

## ORIGINAL ARTICLE

# Rationale, design and methods of the HEALTHY study behavior intervention component

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HEALTHY was a multi-center primary prevention trial designed to reduce risk factors for type 2 diabetes in adolescents. Seven centers each recruited six middle schools that were randomized to either intervention or control. The HEALTHY intervention integrated multiple components in nutrition, physical education, behavior change and communications and promotion. The conceptual rationale as well as the design and development of the behavior intervention component are described. Pilot study data informed the development of the behavior intervention component. Principles of social learning and health-related behavior change were incorporated. One element of the behavior intervention component was a sequence of peer-led, teacher-facilitated learning activities known as FLASH (Fun Learning Activities for Student Health). Five FLASH modules were implemented over five semesters of the HEALTHY study, with the first module delivered in the second semester of the sixth grade and the last module in the second semester of the eighth grade. Each module contained sessions that were designed to be delivered on a weekly basis to foster self-awareness, knowledge, decision-making skills and peer involvement for health behavior change. FLASH behavioral practice incorporated individual and group self-monitoring challenges for eating and activity. Another element of the behavior intervention component was the family outreach strategy for extending changes in physical activity and healthy eating beyond the school day and for supporting the student's lifestyle change choices. Family outreach strategies included the delivery of newsletters and supplemental packages with materials to promote healthy behavior in the home environment during school summer and winter holiday breaks. In conclusion, the HEALTHY behavior intervention component, when integrated with total school food and physical education environmental changes enhanced by communications and promotional campaigns, is a feasible and acceptable mechanism for delivering age-appropriate social learning for healthy eating and physical activity among an ethnically diverse group of middle school students across the United States.

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### Introduction

Rates of overweight and obesity in youth have increased dramatically in the last few decades,<sup>1</sup> and have placed increasing numbers of children and adolescents at risk for type 2 diabetes.<sup>2</sup> The HEALTHY study was designed to reduce

risk factors for type 2 diabetes in a large, ethnically diverse cohort of middle school students followed from the sixth through eighth grades at seven US centers. At each center, six schools were randomized to either intervention or control. Intervention schools received an integrated program of four components targeting nutrition, physical education, health-related behavior and communications to modify environmental, social and individual factors associated with health risk. The behavior intervention component focused on the acquisition of knowledge and skills needed to promote healthy lifestyle choices in and out of school. In this paper,

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we present the conceptual basis for health-related behavior change that was incorporated in the HEALTHY behavior intervention component. We also describe the design process and practical considerations bearing on intervention delivery in multiple school and classroom settings.

## Background and rationale

The HEALTHY behavior change intervention component was informed by research on school-based health promotion grounded in developmental learning frameworks among adolescents and in clinical studies of pediatric health-related behavior modification, particularly those related to the prevention and treatment of obesity. Strategies for promoting behavior change were selected to complement environmental change strategies implemented in the nutrition,<sup>3</sup> physical education<sup>4</sup> and communications<sup>5</sup> components of the HEALTHY intervention. Practical considerations included the selection of a delivery format and structure that maximized reach to all students and that could be administered with fidelity in varied classroom settings and within the existing time constraints.

Research with origins in drug abuse prevention has shown that peer-led interactions are critical components of social influence and behavior change among young adolescents. With conceptual underpinnings in theories of reasoned action<sup>6,7</sup> and cognition,<sup>8</sup> numerous health behavior interventions using a peer influence model in schools have shown a positive effect on health-related beliefs and behaviors in targeted groups of students.<sup>9–15</sup> Additional peer influence studies have shown a significant effect for nutrition practices<sup>16</sup> and exercise self-efficacy sustained beyond the intervention time period.<sup>17</sup> The available evidence also suggests that small group learning interactions that involve goal setting and feedback may create the optimal learning climate for promoting healthy norms and behaviors, because there are strong associations between adolescents' actions and their perceptions of normative behavior among peers.<sup>18,19</sup>

