

**Supplemental Table 1.** Illustrative cases of errors in the implementation, analysis, and reporting of randomization in the obesity and nutrition literature

|   | <b>Implementation</b>   | <b>Best Practices</b>  | <b>Illustrative References and Associated Discussions</b>   |
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| 1 | The study is labeled as an RCT, but not all participants are randomized, or nonrandom allocation methods are used.                | Label a study as randomized only when all participants were allocated using random methods. Procedures can be established <i>a priori</i> to reduce the risk that nonrandom allocation will be unintentionally employed. | <ul style="list-style-type: none"> <li>• Lanarkshire Milk Investigation (nonrandom methods) (1)<sup>a</sup>(2)<sup>b</sup></li> <li>• Nonrandomized convenience sample as control (3)<sup>a</sup>(4)<sup>b</sup>(5)<sup>b</sup></li> <li>• Allocated some intervention participants first (6)<sup>ab</sup></li> <li>• Carlisle's analysis of baseline p-value distributions of 5087 RCTs (7)<sup>c</sup></li> <li>• PREDIMED randomization errors (8)<sup>a</sup>(9)<sup>b</sup>(10)<sup>b</sup>(11)<sup>b</sup>(12)<sup>b</sup></li> <li>• Unlikely randomization of moxibustion and weight-related outcomes (13)<sup>a</sup>(14)<sup>b</sup>(15)<sup>b</sup></li> <li>• Unlikely randomization of vitamin D in patients with lupus erythematosus (16)<sup>ab</sup></li> <li>• Unlikely randomization of food service modifications and weight outcomes (17)<sup>a</sup>(18)<sup>b</sup></li> <li>• Animal study of air pollution exposure on obesity; allocated according to baseline body weight (19)<sup>a</sup>(20)<sup>b</sup></li> <li>• Nutraceutical formulation on hair growth; randomized within groups (21)<sup>a</sup>(22)<sup>b</sup>(23)<sup>b</sup></li> <li>• Supplement on cognitive function; alternating allocation used (24)<sup>a</sup>(25)<sup>b</sup></li> <li>• Study on kiwifruit and vitamin C; some apparent nonrandom allocation (26)<sup>a</sup>(27)<sup>b</sup></li> <li>• Unlikely randomization: "Patients ... were randomly assigned to one of the four dietary regimens based upon dietary preferences." (28)<sup>a</sup>(29)<sup>b</sup></li> </ul> |
| 2 | Allocation concealment is broken by using nonrandom allocation methods, or by using random methods but not adequately concealing. | Electronic or physical allocation codes should be concealed to investigators assigning participants to groups until the time of allocation.  | <ul style="list-style-type: none"> <li>• Supplement on cognitive function; alternating randomization used (24)<sup>a</sup>(25)<sup>b</sup></li> <li>• Lanarkshire Milk Investigation (nonrandom methods) (1)<sup>a</sup>(2)<sup>b</sup></li> <li>• PREDIMED randomization errors (8)<sup>a</sup>(9)<sup>b</sup>(10)<sup>b</sup>(11)<sup>b</sup>(12)<sup>b</sup></li> <li>• Surgical comparisons for the treatment of obesity; hospital chart number used to allocate (nonrandom methods) (30)<sup>a</sup></li> <li>• Iron supplementation and anemia during pregnancy; randomized by day of week (nonrandom methods) (31)<sup>a</sup></li> </ul>  |
| 3 | Different allocation ratios are used within a study but are not accounted for in the analysis.                                    | Changing allocation ratios within or between experiments must be accounted for in statistical analysis.  | <ul style="list-style-type: none"> <li>• Weight loss on telomere length; allocation ratio changed in second phase of study (32)<sup>a</sup>(33)<sup>b</sup></li> <li>• Low-calorie sweeteners and sucrose on weight-related outcomes; allocation ratio changed after higher attrition rate in one group (34)<sup>a</sup></li> </ul>   |
| 4 | Participants who drop out are replaced in a way that is unclear or nonrandom.   | Replacing participants in a randomized design must use random allocation.  | <ul style="list-style-type: none"> <li>• Green tea ointment on pain and wound healing; nonrandom replacement (35)<sup>a</sup>(36)<sup>b</sup>(37)<sup>b</sup></li> <li>• Other various nutrition- and obesity-related studies using vague language about replacement (38-40)<sup>a</sup></li> </ul>   |
|   | <b>Analysis</b>   | <b>Best Practices</b>  | <b>Illustrative References and Associated Discussions</b>   |
| 5 | Non-independence is not accounted for in the design and/or analysis in randomized trials.   | The planning and analysis of group-randomized designs must account for the number of groups and correlations among participants for valid inferences.  | <ul style="list-style-type: none"> <li>• Various nutrition- and obesity-related studies not accounting for clustering in the design and/or analysis (41-43); (44, 45); (41, 43, 46); (44, 45); (47); (48-50); (51-53); (54-57); (58, 59); (60); (61); (62, 63); (64, 65); (66-68); (69); (70); (1, 2)</li> <li>• Review of failure to account for clustering in school-based randomized trials (71)<sup>c</sup></li> <li>• Reviews of best practices and additional discussion of clustering errors (72, 73)<sup>c</sup></li> <li>• Vitamin E on diabetic neuropathy; non-independent within-person measurements (69)<sup>a</sup></li> </ul>  |

