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Innovative techniques to address retention in a behavioral weight-loss trial

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Abstract

Given that retention rates for weight-loss trials have not significantly improved in the past 20 years, identifying effective techniques to enhance retention is critical. This paper describes a conceptual and practical advance that may have improved retention in a behavioral weight-loss trial—the novel application of motivational interviewing techniques to diffuse ambivalence during interactive group-based orientation sessions prior to randomization. These orientation sessions addressed ambivalence about making eating and exercise behavior changes, ambivalence about joining a randomized controlled trial, and unrealistic weight-loss expectations. During these sessions, overweight and obese men and women learned about the health benefits of modest weight loss as well as trial design, the importance of a control condition, random assignment and the impact of dropouts. Participants were then divided into groups of three or four, and asked to generate two pros and two cons of being assigned to a control condition and an active condition. Participants shared their pros and cons with the larger group, while the investigator asked open-ended questions, engaged in reflective listening and avoided taking a 'pro-change' position. Retention was high, with 96% of the participants (N = 162) completing 18-month clinic visits.

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Introduction

Based on the 1999–2000 National Health and Nutrition Examination Survey, 64.5% of US adults are overweight or obese (Flegal *et al*., 2002). To validly test the efficacy of long-term obesity treatments, randomized controlled trials must have minimal participant dropout (Hansen *et al*., 1985; Ribisl *et al*., 1996; Ware, 2003). However, retention over time is challenging (Wilson and Brownell, 1980; Brownell and Wadden, 1992). Across behavioral weight-loss treatment studies, 32% of participants drop out (Davis and Addis, 1999). Given that retention rates for behavioral weight-loss trials have not significantly improved in the past 20 years (Wilson and Brownell, 1980; Brownell and Wadden, 1992), identifying novel techniques that improve participant retention is a critical priority (Jeffery *et al*., 2000).

Ambivalence, defined as '*simultaneous and contradictory attitudes or feelings* (as attraction and repulsion) toward an object, person, or action' (Mish, 1990), is thought to undermine behavior change. Motivational interviewing is 'a directive client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence' (Rollnick and Miller, 1995). One motivational interviewing technique is to build upon a decisional balance exercise (Janis and Mann, 1977; Prochaska and DiClemente, 1983; Miller and Rollnick, 1991; Prochaska *et al*., 1992, 1994; Miller and Rollnick, 2002) by making any existing ambivalence explicit, and normalizing it using open-ended questions and reflective listening to acknowledge that the pros and cons exist *simultaneously* and may be *contradictory* (Miller

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and Rollnick, 1991). This is especially effective when the counselor avoids taking or defending the 'pro-change' position (e.g. reinforcing pros and problem-solving cons with participants) and, thus, avoids provoking participants to take on the 'status quo' position [(Miller and Rollnick, 1991), p. 47]. Recently, motivational interviewing techniques have been used to diffuse ambivalence and increase motivation during the intervention phase of weight-loss, diet and physical activity trials (Smith *et al*., 1997; Resnicow *et al*., 2002).

In this paper, we speculated that these techniques could be applied to diffuse ambivalence prior to trial randomization *to improve retention*. Participants may be ambivalent about being in a randomized weight-loss trial (Burke *et al*., 2003). Participants may see the benefits of joining a trial, such as free treatment and additional support, while at the same time perceive limitations, such as being randomly assigned to a control condition. Participants may even plan to drop out of the trial if they are assigned to the control condition. In one recent behavioral weight-loss trial, a higher percentage of the control condition (41%) did not complete follow-up clinic visits compared to the two active conditions (14 and 23%) (Ciliska, 1998). In addition, participants may be ambivalent about whether they really want to change their eating and activity, resent or resist being told to make these behavioral changes, and drop out (Windhauser *et al*., 1999; Sparks *et al*., 2001; Shepherd, 2002). For example, participants in a controlled feeding study reported that 'not having to shop for and cook food' aided their compliance while at the same time the 'lack of freedom to choose what/when to eat' challenged their compliance (Windhauser *et al*., 1999). Finally, participants may experience ambivalence because of a contradiction between their initial (and unrealistic) expectations that they will lose a lot of weight and their dissatisfaction with the amount of weight they are actually losing (Bennett, 1986; Foster *et al*., 1997; Jeffrey *et al*., 1998; King *et al*., 2002; Wadden *et al*., 2003), prompting participants to drop out of active condition classes or not return for follow-up clinic visits.

