4kg in the CER group and @2kg in the IER group), with no statistical differences between the two diet conditions. Thus, in this trial, MADF was not found to be superior to continuous energy restriction.

The second applicable intervention mentioned in Headland et al's (2016) paper was from Ash et al (2003), in which men with Type 2 diabetes participated in a version of intermittent fasting, in which they restricted intake for 4 consecutive days and then ate normally for the rest of the week. This was compared with a control group and an arm where men ate pre portioned meals. Modest weight and biomarkers improvements were noted initially, however by 18 months none of these changes were maintained and all participants were back to baseline.

A randomised controlled trial (RCT) examining MADF by Trepanowski et al (2017) directly compared an IF regime with a 'standard' calorie controlled diet (similar to the structure of the Fast Track trial). This RCT had a 12 month follow up period, and the results did not support the superiority of MADF over CER. The authors concluded that:

"Alternate-day fasting did not produce superior adherence, weight loss, weight maintenance, or cardioprotection vs daily calorie restriction." (p.937)

In addition to this, the IF group had a higher drop out rate (38%) than the standard calorie restriction group (29%), indicating that subjects in this group found the intense restriction harder to follow. Compared to the calorie restriction group, those in the IF group also developed disturbed eating behaviours:

“Participants in the alternate-day fasting group ate more than prescribed on fast days, and less than prescribed on feast days, while those in the daily calorie restriction group generally met their prescribed energy goals.” (p.930)

Of further note was the finding of significantly elevated LDL cholesterol levels in the IF group at 12 months, compared to the calorie restriction group.

It is of great concern that a trial subjecting adolescents to such an extreme dieting regime as MADF has been granted ethical clearance given the scientific evidence from preceding long term adult trials which show no evidence of superior efficacy over traditional dieting methods, and a return to baseline by 18 months. Moreover, Trepanowski et al’s (2017) trial, which is directly comparable to the structure proposed by the Fast Track study, showed not only that the intervention was not superior to standard calorie restriction, but that participants in the IF group found adherence more difficult, and that it was associated with disturbed eating behaviours and increased cholesterol levels. The assertion by the Fast Track Trial’s researchers that MADF has shown ‘success’ in long term weight loss appears to be in breach of the first principle (P1 - Honesty) of the Australian Code for the Responsible Conduct of Research (NH&MRC, 2018).

The Fast Track trial’s proposed follow up period of just one year is also clearly inadequate and will not be able to capture any long term impacts, such as expected weight regain.

2. Risk of Harm:

Over the past twenty years, eating disorder behaviors have increased exponentially amongst people in larger bodies (Darby et al, 2009, da Luz et al, 2017.) Many eating problems develop in adolescence, with the peak incidence for anorexia and bulimia between the ages of 15 and 19 (Micali et al, 2013). The American Academy of Pediatrics has identified dieting as the number one behaviour associated with increasing the risk of both increasing weight and eating disorders in adolescents (Golden et al, 2016). This relationship can take some years to detect, and may not be evident in reviews of short-term research interventions exploring the immediate impact of a specific diet intervention on psychometric measures. It may take more than one experience of dieting over time for these associations to become clear. As a clinician, my clients consistently report that it was the cumulative experience of several diet

cycles, including the inevitable experience of weight regain, that contributed to the development of their disordered eating symptomatology.

The assertion that dieting in adolescence causes harm is supported by a considerable body of research. In a large prospective cohort study of 9- to 14-year-olds ($N = 16\ 882$) followed for 2 years, dieting was associated with greater weight gain and increased rates of binge eating in both boys and girls (Field et al, 2003). Similarly, in a prospective observational study of 2516 adolescents enrolled in Project Eating Among Teens (Project EAT) followed for 5 years, dieting was associated with a twofold increased risk of weight gain and a 1.5-fold increased risk of binge eating at 5-year follow-up after adjusting for weight status at baseline (Neumark-Sztainer et al, 2007). Stice et al (1999) showed that girls in the average weight range who dieted in the ninth grade were 3 times more likely to be in the overweight BMI range in the 12th grade compared with non-dieters. These findings and others (eg Stice et al, 2005) clearly show that dieting in adolescence is counterproductive to weight loss efforts.

