Pilot Study of the EatFit Intervention to Determine Sample Size and Protocol for a Randomized Controlled Trial

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Background
Research suggests that goal setting can promote health behavior change [1-3]. The use of goal setting as a major component of nutrition and physical activity interventions has the potential to be an important facilitator of behavior change. Setting specific goals provides a strategy for organizing nutrition and physical activity information and skills into practical and manageable steps [2]. Using this strategy, the EatFit intervention was developed. Although goal setting has been shown to promote dietary and physical activity behavior change among adults, it has not been adequately investigated with middle school aged adolescents [1, 4, 5].

EatFit is a theory-driven education intervention designed to improve the dietary and physical activity behaviors of middle school students. The design, implementation and evaluation of the intervention are based on the Social Cognitive Theory (SCT). The SCT attempts to explain behavior and offers approaches to change behavior. The intervention consists of nine hands-on, experiential lessons: nutrition and fitness basics, self-assessment, goal setting, label reading, fast food, breakfast, exercise, energy balance and media. The intervention engages students in personal self-assessment of eating and physical activity behaviors. Based on results of the assessment, students set goals and the intervention provides skill-building activities to help reach those goals. To ensure appropriately designed goals and student autonomy, “guided goal setting” (pre-formulated goals that contain attributes such as specificity, difficulty, and proximity) was employed.

The purpose of this pilot study is to determine sample size and protocol for a randomized controlled trial for a study to answer: ”Is an intervention driven by the social cognitive theory and focused on goal setting effective at producing dietary and physical activity behavior change in middle school adolescents?” Secondly, we will 1) learn ease of implementation of the intervention and 2) examine participants’ understanding of survey items.

Methods
The evaluation instruments were designed to assess participant’s targeted physical activity and dietary self-efficacy and behaviors of self-selected goals. The instruments were cognitively tested and evaluated for content and face validity.

A convenience sample of 49 students was drawn from two periods of a 6th grade health/physical education class from a rural middle school in northern California to participate in the pilot study.

The study design was a one-group pretest-posttest design, where one week prior to the intervention, the pretest was administered to the students, followed by the five week EatFit intervention co-taught by the intervention developers. The posttest was administered one week following the completion of the intervention.

The research protocol was reviewed and approved by the Human Subjects Review Committee at the University of California, Davis (protocol #992799).

Results
Thirty-four participants completed both of the pre and posttests (69%). Fifty-three percent of the students were male. The 6th grade students were 11 years old (N=17) and 12 years old (N=14).
A research brief summarizes a report by Mical Shilts, University of California at Davis, Department of Nutrition. For more information, please contact Mical Shilts at mkshilts@ucdavis.edu. This research project was funded by the Center.

Descriptive statistics, paired T-test (SPSS V.7) and analysis of covariance (SAS V.8) controlling for pretest score and goal selection were conducted. Six variables were investigated (dietary behaviors, physical activity behaviors, dietary self-efficacy, physical activity self-efficacy, dietary goal attainment and physical activity goal attainment).

Twenty-nine to 56% of participants made positive changes depending on the variable (Figure 1). On average, participants made a .24 day (NS) improvement in their targeted dietary behavior goal or the equivalent of 1 day a month (Table 1). A targeted behavior is the specific goal set by the participant at the beginning of the intervention (i.e., choosing low-fat toppings on pizza, drinking water instead of soda, riding their bike to school...). Each participant chose 1 dietary goal and 1 physical activity goal. Students reported a decrease in dietary self-efficacy for the targeted dietary behaviors by -.12 (NS). The most significant changes were in physical activity, where on average, students improved their physical activity levels by .88 day (p<0.02) and self-efficacy by .03 (NS) [Table 1]. Seventy-four percent and 79% of the students rated themselves as making one lasting improvement in their dietary and physical activity behaviors respectively in the previous 2 months.

Sample size calculations for a randomized controlled trial were calculated using this pilot test data (39-205 per group depending on variable).

**Discussion and conclusion**

Based on participants’ self-reported data, the EatFit intervention contributed to positive improvement in dietary and physical activity behaviors, but on average the participants did not make improvements in self-efficacy. One explanation is that students employed more sophisticated thinking on the posttests; in other words, their standards by which they judged themselves changed. The process of setting goals, tracking progress and practicing skills gave students a more accurate picture of the difficulty associated with changing dietary and physical activity behaviors, thus affecting their self-efficacy.

Increasing student’s targeted physical activity levels by .88 day compared to .24 day for dietary behaviors seems to say that the EatFit intervention was more effective at increasing middle school students physical activity levels than increasing positive dietary behaviors. This is reasonable as this population of adolescents seemed more willing to increase their physical activity levels than to change a dietary behavior, such as drinking water instead of soda or eating pizza with lower fat toppings. In addition, we had no statistical method for comparing dietary and physical activity goal difficulty. Consequently, we do not know if our results are due to inherent differences in difficulty of dietary and physical activity goals or merely a matter of interest among these participants. Qualitative research methods could shed some light on this question.

Because this pilot study had a small sample size, no control group or randomization, interpretations are limited to the purpose of calculating sample size.

**References**