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| 6  | Conclusions are drawn from within-group tests instead of between-group in RCTs.  | The proper analysis of RCTs is a direct between-group test.  | <ul style="list-style-type: none"> <li>Isomaltulose vs. sucrose on weight-related outcomes; some conclusions drawn from within-group comparisons (74)<sup>a</sup>(75)<sup>b</sup>(76)<sup>b</sup>(77)<sup>b</sup></li> <li>Other various nutrition- and obesity-related studies drawing conclusions from within-group instead of between-group comparisons (78, 79); (80-82); (83, 84); (85, 86); (87, 88); (89, 90); (91-93); (94, 95); (96-99); (100-102); (103-105); (106-108); (109, 110); (111)</li> <li>Reviews on best practices and additional discussion of these errors (73, 112-116)<sup>c</sup></li> </ul>   |
| 7  | Pooled data does not account for random assignment in the analysis.  | Pooling data within one or multiple studies requires consideration in the statistical analysis.  | <ul style="list-style-type: none"> <li>School-based weight management program on weight gain; combined multiple RCTs without accounting for study (117)<sup>a</sup>(118)<sup>b</sup></li> </ul>  |
| 8  | Missing data is not accounted for in the analysis.   | Following the ITT principle when conducting statistical analysis is the recommended approach to maintain the integrity of randomization. | <ul style="list-style-type: none"> <li>Intermittent vs. continuous energy restriction on body composition and metabolic rate; missing data ignored (100)<sup>a</sup>(101)<sup>b</sup>(102)<sup>b</sup></li> <li>High phytate vs. dephytinized bread on iron status; missing data ignored (96)<sup>a</sup>(97)<sup>b</sup>(98)<sup>b</sup>(99)<sup>b</sup></li> </ul>   |
|    | <b>Reporting</b>   | <b>Best Practices</b>  | <b>Illustrative References and Associated Discussions</b>  |
| 9  | The methods used to randomize are insufficiently or incorrectly reported and may lead to confusion, or in fact do not describe random methods. | Fully report the methods used to randomize subjects by following appropriate reporting guidelines.                                       | <ul style="list-style-type: none"> <li>Dairy- and berry-based snacks on nutritional status and grip strength; insufficient details on randomization method and allocation ratio (119)<sup>a</sup>(120)<sup>b</sup>(121)<sup>b</sup></li> <li>Nutritional intervention on outcomes in individuals with autism spectrum disorder; unreported blocking factors and clustering (41)<sup>a</sup>(46)<sup>b</sup>(43)<sup>b</sup></li> <li>School-based weight management program on weight gain; participant numbers inconsistent with original publications (117)<sup>a</sup>(118)<sup>b</sup></li> <li>Classroom intervention on diabetes control; participant number was odd yet randomized in pairs (122)<sup>a</sup>(123)<sup>b</sup></li> <li>Intervention to increase physical activity in fathers and daughters; whether clustering in analysis was account for unclear (124)<sup>a</sup>(125)<sup>b</sup>(126)<sup>b</sup></li> <li>Breakfast on appetite and satiety; 'semi-random' used for stratified randomization (127)<sup>a</sup></li> <li>Sucralose on metabolic sensitivity to sugar; 'semi-random' used for minimization (128)<sup>a</sup></li> <li>Kiwifruit and vitamin C on vitality; unreported allocation methods (26)<sup>a</sup>(27)<sup>b</sup></li> </ul> |
| 10 | Failing to properly communicate inferences.  | Frame the treatment <i>assignment</i> as the causal effect of interest.  | <ul style="list-style-type: none"> <li>Energy restriction on metabolic outcomes; random assignment is the exposure, not the level of restriction (129)<sup>a</sup>(130)<sup>b</sup></li> </ul>   |

<sup>a</sup> Denotes reference where error occurred

<sup>b</sup> Denotes post-publication discussion or correction of error

<sup>c</sup> Denotes review/tutorial/original research paper about error

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