

PHASE 1 FINAL REPORT:
HEALTHY LIFESTYLE: A FAMILY BASED INTERVENTION FOR OVERWEIGHT CHILDREN
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Phase 1 Project Period: 08/15/2006 - 01/31/2008

<i>Key Personnel</i>	<i>Project Role</i>	<i>Hours on Project</i>
Martin Sheehan, Ph.D.	Principal Investigator	326
Laura Backen Jones	Co-Investigator	13
Pam Yeaton	Research Director	285
Adam Wendt	Media Producer/Director	275
John Light	Research Methodologist	40

The aim of this project was to promote weight loss in children who are overweight or at risk of becoming overweight. We proposed adapting an evidence-based intervention (Golan & Weizman, 2001; Golan, 2005) as a self-administered program that focuses on parents as the key agents of change in the treatment of overweight children. The program, *Healthy Lifestyle: A Family-Based Intervention for Overweight Children (HL)*, used an interactive multimedia approach that integrated media, web and print. The intervention targeted parents of children with a body mass index (BMI) above the 85th percentile (i.e., overweight or at risk for becoming overweight). A Social Cognitive Theory-driven approach was used to increase parents' motivation to change, improve overall family nutrition habits, and encourage a more active family lifestyle.

The Healthy Lifestyle Program provided a mechanism to systematically motivate parents, help them acquire skills, and encourage them to set goals for environmental change. The program relied on skill-building materials and observational learning models delivered via the Internet. Users were able to practice and develop fluency in skills through interactive exercises.

Our Phase I aim was to determine program feasibility by testing Module 1 by seeing whether parents: a) engaged with, used and liked the materials, b) improved their feelings of self-efficacy related to establishing a healthier family lifestyle and helping their child to lose weight, c) increased their knowledge of nutrition, and d) made at least one change in family lifestyle practices recommended in the materials. We expected positive outcomes on these factors, which would establish that the proposed product is effective, practical and viable. Positive outcomes on these five questions were in fact adequate to demonstrate sufficient product feasibility in support of a Phase II application. Additionally, the feasibility trial allowed us to gather important user reactions to guide further development of the materials in Phase II.

Phase I Tasks

- Develop Module 1 prototypes.
 - Develop initial content in conjunction with expert consultants.
 - Conduct a focus group with parents in the target group after developing an initial draft of the instructional materials.
 - Have expert consultants provide input and review final drafts.
- Produce Module 1 materials.
 - Have expert consultants review visual media, interactive exercises and print content.
 - Conduct usability tests on the program's technological features.
- Conduct a small feasibility study with parents of children who are overweight or at risk of becoming overweight in order to determine the utility, efficacy, and viability of Module 1.

Task 1: Develop Module 1 Prototypes

Content for Module 1 was developed in conjunction with the expert consultants and focus group input. The Principal Investigator and project team began by developing specific learning objectives, a detailed

curriculum outline and program flow chart that described the interactive multimedia presentation. This effort was assisted by Dr. Golan, Dr. Karen Cullen, and Mindy Force, a registered dietician. Dr. Golan's experience developing the empirically-validated family focused intervention was a valuable asset in the initial stages of content development. Dr. Cullen, an experienced researcher, licensed dietician and a member of the American Dietetic Association, and Ms. Force helped us in the initial and subsequent stages of the content development.

First, preliminary drafts of the interactive multimedia scripts for Module 1 subject areas were developed: the parent motivational component, the parent knowledge component, and the environmental change component. Once preliminary versions of the materials were drafted, we met for two hours with a focus group of seven parents who had children who were overweight or at risk of becoming overweight. All participants were female; one was Hispanic, one was African-American, and the remaining were Caucasian.