Prospective research clearly shows how dieting can predispose people to developing eating disorders over time. In a large study of 14 to 15 year olds followed for 3 years, dieting was the most important predictor of a developing eating disorder. Importantly, it was reported that **students who severely restricted their energy intake and skipped meals were 18 times more likely to develop an eating disorder than those who did not diet** (Patton et al, 1999).

The Fast Track trial is clearly a severely restrictive diet. All adolescent participants will undergo a VLCD phase of just 800 calories per day for up to the first 4 weeks of the trial. Following this, adolescents in the MADF group will be required to consume as little as 600 calories per day for 3 days of the week, for an entire year. Given what the prospective research shows on dieting severity and risk of eating disorder development, this extreme and prolonged period of dieting is unnecessarily risky and unethical.

In contrast to the high risks being taken by weight loss research trials, a growing body of evidence demonstrates the effectiveness of weight-inclusive, non-diet interventions on improving physical and psychological health, without the harms associated with weight-loss dieting (Tylka et al, 2014 Clifford et al 2015, Mensinger et al 2016). The absence of a non-diet control group in the Fast Track to Health study raises concerns regarding its research merit and integrity, as it compares two potentially harmful diet-based interventions. Furthermore, as the design lacks a “no treatment” control group it will not be

possible to measure the impact of the interventions compared to typically developing adolescents who do not receive treatment.

3. Weight Bias

According to the NH&MRC National Statement on Ethical Conduct in Research (2018), the circumstances in which research with young people is conducted should provide for their safety, emotional and psychological security, and wellbeing. Interventions which target adolescents' body size are implicitly weight-biased and therefore represent a threat to their wellbeing. By their very nature, weight loss interventions pathologize adolescents' growing bodies as 'diseased,' unhealthy or at-risk. Weight bias contributes to weight stigma and weight-related teasing, which have a strong and enduring impact on people's physical and mental health and social well-being.

The impact of weight bias caused by the Fast Track Study on the adolescent, his/her family, the wider community, and the future of all of those involved has been overlooked in favour of a weight-centric intervention which research has shown to be ineffective in the long term in adults. The physical and psychological impact of weight cycling and the internalised sense of shame related to inevitable weight regain driven by physiological responses must be considered in interventions such as this.

Weight bias is not eradicated by changing the level of politeness in language around body size or by supporting larger people to lose weight. Weight bias can only be addressed by ceasing weight-loss interventions and turning towards supporting people of all sizes to learn sustainable health supportive behaviours, as per the recommendations of the RACGP and the American Academy of Paediatrics.

In closing, we would like to reiterate our concerns about the Fast Track to Health study on the grounds that it is based on biased assumptions, lacks research merit and integrity, and is likely to cause harm. We ask that the ethics committee urgently review this study and either discontinue the trial, or modify the study design to remove the MADF arm and replace it with a non-diet arm focused on helping larger adolescents support their long-term physical and mental health. We would be more than happy to provide support and advice in implementing such a change.

Yours Sincerely,

Louise Adams, MAPS

Clinical Psychologist & Founder, UNTRAPPED and Treat Yourself Well Sydney

And endorsed by the following health professionals:

Deb Burgard, PhD, FAED, Psychologist in private practice, San Francisco Bay Area, US

Chevese Turner, Chief Policy & Strategic Office, National Eating Disorders Association (NEDA) and Founder & Former CEO, Binge Eating Disorder Association (BEDA)

