Financial Incentives foR Weight Reduction (FIReWoRk) randomized controlled trial

BIOSTAT 402B: Project Reports

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1 Brief information on the client

Major Client

- Name: Dr. Stephanie Orstad
- Department (title): Grossman School of Medicine, NYU (Research Assistant Professor)
- Purpose of visit: Working on existing clinical trial data to test research question(s) and hypothesis.

Major Consultant

- Name: Dr. Chi-Hong Tseng
- Department: Department of Medicine Statistics Core (DOMStat), UCLA

Second Consultant & Data Analyst

- Name: Kuan-Hung (Peter) Yeh
- Department: Department of Biostatistics, UCLA

2 Aims of the project

The objective of the Financial Incentives foR Weight Reduction (FIReWoRk) randomized controlled trial was to compare the effectiveness of goal-directed versus outcome-based financial incentives on weight loss at 6 months among patients with obesity living in low-income neighborhoods and to compare them to a strategy of provision of weight management resources only. They hypothesized that goal-directed incentives would lead to greater and more sustained weight loss than outcome-based incentives or the provision of behavior change resources alone.

The aim of this study is to examine the effects of two financial incentive strategies developed using behavioral economic theory when added to the provision of weight management resources. The detailed conceptual model for the FIReWoRk project is listed in Figure 2. The two main questions that I helped with are:

1. Whether intervention arm (different study groups) is associated with adherence to health behaviors through conceptually matched psychological mechanisms?

2. Whether psychological mechanisms are associated with weight loss through the change in health behaviors, stratified by study arm/moderator?

3 Detailed project description:

In this study, the main objective is to examine the effects of two financial incentive strategies developed using behavioral economic theory when added to the provision of weight management resources. This was a three-arm, randomized controlled trial conducted in three hospital-based clinics in New York City (Bellevue Hospital and NYU Langone Brooklyn) and Los Angeles (UCLA-Olive View). A total of 1,280 adults with obesity living in low-income neighborhoods were invited to participate and 668 were enrolled. The intervention arms consist of three groups, including Resources only, Outcome-based incentives, and Goal-directed incentives which elaborate as follows.

- Resources only:
  Participants receive a list of local weight management programs & a voucher for 1 year of WW Freestyle (formerly Weight Watchers) membership.

- Outcome-based incentives:
  Resources only plus earning up to $750 over 6 months for losing $\geq$1.5% to $\geq$5% of their baseline weight.

- Goal-directed incentives:
  Resources only plus earning up to $750 over 6 months for engaging in the following evidence-based weight loss behaviors: weight management program participation, self-monitoring weight and diet, and physical activity.

The detailed time schedule for receiving financial incentives for meeting the goals is listed in Figure 2. in the Appendix. The assessments occur at baseline, 30 days, and 2, 3, 4, 5, 6, 9, and 12 months. The primary & secondary outcomes are (1). The percentage of patients who achieve a $\geq$ 5% reduction in baseline weight at 6 months and (2). Weight management program attendance, waist circumference, blood pressure, and quality of life. They did a survey to measure Sociodemographics information, Chronic health conditions, Physical activity, Quality of life, etc. They also measured some biometrics such as Height, Weight, Blood pressure, Waist circumference, etc. All three study groups were assigned identical follow-up visit schedules (monthly check-in visits in the first six months) in order to limit potential confounding attributable to different intensities of human interaction.

4 Specific questions of interest for you as a statistical consultant

As I mentioned in Part 2, the two main questions our client wants to know are (1).Whether conceptually matched psychological mechanisms will explain differences in behavior change over time in different intervention arms & (2).Whether psychological mechanisms are associated with weight loss through the change in health behaviors, stratified by study arm/moderator. To answer those questions, Chi-Hong and I decide to design a mediation analysis model to try to find out the answer to those research aims. We drew DAGs (Directed Acyclic Graph) to explain the relationship we're interested in Appendix.

In Figure 3, we hypothesized that different intervention arms have an association effect with weight loss (direct effect; path c) and there's also an association effect via behavior change to weight loss (indirect effect; path a and b). In Figure 4, we hypothesized that psychological mechanisms have an association effect with weight loss (direct effect; path c) and there's also an association effect via behavior change to weight loss (indirect effect; path a and b) which is stratified by the study arm (moderated mediation).

Based on the two DAGs, we used linear mixed-effects models to estimate the total and indirect effects on changing health behaviors through psychological mechanisms for different intervention arms at 6-month, 9-month, and 12-month follow-up times for each health behavior & psychological mechanisms pair. The indirect effect of different intervention arms at each follow-up time point is estimated using the difference of coefficients in fixed effects of treatment–time interaction. After calculating the indirect effect, we used bootstrapping method to resample the data iteratively and provide distributions of values for calculating 95% confidence intervals around the indirect effect.