This paper describes a conceptual and practical advance that we speculate may have contributed to high retention rates in a recently completed randomized behavioral weight-loss trial—the novel application of motivational interviewing techniques to diffuse ambivalence during orientation sessions prior to randomization. In interactive small group orientation sessions, we addressed ambivalence about joining a randomized controlled trial, ambivalence about making eating and activity behavior changes, and unrealistic weight-loss expectations. We explain how the orientation sessions were conducted, present a content analysis of participants' responses during the sessions and report the trial retention rates. Given the current obesity epidemic, the crucial importance of retention in weight-loss research and the lack of even descriptive research on retention techniques in the weight-loss field, we believe that this descriptive paper will be of value for guiding practice and provoking further research on effective retention strategies.

Method

Overall design of original randomized trial

The Stanford Healthy Weight Project is a randomized weight-loss efficacy trial that recruited overweight and obese adults (ages 25–80 years; BMI 27–37 kg/m^2) in a major metropolitan area who wanted to lose a modest amount of weight (10–15 pounds). Eligibility characteristics were similar to other behavioral weight-loss studies (Davis and Addis, 1999) and are summarized in Table I (Beck *et al*., 1961; Block *et al*., 1986; Pate *et al*., 1995; Stice *et al*., 2000).

Participants were randomly assigned to one of three study conditions: a control condition or one of two active behavioral weight-loss conditions. The control condition was allowed to enroll in any behavioral treatment programs (e.g. Weight Watchers) available in the community that did not include medication or very-low calorie diets. Both active conditions attended 14 weight-loss classes for the first 6 months of the trial without continued contact after classes ended. All three conditions were asked to attend four clinic visits, one every 6 months for

18 months. Participants were recruited in three cohorts via local radio stations, and articles in local community, regional and university-based newspapers (Kiernan *et al*., 2001).

Current descriptive study

The current descriptive study is based on orientation session data from Cohort 1 of the trial; however, trial protocols were similar for all three cohorts. To examine replicability, retention rates across all three cohorts are presented.

Table I. *Eligibility criteria at screening timepoints*

Telephone screening eligibility criteria
Age ⩾25
BMI 27–37
Non-diabetic
Willing to be randomly assigned to any of the three groups
Available for active condition class meetings
Planning to remain in the area for the next 2 years
Not pregnant or planning to become pregnant in the next 2 years
Not following a special diet (e.g. Pritkin)
Not participating in another research trial
Not participating in another weight-loss program
Mail screening eligibility criteria
Completed and returned questionnaire packet
Total calorie intake 500–5000 kcal (Block Food Frequency Questionnaire) (Block *et al*., 1986)
Total calories from fat ⩾30% (Block Food Frequency Questionnaire) (Block *et al*., 1986)
Physically inactive (American College of Sports Medicine) (Pate *et al*., 1995)
Able to participate in physical activity
Free of heart disease
Stable on blood pressure, cholesterol and hormone medications for ⩾3 months
Not taking weight-loss medication
Not dysphoric (Beck Depression Inventory ⩽18) (Beck *et al*., 1961)
Not binge eating or bulimic (Eating Disorder Diagnostic Scale) (Stice *et al*., 2000)
Baseline clinic visit eligibility criteria
Completed questionnaire packet
Refrained from eating, drinking besides water, exercising, and smoking for 2 hours prior to clinic visit
No uncontrolled hypertension as measured at clinic visit
Written permission to participate from a physician if two or more cardiovascular risk factors were present
Committed to attending subsequent clinic visits
Committed to attending active condition classes if applicable

Participants

Of the 72 potential participants who attended an orientation session in Cohort 1, 51 participants (71%) were randomized to the trial. Of the 21 participants not randomized, 14 did not schedule or attend a baseline clinic visit and seven attended the baseline clinic visit, but were not randomized due to schedule conflicts and/or uncontrolled high blood pressure. There were no clinically significant differences in initial characteristics between participants who were and were not randomized (Table II).