Successful alcohol, tobacco and drug prevention programs for youth incorporate elements to address the cognitive, social and behavioral developments that characterize the middle school years, such as increasing ability for complex thought and awareness of the world, greater reliance on peer acceptance, as well as experimentation with behaviors and roles to establish identity. The most effective school-based prevention programs for health behavior change have been those providing multi-year intervention because the benefits of short-term middle school programs (that is, a single semester or year) fade as the adolescent matures.<sup>20</sup> In addition, the most robust findings have been associated with programs that present an array of behavioral choices and alternatives, and that assist the adolescent in learning how to substitute a healthier action for a less healthy

behavior.<sup>21,22</sup> Finally, fidelity to a behavior intervention is critical,<sup>23</sup> and its success is enhanced by providing teachers with a standardized delivery format accompanied by clear and simple instructions.

Obesity prevention and intervention research documents that direct skills training and practice, including self-monitoring, are key for attaining a healthy energy balance and a healthy body weight.<sup>24–26</sup> With the focus of the HEALTHY study on reducing risk factors for the development of type 2 diabetes, it was essential for the behavioral portion of the intervention to teach skills to self-manage energy balance and reduce risk for obesity.<sup>24</sup> In non-school settings, pediatric family-based interventions that focus on goal setting and self-monitoring for small, incremental lifestyle changes to increase energy expenditure (for example, taking more pedometer-measured steps in a day) and decrease energy intake (for example, reducing sugar-added beverages) have been shown to influence healthy weight outcomes.<sup>27,28</sup> Other research studies have documented an association between specific behaviors and negative health outcomes in youth, particularly the intake of beverages with added sugar and high levels of sedentary behavior.<sup>29–36</sup> Epstein *et al.*<sup>37</sup> have suggested that a tandem, complementary approach to energy balance behavior change, which provides comprehensive skills training on how to increase consumption of healthy foods and at the same time reduce intake of unhealthy foods, was associated with the most robust weight outcomes in youth. Thus, behavioral skills training elements were included systematically throughout the HEALTHY behavior intervention component.

School-based health promotion programs (for example, those targeting youth violence) also engage parents through direct communication, such as newsletters or parent workshops.<sup>38,39</sup> Therefore, the HEALTHY study incorporated efforts to inform the family about the changes happening at school, and specified how families could facilitate the behavior changes necessary for diabetes prevention. One approach that has shown promise in reaching and motivating the families of middle school students has been the use of 'role model' stories about individuals, representative of the target population, who explained how they have influenced their families to change behaviors.<sup>39</sup> The HEALTHY behavior intervention component incorporated newsletters, some featuring role model stories, and other family-directed communication to support the intervention activities occurring in the school environment.

In summary, the HEALTHY study used a peer-learning approach, combined with behavioral skills development and enhanced by family outreach, to generate healthy behavior change in young adolescents. The combination of the behavior intervention with the nutrition, physical education and communication modifications in the school environment comprised a robust intervention to reduce risk factors for type 2 diabetes, which was tested in the HEALTHY study.

## Behavior intervention pilot study

A half-year pilot study with sixth grade students was conducted in the fall of 2005 at one school per study center to test elements of the behavior intervention component. Overall, the pilot was conducted in 63 classrooms with 1632 sixth graders applying demographic recruitment criteria similar to those in the main trial.<sup>40</sup> The objective of the pilot study was to gain experience focusing on specific behavior change targets, to evaluate feasibility of implementation, to measure self-reported behavior change using a brief pre- and post-intervention survey and to gather other formative information.<sup>41</sup> Four schools implemented a module designed to increase the intake of water and decrease the intake of sugar-added beverages, and three schools tested a module to increase physical activity and reduce sedentary behavior.