5 Your advice to the client and follow-up action

After presenting at Biostat 402B consulting class, I received a lot of advice and I have a discussion about the analysis methods we used with Chi-Hong and our client to make sure that we are on the right track for answering the scientific questions clients want to solve. We figured out that there is a slightly different analysis method for answering questions 1 & 2, the first questions can be addressed by simple mediation analysis by comparing the model coefficients that included the mediators with the ones that don't include them. However, the second question is not simply a mediation analysis, it needs to stratify by the intervention arms. Therefore, to answer whether psychological mechanisms are associated with weight loss through the change in health behaviors, stratified by study arm/moderator. The linear mixed-effects model needs to include the interaction terms for psychological mechanisms times study arm and time (three-way interaction) and then calculated the difference of coefficients in the model with & without mediators (behaviors in this question).

For my follow-up actions, I conducted the modeling for these two questions, calculating the indirect effect and using bootstrapping to obtain 95% confidence intervals around the indirect effect to determine whether this is a significant indirect effect or not. For questions 1, two out of five health behavior & psychological mechanisms pair there exists at least one significant intrinsic mediator for each time point. For question 2, three out of five psychological mechanisms are significantly

associated with weight loss through the change in health behaviors when stratified by the study arm. The detailed results are still under review and will publish shortly.

6 Did you do any research on your own before you advise the client?

This project is my first time doing meditation analysis. Therefore, I read plenty of textbooks and papers on these topics and how to do this kind of analysis in R language. The most useful information source I found is a paper from *Biostatistics (2017)* which I listed below.

- *Saunders, Christina Blume, Jeffrey. (2017). A classical regression framework for mediation analysis: Fitting one model to estimate mediation effects. Biostatistics (Oxford, England). 19. 10.1093/biostatistics/kxx054.*

This paper describes a classical regression framework for conducting mediation analyses in which estimates of causal mediation effects and their variance are obtained from the fit of a single regression model. Although we used a linear mix-effect model instead of linear regression for our modeling, this paper still provides some useful examples to illustrate the advantages of the classical regression framework and we can extend to a different kind of modeling when we encounter more complex designs or real-world examples. Moreover, it also provided a comprehensive review of the literature on mediation analysis and its pros and cons which helps people find different mediation analysis approaches very easily.

7 Appendix

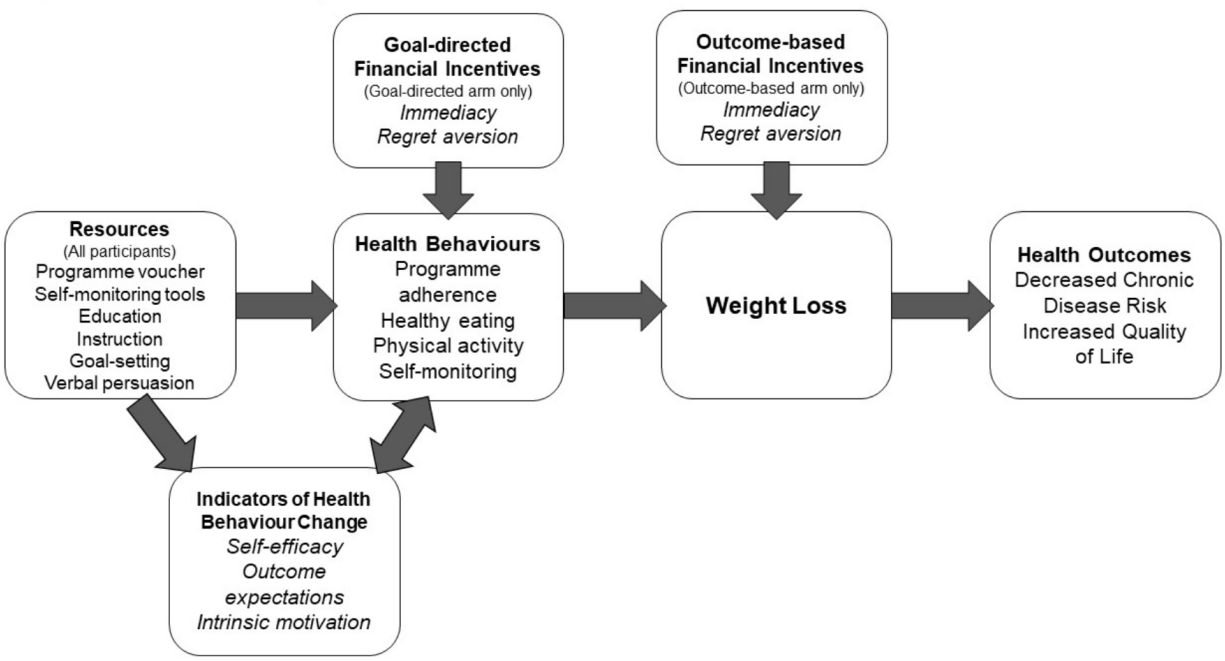

Figure 1. FIReWoRk conceptual model.

