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Corrigendum to “Optimization of remotely delivered intensive lifestyle treatment for obesity using the Multiphase Optimization Strategy: Opt-IN study protocol”

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In Pellegrini et al. [1], we reported the use of a fractional factorial experimental design to examine five intervention components under consideration for inclusion in a weight loss intervention. We recently discovered that due to a clerical error, the experimental design we presented in that article, which is the design we had been implementing, was not identical to the design we originally selected and intended to implement. In this corrigendum, we present the fractional factorial design we intended to apply in Pellegrini et al., and explain how we decided to address the problem of inadvertent implementation of a partially incorrect experimental design.

Intended fractional factorial design for Pellegrini et al

The design presented in Pellegrini et al. is a balanced fractional factorial design, but it does not have the statistical properties described in the text. The intended design, which is shown in Table 1, is a 2^{5-1} Resolution V design. In a Resolution V design each main effect is aliased with one four-way interaction or the five-way interaction, and each two-way interaction is aliased with one three-way or higher-order interaction.

Expansion to a complete factorial design

When we discovered the error described above, enrollment in the 16 experimental conditions discussed in Pellegrini et al. was almost exactly halfway completed. Our options when we discovered the error were: (a) continue with the design in Pellegrini et al., and analyze it as a 2^{5-1} fractional factorial even though it did not have the exact statistical properties we desired; (b) continue with the design in Pellegrini et al., and then in the data analysis phase treat it like a 2^4 complete factorial (An after-the-fact reduction of this kind is always possible with balanced fractional factorial designs (see Wu & Hamada [2]); however this would have meant we could examine only four components.); or (c) expand the design to a complete 2^5 factorial with 32 experimental conditions, which would eliminate aliasing of effects among the experimental factors and enable us to examine all five components.

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We believe our best option is (c), and hence expanded the design to a complete 2^5 factorial with 32 experimental conditions. All 16 of the conditions comprising the Pellegrini et al. design that we were in the process of implementing appear in the complete factorial design, so expanding the design involved keeping the conditions we already had implemented and adding the remaining 16 conditions. As discussed in Collins et al. [3], increasing the number of experimental conditions by changing an experiment from a fractional to a complete factorial does not require increasing the overall number of subjects. Fractional factorial experiments and their complete factorial counterparts require exactly the same N to achieve the same expected level of power. Unlike the RCT, factorial experiments are not powered for direct comparison of individual experimental conditions; rather, they are powered for detection of main effects and interactions. Therefore, power in any factorial experiment is a function of the overall N rather than per-condition sample size (see Collins, Dziak, Kugler, & Trail, [4]). If a design is expanded from a fractional factorial to a complete factorial, power is maintained as long as the overall N is maintained, although the per-condition sample size will decrease because this N is divided among more experimental conditions.

The complete factorial experiment we are currently implementing is shown in Table 2. Our original experiment was adequately powered with $N = 560$, and the new experiment is adequately powered with this same N . In the new design, we plan to randomize approximately $560/32 = 17$ or 18 subjects to each experimental condition. Conditions 1–16 now have this number of subjects, so we have stopped randomizing to those conditions and have begun randomizing all remaining subjects to conditions 17–32. We acknowledge that some effects may now be confounded with time, because we implemented the first 16 experimental conditions in the first half of the study and the second 16 conditions in the second half of the study.

Conclusions

Large factorial experiments can be logistically complex, and mistakes are possible. The mistake described in this corrigendum was caused by a cut-and-paste clerical error. This was a major error, but we do not believe that it has biased the experiment because its detection and correction both occurred blind to knowledge of any results in the data being collected.

Although we would have preferred not to have made this mistake (and have taken steps to ensure it does not happen in future research), the experience has reassured us that factorial experiments are robust, and that it is possible to recover from even serious implementation difficulties. Even if we had not discovered the problem before the experiment was complete, or had not been able to retool to implement 16 additional experimental conditions, we had two other viable alternatives, as described above. At the very worst, these alternatives would have enabled us to examine the main effects of four or five (depending on whether we chose alternative (b) or (a), respectively) components, and selected interactions. This was encouraging because our primary objective was estimation of main effects. This is a screening experiment, conducted for the purpose of identifying which components demonstrate a positive effect on the outcome and should be considered for inclusion in an optimized weight loss intervention, and which should be screened out. The decisions about which components to consider further and which to screen out are made primarily on the

basis of main effects and then reconsidered in the light of any interactions [5], as is standard in engineering and other fields that use screening experiments [2].

We remind readers that there are many fractional factorial designs to choose from. We strongly suggest that readers who wish to implement a fractional factorial experiment in their work not copy the design in Table 1 or any other fractional factorial design that may appear in the literature, but instead use software such as PROC FACTEX in SAS[®] [6] to select the right design for their needs. For more about how to do this, please refer to Collins, Dziak, and Li [3].

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Table 1

Intended Fractional Factorial Design

Condition	Coaching Sessions	PCP Report	Texts	Meal Replacement Recommendations	Buddy Training
1	12	Yes	No	No	Yes
2	12	Yes	No	Yes	No
3	12	Yes	Yes	No	No
4	12	Yes	Yes	Yes	Yes
5	12	No	No	No	No
6	12	No	No	Yes	Yes
7	12	No	Yes	No	Yes
8	12	No	Yes	Yes	No
9	24	Yes	No	No	No
10	24	Yes	No	Yes	Yes
11	24	Yes	Yes	No	Yes
12	24	Yes	Yes	Yes	No
13	24	No	No	No	Yes
14	24	No	No	Yes	No
15	24	No	Yes	No	No
16	24	No	Yes	Yes	Yes

Table 2

Full Factorial Design with 32 conditions

Condition	Coaching Sessions	Report to PCP	Text Messages	Meal Replacement Recommendations	Buddy Training
1	12	YES	NO	NO	NO
2	12	YES	NO	YES	YES
3	12	YES	YES	NO	YES
4	12	YES	YES	YES	NO
5	12	NO	NO	NO	YES
6	12	NO	NO	YES	NO
7	12	NO	YES	NO	NO
8	12	NO	YES	YES	YES
9	24	YES	NO	NO	NO
10	24	YES	NO	YES	YES
11	24	YES	YES	NO	YES
12	24	YES	YES	YES	NO
13	24	NO	NO	NO	YES
14	24	NO	NO	YES	NO
15	24	NO	YES	NO	NO
16	24	NO	YES	YES	YES
17	12	NO	NO	NO	NO
18	12	NO	NO	YES	YES
19	12	NO	YES	NO	YES
20	12	NO	YES	YES	NO
21	12	YES	NO	NO	YES
22	12	YES	NO	YES	NO
23	12	YES	YES	NO	NO
24	12	YES	YES	YES	YES
25	24	NO	NO	NO	NO
26	24	NO	NO	YES	YES

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Condition	Coaching Sessions	Report to PCP	Text Messages	Meal Replacement Recommendations	Buddy Training
27	24	NO	YES	NO	YES
28	24	NO	YES	YES	NO
29	24	YES	NO	NO	YES
30	24	YES	NO	YES	NO
31	24	YES	YES	NO	NO
32	24	YES	YES	YES	YES