Orientation sessions

Individuals who were eligible to participate after a phone and mail screening were invited to attend an interactive group-based orientation session prior to the baseline clinic visit and randomization. Led by the trial principal investigator (M. K.), these 1-hour sessions combined motivational interviewing techniques (Miller and Rollnick, 1991, 2002) with active learning principles (Meyers and Jones, 1993) to explicitly address the demands of joining a randomized controlled trial, making eating and activity changes, and weight-loss expectations.

Table II. *Means, SDs and percentages for demographic characteristics of participants*

Characteristic	Attended orientation session			
	Not randomized		Randomized	
N	21		51	
Gender				
female	14	67%	33	65%
male	7	33%	18	35%
Ethnic group				
white	17	81%	45	88%
non-white	4	19%	6	12%
Marital status				
single	2	9%	7	14%
married/living with partner	17	81%	36	71%
separated/divorced/ widowed	2	9%	8	16%
Age (years)	49.3	10.9	53.1	10.4
Education (years)	15.6	1.8	16.5	2.3
Initial BMI (kg/m^2)	30.1	2.2	30.0	2.4

In the didactic portion of the session which included a handout of the session's key points, potential participants first heard an explanation about cardiovascular health benefits of losing a *modest* amount of weight (10–15 pounds) at a slow rate of loss (Goldstein, 1992; National Institues of Health/National Heart Lung and Blood Institute, 1998; Tate *et al*., 2001; Knowler *et al*., 2002) and were explicitly told that this trial would not be a good match for people seeking to quickly lose a lot of weight. Participants then heard about the importance of this trial and the specific commitments required (e.g. study conditions, clinic visits, classes). Participants were told that if they were assigned to the active condition classes they would be asked to complete homework, and make eating and activity changes. Participants were given a schedule with the dates for clinic visits and active condition classes, asked not to enroll if they knew in advance they would miss two or more classes, and asked to commit to attending a makeup class for any missed classes.

To promote commitment to the scientific portion of the trial, participants then learned about the importance of a control condition, random assignment and attrition bias. For instance, participants reviewed graphs illustrating how trial results would be biased toward success if unsuccessful participants did not return to subsequent clinic visits. Participants were asked to think of reasons why the next 18 months might *not* be a good time for trial participation (e.g. planning a daughter's wedding) and whether they would return to clinic visits if they '*gained* 15 pounds'.

Participants in each orientation session were then divided into small groups of three or four, and asked to generate two pros and two cons of being assigned to the control condition and to the active conditions. The principal investigator left the room during the small group discussions, and then reassembled the small groups to share their pros and cons with the whole group. In this discussion, the investigator did *not* follow a typical health education approach (i.e. emphasizing the pros and encouraging participants to problem solve the cons). Rather, consistent with motivational interviewing principles (Miller and Rollnick, 1991, 2002), the principal investigator asked open-ended questions and engaged in reflective listening. The investigator gave equal weight and consideration to *all* responses, avoided the 'pro-change' position (Miller and Rollnick, 1991, 2002), ensured that each small group shared at least one response, and wrote *all* responses in a 2 × 2 grid on a white board. The pros and cons discussion began with a focus on the cons of the control condition (i.e. the most salient reasons *not* to participate). The pros of the control condition were discussed next, followed by the pros of the active conditions. The discussion purposely ended with the cons of the active conditions. This section concluded with the statement that the investigator was attempting the 'opposite of a hard sell'. The investigator encouraged participants to consider *all* pros and cons and to recognize that they would be making two commitments—one to themselves (i.e. time, behavior change) and one to ensure the trial's scientific quality (i.e. returning to all clinic visits).

Additional retention techniques

Additional retention techniques advocated by other epidemiological research studies and clinical trials were integrated throughout the trial's recruitment and retention phases (Table III) (Bindman *et al*., 1993; Ribisl *et al*., 1996; Senturia *et al*., 1998; Kiernan *et al*., 2000; Janson *et al*., 2001; Prinz *et al*., 2001).

Results

Orientation session results

The 72 potential participants attended one of seven orientation sessions *before randomization*. Because participants generated responses in small groups and shared them with the larger group, we analyzed the 130 responses by orientation session rather than by individual. A similar number of responses (M = 18.6) was generated across all orientation sessions [χ^2 (6, N = 130) = 1.49; P = 0.96)]. The number of responses was equally distributed across the 2 × 2 grid (pros/cons and active conditions/control condition) [χ^2 (3, N = 130) = 1.26; P = 0.74)].