Focus group participants were recruited through local pediatricians, local minority organizations, and public health clinic referrals. The focus group methods followed guidelines developed by Krueger (1994): (a) determine the questioning route, (b) carefully recruit participants, (c) use a skillful moderator, (d) analyze the focus group sessions, and (e) report the results. We developed a set of pre-determined questions that were used to elicit open-ended feedback. Questions were asked about past efforts to help their child lose weight, in what areas the parents served as a role model for their child in terms of healthy eating and physical activity, how willing they were to change their lifestyle in order to help their child lose weight, and any other concerns. All parents reported previous attempts to help their child lose weight ranging from serving nutritional foods, limiting fast foods, and encouraging them to be more active. The main barriers reported were eating too much fast food, watching too much TV, and eating too many unhealthy foods at home. Five parents thought that they were good role models. Six reported never or rarely eating together as a family. Five reported that they did not limit time spent watching TV. All participants said they were very willing to change their lifestyle in order to have a positive impact on their child. Most of the parents did not know what information they might need in order to make a change. Concerns that emerged included lack of control over what their children eat at school, their children's refusal to exercise, and lack of time to prepare healthier meals.

Focus group participants were paid \$35. Information from the focus group was used in script revisions and helped in the decision to focus on simple concrete things parents could do around eating habits; i.e. the *Five Onlys* (only eat at a table, only eat while seated, only eat from a proper plate, only eat while doing nothing else, and only eat when hungry or at meal times).

Task 2: Produce Module 1 Materials

Production of program materials took place over the course of three months. Assets included multimedia (text, video, graphics and animations), interactive activities using Adobe Flash and ActionScript programming language, and print materials (downloadable Adobe PDF documents). IRIS Media's creative and technical staff was led by the Media Producer, Adam Wendt. The team made every effort to ensure that viewers were engaged with the materials by showing rather than telling, by demonstrating rather than lecturing.

Specialized development tools were required that integrated the "high-bandwidth" delivery capability of Flash Video with the interactive capabilities of the Internet. ColdFusion application servers allowed for a custom content management system to be used in conjunction with SQL databases to load, manage and deliver program assets to study participants using Flash Media Server 2.

Multimedia elements (real-time video, graphics, captions, audio and animation) were produced using professional production standards. IRIS Media specializes in skill-based, modeled instruction; using realism and natural settings rather than exposition and "talking heads." Video footage was filmed on location in real homes. To shoot video footage, we used the SONY professional digital video format, DVCAM, and professional lighting and grip equipment. Video post-production took place at IRIS Media's studio using professional video and audio equipment. The Principal Investigator and development team staff viewed digital offline versions of video sequences and provided feedback during post-production.

After final review by project staff and consultants, web-delivered assets were thoroughly tested prior to launch, first by project staff, then by IRIS Media technical and professional staff not specifically involved in

production of the product. Additionally, the expert consultants reviewed the media content, and their suggestions were incorporated into the program.

Task 3: Assess Module 1 Feasibility with Parents of Overweight Children or Those at Risk of Becoming Overweight.

Overview of research design. This product was designed to maximize access to a parent education program by giving parents a wide choice of technologies to use. We believe that the effectiveness of these materials comes primarily through instructional design, content and interactivity, rather than the specific technologies used. Our feasibility study was conducted using online methods. Parents were required to have access to at least a dial-up Internet connection to complete the study module and the assessments.

To establish the program feasibility, we focused on answering five questions critical to program utility, efficacy, and viability: 1) Did parents engage with, use, and like the materials?; 2) Did the program increase parents' sense of self-efficacy and their motivation to make changes in family eating and activity habits?; 3) Did the program improve parents' knowledge about nutrition?; and 4) Did the program motivate parents to make at least one change in family behavior related to weight control?. Positive outcomes on these five questions were adequate to demonstrate sufficient product feasibility in support of a Phase II application. The feasibility trial also allowed us to gather important user reactions to guide further development of the materials.

Participants. The sample consisted of 19 parents with Internet access who had at least one child who was at or above the 85th percentile of BMI for age and gender (i.e., overweight or at risk for becoming overweight), and between the ages of 7 and 11. Participation was open to parents in both two-parent and single-parent families. The attrition rate was approximately 24%: 25 parents were recruited, with 19 completing the study.

Participating parents completed Module 1 of *Healthy Lifestyle* on Iris Ed Online (IEO). Those who completed the program and assessments were paid \$100: \$50 for each of two assessments (baseline and exit).