Dr Linda Bacon, PhD, Health Researcher

University of California, Davis

Meg McClintock, accredited practising dietitian

Choose Nutrition Maitland & North Sydney

Fiona Willer, advanced accredited practicing dietitian

Health Not Diets

Susan Williams, accredited practicing dietitian

Zest Nutrition

Kerrie Beake, nutritionist

HAES Health

Nicole McDermid, social worker

The Embodied Journey

Shelley Lask, fitness trainer

Body Positive Health & Fitness

Janet Lowndes, psychologist & Director

Mind Body Well

Natalie Haider, psychologist

Psyched4success

Fumi Sumehara, accredited practising dietitian

Dancers Don't Diet

Sarah Harry, psychotherapist

Co-director, Body Positive Australia & Director, Fat Yoga

Fiona Sutherland, accredited practising dietitian & Director,

The Mindful Dietitian

Nina Mills, accredited practicing dietitian

Feel Good Eating

Olivia Patrick, clinical psychologist & Director

Shape Your Mind

Carlia Lozo, accredited practicing dietitian & Director

Welcome to Wellbeing

Shane Jeffery, accredited practising dietitian & Director,

River Oak Health

Bronwyn Wood, Health psychologist & Director

Step Psychology

Anna Hearn, Personal Trainer & Founder

Haven Wellness Fitness & Yoga

Rhea Bergmann, accredited practicing dietitian & psychotherapist

Mind-Full of Food Nutrition Counselling

Ashlee Bennett, art therapist

Insight Art Therapy

Casey Conroy, accredited practising dietitian

Funky Forest Health & Wellbeing

Jodie Arnot, registered counsellor

Deb Blakely, accredited practising dietitian

Kids Dig Food

Dr. Annette Ostermeyer, Clinical Psychologist

Affinity Women's Health

Sarah Peck, accredited practicing dietitian

Body Balance Nutrition

Jessica Campbell, Nutritionist and Director,

Body Balance Nutrition

Organisations who support this ethical complaint:



The National Association for the Advancement of Fat Acceptance (NAAFA)



The Association for Size Diversity & Health (ASDAH)

Please also note this [**position statement from FEAST**](#) regarding the Fast Track Trial

References

Arguin, H.; Dionne, I.J.; Senechal, M.; Bouchard, D.R.; Carpentier, A.C.; Ardilouze, J.L.; Tremblay, A.; Leblanc, C.; Brochu, M. Short- and long-term effects of continuous *versus* intermittent restrictive diet approaches on body composition and the metabolic profile in overweight and obese postmenopausal women: A pilot study. *Menopause* **2012**, *19*, 870–876.

Ash, S.; Reeves, M.M.; Yeo, S.; Morrison, G.; Carey, D.; Capra, S. Effect of intensive dietetic interventions on weight and glycaemic control in overweight men with type II diabetes: A randomised trial. *Int. J. Obes.* **2003**, *27*, 797–802.

National Health and Medical Research Council (2018). Australian Code for Responsible Conduct of Research.

Clifford, D., Ozier, A., Bundros, J., Moore, J., Kreiser, A., & Morris, M (2015). Impact of non-diet approaches on attitudes, behaviors, and health outcomes: a systematic review. *J Nutr Educ Behav.* Mar-Apr;47(2):143-55.e1. doi: 10.1016/j.jneb.2014.12.002.

da Luz, FQ, Sainsbury, A, Mannan, H, Touyz, S, Mitchison, D, and Hay, P. Prevalence of obesity and comorbid eating disorder behaviors in South Australia from 1995 to 2015. *International Journal of Obesity.* (2017) 41. 10.1038/ijo.2017.79.

Darby, A., Hay, P., Mond, J., Quirk, F., Buttner, P., Kennedy, L. The rising prevalence of comorbid obesity and eating disorder behaviors from 1995 to 2005. *International Journal of Eating Disorders*. 2009 Mar (42):104-8 doi: 10.1002/eat.20601.

Field AE, Austin SB, Taylor CB, et al. Relation between dieting and weight change among preadolescents and adolescents. *Pediatrics*. 2003;112(4):900–906 pmid:14523184

Golden NH, Schneider M, Wood C, AAP COMMITTEE ON NUTRITION. Preventing Obesity and Eating Disorders in Adolescents. *Pediatrics*. 2016;138(3):e20161649

Headland, M., Clifton, P., Carter, S., & Keogh, J. Weight-Loss Outcomes: A Systematic Review and Meta-Analysis of Intermittent Energy Restriction Trials Lasting a Minimum of 6 Months. *Nutrients*, 2016; 8(6), 354; doi:10.3390/nu8060354

Keogh, J.B.; Pedersen, E.; Petersen, K.S.; Clifton, P.M. Effects of intermittent compared to continuous energy restriction on short-term weight loss and long-term weight loss maintenance. *Clin. Obes.* **2014**, 4, 150–156.