In a content analysis (Patton, 1980), two raters independently sorted the 130 pro/con responses

Table III. *Additional retention enhancement techniques*

Create 'project identity' that participants can recognize by using similar colors and fonts on trial materials
Track eligibility status of potential participants on a computer database
Write protocols to systematically address common participant questions
Adhere to trial protocols and procedures
Provide support to all participants
Offer flexible scheduling
Attempt to be on time for clinic appointments
Make multiple attempts to contact participants for complete data by phone and mail
Encourage participants who move from the area to continue completing questionnaires, and have clinic data (e.g. weight, blood pressure) collected and verified by another health professional
Send birthday cards to all participants
Determine two secondary contacts by asking participants to sign letters notifying contacts of trial participation and giving permission to provide forwarding information (letters also served as an *implicit* behavioral commitment to complete the trial)

into thematic categories. There was high inter-rater agreement (interclass correlation $\alpha = 0.99$). Table IV presents the number and percentage of orientation sessions in which categories were generated. The thematic categories are presented in a 2×2 grid, i.e. by pros/cons and by type of study condition (active conditions/control condition).

Many thematic categories focused on losing weight, making behavioral changes, structure/discipline, time commitment, social support and learning. Some reasons for joining a randomized controlled trial discussed in previous studies, e.g. helping the trial or science (Mattson *et al*., 1985), were mentioned infrequently. Participants' responses fell into distinct (and many) thematic categories in each of the seven orientation sessions rather than into the same (and few) thematic categories in each of the seven sessions.

To determine whether participants expressed ambivalence about joining a randomized trial, ambivalence about making behavior changes and unrealistic weight-loss expectations, we examined three sets of comparisons. First, in perhaps the most interesting demonstration of ambivalence, participants generated the *same* response both as a pro and a con for the *same* type of study condition. For instance, illustrating participants' ambivalence about joining a randomized trial, the *same* response was generated both as a con ('structured/inflexible') and a pro ('structure/discipline') of being assigned to the active conditions. Second, as would be expected in a pro/con activity, participants also generated *opposite* responses for *different* types of study conditions. For instance, regarding their ambivalence about making behavior changes, the response ('have to make behavioral changes/do uncomfortable things/hard to change') was generated as a con of being assigned to the active condition, whereas the *opposite* response ('eat or do what you want') was generated as a pro of being assigned to the control condition. Thus, participants may have a preference for one condition even though they would have to agree to random assignment and the possibility of being assigned to their non-preferred condition. Third, participants also generated the *same* response for *different* types of study conditions. Illustrating participants' realization that weight-loss expectations may not be fulfilled (and in fact may not lose any weight in this trial), the response ('may not lose weight/may not be successful') was a frequently mentioned con not only of being assigned to the control condition, but also of being assigned to the active conditions.

Retention results

Of the 51 participants randomized to the trial in Cohort 1, 50 (98%) completed the 6-month clinic visit, 48 (94%) completed the 12-month clinic visit and 48 (94%) completed the 18-month clinic visit. Overall, of the 162 participants randomized across all three cohorts, 159 (98%) completed the 6-month clinic visit, 157 (97%) completed the 12-month clinic visit and 156 (96%) completed the 18-month clinic visit, with no differential dropout by study condition.

Discussion

Although orientation sessions are often used to recruit participants into randomized trials, this

Table IV. *Number and percent of orientation sessions in which responses were generated by pros/cons and type of study condition (active condition/control condition)*[a]