Procedures. Parents were recruited via flyers and posters sent to medical clinics, hospitals, libraries, bookstores, school health clinics, community programs for ethnic minorities, and pediatricians' offices throughout the states of Oregon and Washington. These flyers and posters briefly explained the study and provided an Internet address for the online assessments and an email address for contacting project staff with questions or concerns. When interested participants arrived at the baseline assessment website, they were screened for eligibility (e.g., age, height, and weight of their child). If eligible, they then completed an online informed consent and the baseline assessment. Upon completion of the assessment, participants were given immediate access to program materials at the web delivery interface, IRIS Ed Online (IEO), a training delivery platform that has been developed to enhance the reach of public health interventions and expand the dissemination of skill-based training. Motivational emails, serving as a source of encouragement to continue practicing what was learned in the first module, were sent four days after program completion, and again four days later. Participants were encouraged to complete the module in two sessions. Four days after the last email was sent, participants were asked to complete the online exit assessment.

Instruments. The baseline assessment consisted of a demographics questionnaire, the Family Eating and Activity Habits Questionnaire, the Parent Motivation and Confidence Scale, and the Parent Self-Efficacy Scale. The exit assessment consisted of repeated administration of the baseline instruments, the Behavioral Intention Checklist (retrospective pre- and post-test), and the User Acceptance and Satisfaction Questionnaire.

Demographics. Project staff developed this brief questionnaire of items covering relevant demographic variables such as gender, age, ethnic background, income, and education for parents and children.

Family Eating and Activity Habits Questionnaire (FEAH; Golan & Weizman, 1998). This 29-item questionnaire targets factors that facilitate childhood obesity and monitors environmental changes and family behavior modifications associated with weight loss. Items refer to the responding parent, his/her spouse, and the child. The questionnaire contains four scales: 1) Activity Level (AL): four items measuring frequency of physical and sedentary activity by parent, spouse, and target child; 2) Stimulus Exposure (SE): eight items addressing presence and availability of snacks and sweets in the home, and amount of child autonomy in buying or eating these foods; 3) Eating Related to Hunger (ERH): four items relating to initiating eating, eating and hunger; dealing with lack of appetite at mealtime; and eating during mealtime when not hungry; and 4)

Eating Style (ES): thirteen items address eating while standing, watching TV, doing homework or reading; eating as a result of stress (anger, frustration, boredom); eating between meals; second helpings; and parental presence when child is eating.

Chronbach's alpha for the four scales is reported as .82 (AL), .78 (SE), .86 (ERH) and .88 (ES). Test-retest reliability for individual items and the total score ranges from .78 to .90 (median .84); total score test-retest reliability is .85. Scores on the four scales have been shown to have adequate concurrent validity by discriminating between normal-weight and overweight children. Pearson correlations between self and spouse report range from .81 to .94. Predictive validity has been established through use of the questionnaire in a clinical intervention with families with overweight children (Golan & Weizman, 1998).

Parent Self-Efficacy Scale (PSES): Project staff developed this 15-item questionnaire, which included items adapted from Brownell's (1990) Dieting Readiness Test, to measure parents' feelings of self-efficacy related to creating a healthier family lifestyle and their motivation to change eating patterns in the home,

Parent Motivation and Confidence Scale. This 8-item questionnaire was administered pre- and post- to measure parents' motivation to change and confidence about weight management for their child. Some items were adapted from Dieting Readiness Test (Brownell, 1990); others were created by project staff.

Program Usage: IEO web logs provided data on users' program completion, time spent interacting with program materials, and number of visits to program components.

Behavioral Intention Checklist: This was a retrospective pre- and post-test administered after the study was completed, and consisted of five questions based on the *Five Onlys* from the instructional module.

User Acceptance and Satisfaction Questionnaire: This questionnaire consisted of 20 multiple-format items (Likert scales, binary, and open-ended) to obtain quantitative and qualitative evaluations.

Feasibility Benchmarks

The Phase I proposal set forth the following benchmarks as a measure of feasibility.