Table 1 Financial incentives awarded for meeting monthly behavioural goals and weight loss outcomes

	Time point	Goal-directed incentives*	Outcome-based incentives
Behavioural goals			
Enrolment and active participation† in an evidence-based‡ weight management programme	1, 2, 3, 4, 5 or 6 months	$150	$0
Active participation† in an evidence-based‡ weight management programme	2, 3, 4, 5 and 6 months	$60	$0
Food journal use§	1, 2, 3, 4, 5 and 6 months	$20	$0
Achievement of ≥75 min of physical activity per week	1, 2 and 3 months	$20	$0
Achievement of ≥150 min of physical activity per week¶	4, 5 and 6 months	$20	$0
Self-weighing**	1, 2, 3, 4, 5 and 6 months	$10	$0
Weight loss outcomes			
Weight loss (≥1.5% to ≥2.5%)	1 month	$0	$50–$100††
Weight loss (≥2.5% to ≥5%)	2 and 3 months	$0	$50–$100‡‡
Weight loss (≥2.5% to ≥5%)	4, 5 and 6 months	$0	$100–$150§§
Total incentives (maximum)		$750	$750

Figure 2. Interventions Overview.

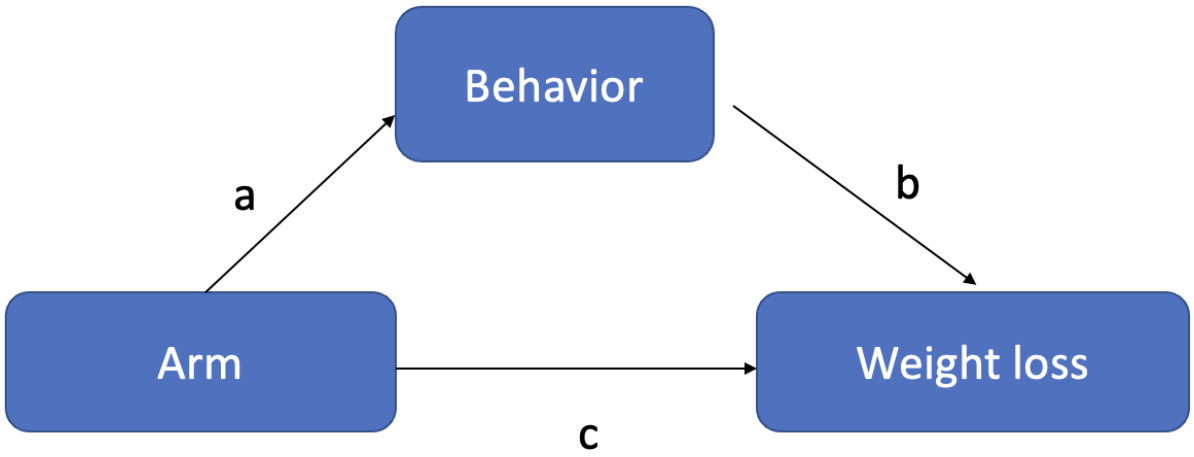

Figure 3. Intervention to Weight loss via Behavior change.

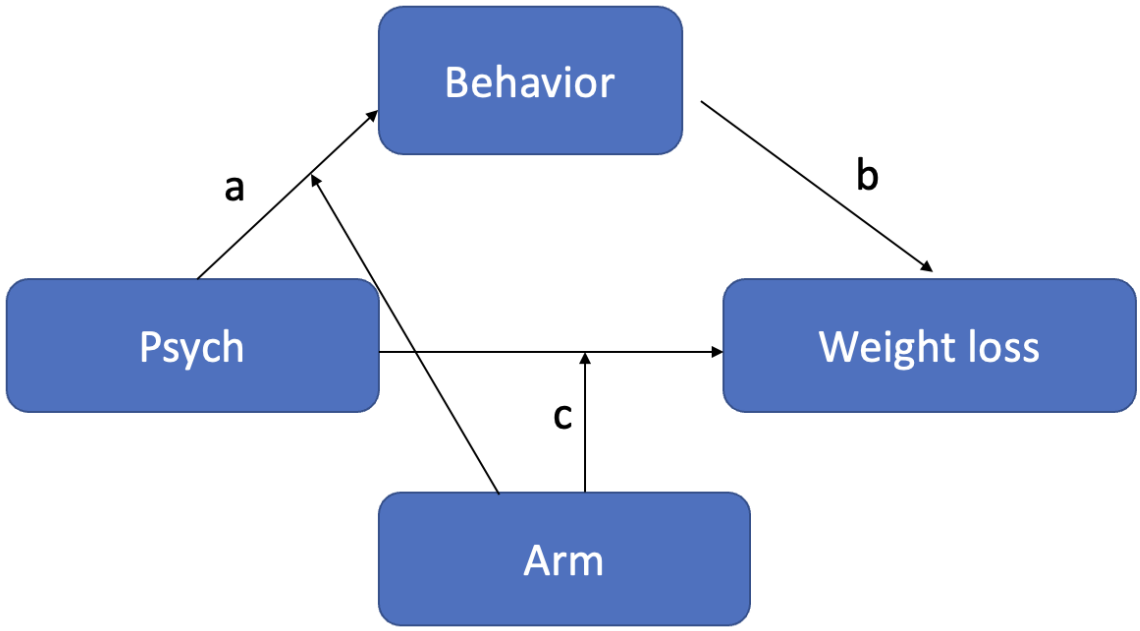

Figure 4. Psychological mechanisms to Weight loss via Behavior change.