	No. and percent of orientation sessions			No. and percent of orientation sessions	
	N	%		*N*	%
PROS of being assigned to an active condition			*PROS of being assigned to the control condition*		
Support/encouragement	6	86	Less time commitment/no class time	7	100
Learning/education	5	71	Eat or do what you want/can continue what already doing/status quo	4	57
Structure/discipline	4	57	Fewer demands/less work/less effort	3	43
Motivation/incentive	4	57	Self-structured/flexible	2	29
May lose weight/may be successful may lose and maintain	4	57	Eventually get class information	2	29
Change exercise/eating habits/behavior	3	43	Get feedback reports	2	29
Health improvement/benefits (*not* explicitly eating or exercise)	3	43	Help the study/help science	2	29
Structured monitoring	1	14	Can still do other programs	1	14
May feel better	1	14	Have clinic visits	1	14
Sense of purpose	1	14	Self-accomplishment	1	14
Involvement	1	14	May lose weight/may be successful	1	14
CONS of being assigned to an active condition			*CONS of being assigned to the control condition*		
Time commitment/class time	6	86	Unstructured/no direction/no control	6	86
May not lose weight/may gain/may not be successful (may not work)	4	57	May not lose weight/may not be successful/no benefits	6	86
Have to make behavioral changes/do uncomfortable things/hard to change	3	43	No support system/alone	4	57
Structured/inflexible	2	29	No commitment/uninvolved	3	43
May not like it/may not be appropriate	2	29	Less information/less learning	3	43
Demands/work/homework	2	29	Less motivating	2	29
May not like groups	2	29	Eighteen-month delay	2	29
Peer pressure	1	14	May get worse	1	14
Feel dependent on classes	1	14	May lose interest	1	14
May already know information	1	14			
Family may not like it	1	14			
Things happen that make class difficult	1	14			
Instructor characteristics	1	14			

[a]There were seven orientation sessions.

study describes a conceptual and practical advance that we speculate *may enhance retention* in a behavioral weight-loss trial—the novel application of motivational interviewing techniques to diffuse ambivalence during interactive group-based orientation sessions prior to randomization.

Retention in this trial was very high—96% at 18 months. In recent similar behavioral weight-loss trials, between 13 and 41% of participants dropped out by post-treatment follow-up (Perri *et al*., 1997; Jeffery and French, 1999; Sbrocco *et al*., 1999; Tate *et al*., 2001, 2003; Foster *et al*., 2003; Heshka *et al*., 2003). However, direct comparisons are difficult given that eligibility criteria, number of classes, follow-up length and other requirements vary widely across trials. For instance, although a few recent trials have also had little dropout (3–9%), the trials had weekly contact with participants *throughout* the trial and/or the trials were shorter in total duration (6–12 months total) (Blumenthal *et al*., 2000; Stevens *et al*., 2001; Irwin *et al*., 2003; Jakicic *et al*., 2003). In contrast, our 1-year follow-up after the 6-month classes ended did not include continued contact and the trial was longer in total duration.

Using motivational interviewing techniques in an open-ended and reflective manner to involve participants in a discussion of the study design, scientific rationale and trial's pros/cons may have potentially increased motivation, decreased potential for disappointment, empowered participants to make changes, fostered participant 'buy-in' and, thus, encouraged high retention at follow-up (Miller and Rollnick, 1991, 2002). Consistent with active learning principles, participants heard a variety of pros and cons, which may have carried more weight because responses were generated by fellow participants rather than by the investigator (Meyers and Jones, 1993).

These descriptive results are only suggestive, in part because the application of motivational interviewing principles in interactive group-based orientation sessions was supplemented with other recommended retention techniques (King *et al*., 1991; Bindman *et al*., 1993; Ribisl *et al*., 1996; Senturia *et al*., 1998; Kiernan *et al*., 2000; Janson *et al*., 2001; Prinz *et al*., 2001). Most critically, to definitively assess the impact of these orientation sessions, this retention technique itself would need to be tested using a randomized design. Future research is also needed to systematically determine the impact of these sessions on participant trust and satisfaction as well as the replicability across participant subgroups (i.e. by education, gender, age or ethnicity), session facilitators and types of behavioral interventions.

Whereas low retention rates can undermine the findings of randomized trials by threatening internal validity, there are limitations to using motivational interviewing techniques to improve retention. Like multiple eligibility criteria, rigorous screening procedures and burdensome trial requirements, these techniques may discourage unmotivated participants from entering a trial and compromise generalizability (Wilson and Brownell, 1980). However, bias in participant selection may be an acceptable cost for efficacy trials seeking to maximize retention.

Past research on retention in behavioral weight-loss studies has primarily focused on participant characteristics between dropouts and completers (Hjoerdis and Gunnar, 1989; Clark *et al*., 1996; Davis and Addis, 1999). Research on techniques to actually improve retention is rare. We hope this descriptive paper will provoke further experimental research about optimal retention strategies.

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