1. Program Usage: At least 75% of the parents complete the online program as determined by program web logs.
2. Change in Behavior/*Five Onlys*: At least 75% of the parents make changes in their family eating and activity habits as measured by the *Five Onlys*.
3. Self Efficacy: At least 75% of the parents report an increased sense of self-efficacy and motivation in managing their child's weight as measured by Parent Self-Efficacy Scale (PSES).
4. Parent Motivation and Confidence: At least 75% of the parents report an increased sense of motivation in managing their child's weight as measured by Parent Motivation and Confidence Scale (PMCS).
5. At least 75% of the parents report making at least one change in family home food environment.
6. At least 75% of the parents rate the program as very good to excellent (four or five on five-point Likert-type scales) on usage, interest, comprehensibility, acceptability, and persuasiveness.

Summary scores on the FEAH were computed using methods described by Golan and Weizman (1998).

The PSES was scored as means of Likert scales or sums of binary items, as appropriate. FEAH results were scored as the sum of correct answers. Scores on the sub-scales of the User Acceptance Questionnaire were scored as either the mean of Likert scales or the sum of binary items, as appropriate. A thematic analysis was conducted on qualitative items from the FEAH, PSES and User Acceptance Questionnaire.

Sample Characteristics

The sample of parents was entirely female, 74% white, 37% college graduates, with an average age of about 42. These women were significantly overweight, with an average BMI of 32.8. Participating children were more evenly divided on gender (58% female), were 74% white, with an average age of 9.1 years, and average BMI of 26.0.

Table 1 – Feasibility Study Results

	Construct	Feasibility Benchmarks	Data Source	Results
1	Program	At least 75% of parents complete the online program.	Web logs	76% of recruited

	Usage			parents completed the program
2	Behavioral Intention	At least 75% of parents report at least one change in their eating behavior based on the <i>Five Onlys</i> .	Behavioral Intention Checklist	89% of parents reported change in at least one of these behaviors
3	Self Efficacy	At least 75% of parents report increased self-efficacy in managing their child's weight.	Parent Self-Efficacy Scale (PSES)	Statistically significant improvement in self efficacy
4	Parent Motivation & Confidence	At least 75% of parents report increased motivation in managing their child's weight.	Parent Motivation & Confidence Scale	Trend toward significant improvement in motivation and confidence
5	Change in Behavior/ Environment	At least 75% of parents report making at least one improvement in the family home food environment and/or eating behavior	Family Eating & Activity Habits Questionnaire	100% of parents made at least one change
6	User Satisfaction & Acceptance	At least 75% of parents rate the program as very good to excellent (four or five on five-point Likert scales) on usage, interest, comprehensibility, acceptability, and persuasiveness.	User Acceptance & Satisfaction Questionnaire	All items but one exceeded 75% in "mostly agree" or "strongly agree" ratings.

Results

Program Usage. 76% of the originally-recruited participants completed the study (19/25). Descriptive statistics of frequency distributions were used to report the percentages of parents who used the program materials, as shown below. Result showed that: 1) 100% of parents watched and interacted with the program, fulfilling their requirement for study completion; 2) Patterns of website usage reflected varied learning styles. (e.g., The Tip Sheet was the most popular for repeat access); 3) The average session length was almost 24 minutes; and 4) Several parents accessed the site on three or more separate occasions.

Behavioral Intention. A single sample 2-tailed t test compared average retrospective change per item to zero. The resulting t value was 6.74 with 18 d.f., a 2-tailed p-value of less than .001. Parents retrospectively rated their frequency of proper eating habits (as reflected in the *Five Onlys*) as highly improved after program exposure, compared to baseline.

Parent Self-Efficacy and Motivation. Two-tailed_paired samples t-tests on the wave 2 – wave 1 scores were used to test for significant improvement in self-efficacy and motivation to change scores from the PSES and PMCS. There was a non-significant trend towards improvement in motivation and confidence ($p>0.20$), however, self-efficacy scores showed significant improvement ($p<.018$).