The pilot study examined three specific behavior intervention elements. First, FLASH (Fun Learning Activities for Student Health) was designed as a module consisting of eight brief classroom-based, teacher-facilitated learning sessions using a student workbook and delivered according to standard instructions provided in a companion teacher manual. Students completed a self-assessment in the first and last sessions. Second, the 'more-less campaign' was a separate self-monitoring initiative in which students were instructed to use a tracking booklet worn on a neck lanyard. The booklet prompted students to track 2 days of target behaviors per week over a 3-week campaign period. Each weekly record was to be returned to the student's designated classroom for a small tangible reward (for example, pencils, wristbands). The third element was a family outreach newsletter, produced in both English and Spanish, that contained a variety of personal testimonials for healthy behavior change, recipes, graphics and health-related information. Along with the newsletter, a response postcard was included with directions for the family members to complete and return it. These postcards were used to determine approximately the number of households that received and opened the newsletter package. A small incentive was distributed to the child at the school for each family who returned the postcard.

### *FLASH results*

All classroom teachers received ~4 h of training conducted according to a standardized training protocol before the start of intervention. Teachers were trained by study staff known as health promotion coordinators who also provided assistance during classroom FLASH sessions. All teachers were able to administer all eight FLASH sessions. The average session length was 23 min (range: 11–60 min). Completion times were somewhat longer than anticipated, and reflected that some teachers were using the session to fill a whole class period. Between 93 and 100% of the FLASH workbook activities were actually completed by the students. Student

self-assessments were completed during the first and last FLASH class sessions. Results indicated that students endorsed drinking more water and fewer sugar-added beverages, as well as performing more physical activity and fewer sedentary behaviors over the pilot study period. Process evaluation interviews with teachers and study staff showed that teachers found FLASH highly acceptable, although some instructions in the teacher manual needed clarification. Some teachers reported that more than 20 min of classroom time was needed to deliver FLASH to maximize student participation, particularly during the 'hands-on' interactive games and creative projects. Student interviews and focus groups showed that the highly interactive FLASH sessions were most appealing. On the basis of these pilot study findings, FLASH teacher manual instructions were revised, FLASH session activities were designed to include more interactive and creative elements, and teachers were prepared during training to anticipate using up to 30 min for each FLASH session.

### *More-less campaign results*

Return rates for the three self-monitoring records were 50, 42 and 34% during weeks 1, 2 and 3, respectively. Separate process evaluation interviews with teachers, study staff and students documented general enthusiasm for the campaign. Although small incentives produced positive momentum, there were concerns about 'cheating' (that is, exaggerating accomplishments to gain incentives). Some of the monitoring instructions were viewed as too complex, and the monitoring period as too long for optimal sixth grade participation. On the basis of these data, self-monitoring and behavioral challenge practice efforts were simplified, made more interactive and incorporated into the FLASH sessions. Self-monitoring tasks were designed to be shorter in duration, more circumscribed and with incentive distribution based on documented effort or participation rather than on achievement of goals or competition.

### *Family newsletter results*

Across the seven schools participating in the pilot study, 27% of parents returned the postcard indicating that they had received the newsletter (range: 20–67%). These data supported including the newsletter in the main trial.

## HEALTHY behavior intervention component

All protocols, procedures and intervention materials were developed and written by the Behavior Committee, which included investigators with relevant expertise from the entire study group. The committee formed smaller working groups to address specific tasks. FLASH modules were written by a working group that included investigators and intervention staff from all seven study centers, as well as experts

in nutrition and physical activity. FLASH development involved an iterative design and review process accomplished through weekly conference calls and face-to-face meetings. A total of five FLASH modules were created, one for each semester of the intervention, and each took ~6 months to complete. Module development for the latter semesters took place once the intervention was underway, and formative feedback that reflected implementation concerns reported by classroom teachers and other personnel in the field was considered in the development of subsequent modules.

Other behavior intervention elements were the family newsletter and school-break challenge packages. There were seven newsletter issues distributed. School-break challenge packages were distributed for the summer break between the seventh and eighth grades and for the winter holiday break for the eighth grade. The packages included materials to get the families involved in making healthy behavior changes, as well as supporting changes that the student was making. These elements were designed by the Family Outreach Working Group. The working groups revised the materials on the basis of input from across the study group and worked closely with media and print production companies to incorporate appealing graphics and images that reflected the diversity of the HEALTHY study schools. Overall, this design process contributed to study-wide integration of the behavior intervention with the nutrition, physical activity and communication intervention components.<sup>3-5</sup>

Each center hired a full-time staff member to serve as the health promotion coordinator and three HEALTHY assistants. The health promotion coordinator oversaw the implementation of the behavior intervention component and its integration into other aspects of the intervention. The health promotion coordinator trained both the classroom teachers and the HEALTHY assistants on each FLASH module, and monitored and guided teacher performance.