Lantz, H.; Peltonen, M.; Agren, L.; Torgerson, J.S. Intermittent *versus* on-demand use of a very low calorie diet: A randomized 2-year clinical trial. *J. Intern. Med.* **2003**, 253, 463–471.

Mensingher, JL, Calogero, RM, Stranges, S, & Tylka, T (2016). .A weight-neutral versus weight-loss approach for health promotion in women with high BMI: A randomized-controlled trial. *Appetite*, Oct 1;105:364-74. doi: 10.1016/j.appet.2016.06.006. Epub 2016 Jun 8.

Micali, N., Hagberg, K. W., Petersen, I., & Treasure, J. L. (2013). The incidence of eating disorders in the UK in 2000-2009: Findings from the General Practice Research Database. *BMJ Open*, 3(5), e002646.

Neumark-Sztainer DR, Wall MM, Haines JI, Story MT, Sherwood NE, van den Berg PA. Shared risk and protective factors for overweight and disordered eating in adolescents. *Am J Prev Med*. 2007;33(5):359–369 pmid:17950400

National Health and Medical Research Council (2018). Australian Code for Responsible Conduct of Research.

National Health & Medical Research Council. The *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*

National Health and Medical Research Council. ***Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia.*** Melbourne: NHMRC; 2013

Patton GC, Selzer R, Coffey C, Carlin JB, Wolfe R. Onset of adolescent eating disorders: population based cohort study over 3 years. *BMJ.* 1999;318(7186):765–768 pmid:10082698

Royal Australian College of Physicians (RACP). Position Statement on Obesity (2018)

Siahpush, Tibbits, Raees, Singh, Kessler & Huang, Dieting Increases the Likelihood of Subsequent Obesity and BMI Gain: Results from a Prospective Study of an Australian National Sample. *Int J Behav Med.* 2015 Oct;22(5):662-71. doi: 10.1007/s12529-015-9463-5.

Stice E, Cameron RP, Killen JD, Hayward C, Taylor CB. Naturalistic weight-reduction efforts prospectively predict growth in relative weight and onset of obesity among female adolescents. *J Consult Clin Psychol.* 1999;67(6):967–974 pmid:10596518

Stice E, Presnell K, Shaw H, Rohde P. Psychological and behavioral risk factors for obesity onset in adolescent girls: a prospective study. *J Consult Clin Psychol.* 2005;73(2):195–202 pmid:15796626

Tracy L. Tylka, Rachel A. Annunziato, Deb Burgard, et al., “The Weight-Inclusive versus Weight-Normative Approach to Health: Evaluating the Evidence for Prioritizing Well-Being over Weight Loss,” *Journal of Obesity*, vol. 2014, Article ID 983495, 18 pages, 2014.
<https://doi.org/10.1155/2014/983495>.

Trepanowski, JF, Kroeger, CM, Barnosky, A., Klempel, MC, Bhutani, S., Hoddy, KK., Gabel, K., Freels, S., Rigdon, J., Rood, J., Ravussin, E., & Varady, KA. Effect of Alternate-Day Fasting on Weight Loss, Weight Maintenance, and Cardioprotection Among Metabolically Healthy Obese Adults: A Randomized Clinical Trial. *JAMA Intern Med.* 2017 Jul 1;177(7):930-938. doi: 10.1001/jamainternmed.2017.0936.

Wing, R.R.; Jeffery, R.W. Prescribed “breaks” as a means to disrupt weight control efforts. *Obes. Res.* **2003**, *11*, 287–291.

Wing, R.R.; Blair, E.; Marcus, M.; Epstein, L.H.; Harvey, J. Year-long weight loss treatment for obese patients with type II diabetes: Does including an intermittent very-low-calorie diet improve outcome? *Am. J. Med.* **1994**, *97*, 354–362.