Change in Family Behavior and Environment. Two-tailed paired samples t-tests were again used to examine pre-to-post changes. Results are shown in Table 2 below. Activity changes were broken down into healthy and sedentary in order to determine which were affected by program participation. It is evident that both parent and child successfully managed to reduce time spent on sedentary activities (2 tailed $p<.01$, approximately, for each). A trend to increase in healthy activities approached significance for parents ($p<.15$) but not for children ($p>.55$).

Stimulus exposure was also found to improve significantly ($p<.022$), as did eating when hungry ($p<.002$). Similarly, parent eating style and parent eating place improved ($p<.002$ and $p<.06$, respectively), while for the child, a trend was observed towards improved eating style ($p<.22$), and there was a significant improvement in proper eating place ($p<.004$). Finally, a non-significant trend improvement was found for extent to which the parent eats with the child ($p>.54$).

Table 2 – Outcome Differences: Changes in Family Behavior

Scale	Paired Differences Wave 2 - Wave 1	t	df	Significance (2-tailed)
Parent Motivation and Confidence Scale	0.14286	1.321	18	0.203
Self-Efficacy to Regulate Eating Habits	8.5118	2.596	18	0.018
Parent: Hours/Week watching TV, video games	-7.57895	-2.871	18	0.01
Child: Hours/Week watching TV, video games	-7.89474	-2.83	18	0.011
Parent: Hours/Week healthy activities	1.68421	1.512	18	0.148
Child: Hours/Week healthy activities	1	0.608	18	0.551
Stimulus Exposure	-1.21063	-2.485	18	0.023
Eating When Hungry	-3.57895	-9.692	18	0
Parent: Healthy Eating Style	0.53383	4.288	18	0
Child: Healthy Eating Style	0.26316	1.287	18	0.214
Parent: Healthy Eating Place	0.44737	2.016	18	0.059
Child: Healthy Eating Place	0.81579	3.452	18	0.003
Amount Parent Eats with Child	0.09211	0.626	18	0.539

1-tailed p-values are 0.5 x the 2-tailed values shown in the table

Consumer Satisfaction. Table 3 below shows the percentage of respondents who were at least “somewhat satisfied” when reporting on consumer satisfaction criteria. All but three items had satisfaction ratings of at least 84% (16 out of 19 respondents): the lowest rating (63%) was for “This information was new to me,” followed by “This program was designed for parents like me” (74%), and “I was satisfied with quality of training” (79%).

Table 3 – Consumer Satisfaction: Percentage Somewhat or Completely Satisfied

Item	% Satisfied
Satisfied with quality of training	79
Satisfied with quality of information	89
Training met my expectations	84
Would recommend this training to other parents	95
Training was well organized	84
Easy to understand the ideas that were presented	100
The information was new to me	63
Agree with the ideas that were presented.	100
Likely to use many of the strategies presented.	89
Materials gave me new ideas for weight management	84
Training was engaging, held my interest	89
Easy for me to implement	79
Will help us develop a healthy family lifestyle	89
Training was comprehensive	89
Training was designed for parents like me	74
Training reflected situations that seemed real	84

Usability. Program usability was rated very high for nearly all items. Aside from one item relating to expectations about the content of online training (53%), ratings of “mostly” or “strongly” agree with usability criteria varied from a low of 79% up to 100%.

Strengths and Limitations

This project has the potential to provide much-needed material to help a high risk group (overweight and obese children) achieve and maintain weight loss by increasing physical activity, improving nutritional habits, and building a healthy lifestyle. At its foundation is a blend of well-established methods for weight loss for the general population, family-based interventions, and instructional methods and technology to make previously unavailable material accessible to families with overweight children. Overall results present strong support for the program’s effectiveness.

In Phase I, we developed Module 1 of the complete program and conducted a pilot test of those materials. While this pilot test established the efficacy of the materials and yielded valuable information for informing content of the Phase II product and the design of the Phase II study, results from this limited sample may not be generalized to the population of overweight individuals with ID. In Phase II, we will conduct a randomized field test of the complete product, using a wait-list control design, to establish the efficacy of the complete curriculum in achieving weight loss and improving physical activity and nutritional habits.