AED Academy for Eating Disorders

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Academy for Eating Disorders (AED)
Research Risk/Benefit Ethics Position Statement
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Background: A study being conducted in Australia called "Fast Track to Health: The effect of a modified alternate day fasting diet pattern on weight loss and well-being among young people above a healthy weight" prompted a call among members of the AED to consider whether the research conflicts with aspects of the AED's mission ("*a global professional association committed to leadership in eating disorders research, education, treatment, and prevention*"). Among the concerns raised were that this study exposes research participants to serious short- and long-term medical and psychological risks while having limited prospects for benefiting them. Given our focus on leading in eating disorders research and prevention, the AED Board of Directors concluded that defining the organization's position on the ethical treatment of human participants in research is indeed consistent with our mission. In particular, **the AED aims to clarify our position on the importance of fully considering the risk of increasing eating disorders and related problems, alongside the gravity of such risk for those put in harm's way, when judging the risk to benefit ratio of research.** The Australia and New Zealand Academy for Eating Disorders (ANZAED) released a statement regarding several specific aspects of the Fast Track study, which the AED supports.

Risk and Benefit: Globally, the Declaration of Helsinki (most recently amended in October of 2013) provides guidance on the ethical treatment of human research participants. Two dimensions are particularly important for judging the impact of a study's procedures on human research participants: *risk* and *benefit*. Specifically, the Declaration states,

> "*All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation*" (emphasis added).

It further states:

> "*When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.*"

The choice of words is purposeful and indicates that risks and benefits are judged unequally according to their probabilities. "Predictable" risks are to be considered alongside "foreseeable" benefits. The distinction is between what is within the realm of possibility (i.e., predictable) and what may be reasonably anticipated (i.e.,

foreseeable). In other words, the benefits that can be reasonably anticipated to occur must offset the possible risks.

Eating disorders are serious. They are associated with death, disability, increased risk of medical and psychological problems, and financial burden at the level of the individual, family, and society (Micali et al., 2015; Whiteford et al., 2013). **When research poses the possibility of increasing one's risk of an eating disorder, or risk of exposure to the effects of eating disorder behaviors (e.g., severe caloric restriction), the reasonably anticipated benefits should be large**.

Vulnerable Populations: The Declaration of Helsinki also provides special protections for vulnerable populations. It states,

> "*Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research*" (emphasis added).

Children and adolescents are a vulnerable population. They are an especially vulnerable population from the standpoint of eating disorders, because the peak ages of onset primarily occur during this time (APA, 2013). Thus, the assessment of risk for eating disorders, and the risk of exposure to the effects of eating disorder behaviors, imbued by a research design must include an appreciation of the vulnerability of the population being exposed to those risks. **In children and adolescents, risks related to research participation are heightened. To protect them, we are obligated to pursue a conservative approach to their involvement in research.**

Returning to the impetus for this position statement: A variety of valid criticisms have been raised. Stated simply, we concluded that the reasonably anticipated benefits of the "Fast Track" trial do not outweigh the possible risks, particularly in light of the age of the population sampled (13-17 years).

With regard to risks, the risk for eating disorders and related problems are acknowledged by the researchers and the ethical governing body, so they are not reviewed in detail here. However, as a few examples, prospective research in adolescents has documented increased risk for the onset of binge eating associated with dieting (Allen et al., 2008) and the overvaluation of body weight (Sonneville et al., 2015), which weight-loss interventions may foster. Experimental research using animal models provides intriguing insight into possible biological mechanisms explaining the risk that caloric restriction poses to the subsequent development of binge eating (Pankevich et al., 2010). In addition, the effects of severe caloric restriction can be serious (e.g., nutrient deficiencies, organ damage, dehydration, headaches, susceptibility to infectious disease, and even death) and are generally poorly documented in research employing fasting (Horne, Muhlestein, & Anderson, 2015). In fact, models of restrictive diets for weight loss in adolescents indicate that it is difficult to design a modified alternate-day fasting diet for adolescents that meets their nutrient needs while also meeting energy restriction requirements (Lister et al., 2017).

With regard to benefits, there are no data on the effects (positive or negative) of modified alternate-day fasting in children or adolescents to our knowledge, and three recent meta-analyses of such trials came to the conclusion that randomized, controlled trials comparing versions of alternate-day fasting to typical daily restriction of intake in adults indicate no differences, with only slight nuance in one meta-analysis indicating the possibility of an advantage to alternate-day fasting on fat-free mass change (Alhamdan et al. 2016; Harris et al., 2018; Seimon et al., 2015). In brief, it is not clear what benefits beyond a typically restrictive diet (i.e., the comparison condition in the "Fast Track" trial) one should reasonably anticipate, as there is strong evidence that there are not benefits in adults. **Research that promises few to no reasonably anticipated benefits alongside serious risks in a vulnerable population, such as appears to be the case in this study, should not proceed.**

What this position statement is not: The AED aims to promote science and be science-based. The AED does not aim to police science on a study-by-study basis. The "Fast Track" trial and the upheaval it inspired provided an opportunity for the AED to clarify its position on the seriousness of eating disorders and related problems, as they pertain to the evaluation of risk/benefit in research, to ensure the protection of human research subjects and the integrity of research in our and related fields. Addressing the health needs of higher weight people is an urgent issue. Substantial evidence indicates that people at higher weights have elevated risks of certain health problems (e.g., medical and psychological, including eating disorders) and are likely to experience harms from weight stigma and discrimination that result in health disparities. When researchers have legitimate scientific questions that involve eating disorders, the AED aims to provide assistance through our wealth of expert members on the design and conduct of research that will move us forward while protecting the very people we rely upon to make discoveries.

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