#### *Structure of FLASH sessions*

Each FLASH session was a self-contained learning unit with clearly stated objectives. The basic FLASH materials were a teacher manual and a student workbook, available in English or Spanish and written at a fifth grade reading level. Other materials, described below, were provided to enhance session delivery and promote behavior change. There were 10 sessions in modules 1-4 and 8 in module 5, designed to be delivered one session per week. Each session began with a statement of the session goal(s). The FLASH teacher manual provided a scripted introduction, main talking points and conclusion for each activity. Multiple settings, including homeroom, science and other academic classes, study halls, health and electives, were used. FLASH sessions were designed to be completed in no more than 30 min from the time of distribution of materials to their collection and storage. However, teachers could opt to fill the entire class

period, and the study provided suggestions for supplemental activities.

#### *Overview of FLASH cumulative learning sequence*

Across all FLASH modules, there was a common format and sequencing of learning activities organized according to a progression of health behavior change themes. Table 1 summarizes the dimensions of the five FLASH in-class modules. A specific behavior change theme was identified for each of the five semesters of the intervention, starting in the second half of the sixth grade and continuing through the seventh and eighth grades. The themes served as a common focus and point of integration for all intervention components in the HEALTHY study, and were designed to reflect the increasing cognitive complexity and social awareness of middle school students. The fifth and last FLASH module provided an opportunity to integrate and review learning and skills acquired across all previous FLASH modules.

As the learning content progressively built a core health sciences knowledge base and skills across the five semester themes, modules were also designed to build enthusiasm for the behavior change through enjoyable, grade-appropriate learning activities with increasing levels of peer interaction, involvement and feedback. Each student completed a brief self-assessment checklist in the first session of each module, which established a baseline level of awareness for an array of nutrition and physical activity choices and behaviors that were the primary targets of intervention during the semester. Initial activities used to enhance knowledge acquisition included puzzles, cryptograms, true-false questions and interactive games. The middle sessions of FLASH were designed to help students become more skilled in direct observation or self-monitoring (for example, keeping track of eating/beverage consumption and physical activity behaviors both in and out of school), problem solving and goal setting while keeping them engaged through an interactive peer-learning approach. The final sessions were reserved for the production and presentation of a student project, such as posters, public service announcements, a marketing campaign for a new healthy snack product, movement routines and other creative group activities with a health behavior change focus or message. These creative products were presented in the FLASH class and shared later with other classes and even with other schools at other centers. Students also completed the same brief self-assessment checklist in the final session as they did in the first session as a means of measuring personal progress. They could check back to the beginning of their workbook and compare their responses at the start and at the end of the FLASH module.

#### *FLASH peer influence approach*

All FLASH modules and sessions were designed to foster peer engagement and influence. The learning activities were

**Table 1** Summary of FLASH modules

Semester	Semester theme	FLASH module	Knowledge foundation	Behavioral skills practice self-monitoring tasks	Creative activity	Theme enhancer (other rewards)
Winter/spring sixth grade	Water vs added sugar beverages	Water and you	Rethink your drink: benefits of water vs risks of sugar-added drinks	Observe self and others, aim for five cups of water a day Track number of cups of water during one school day	Water message poster	Water bottle (peer recognition)
Fall seventh grade	Physical activity vs sedentary behavior	Activity and you	Move more/sit less: benefits of being active vs risks of being inactive	Monitor activity levels, set goals, make plans for replacing inactive time with active time Track number of steps involved in school activities and on week day vs weekend day	Activity message radio spot	Pedometer (peer and teacher recognition)
Winter/spring seventh grade	High-quality vs low-quality food	Let's eat healthy	Food facts for choosing healthy: benefits of high-quality food vs risks of low-quality food	Monitor food quality, set goals, problem solve about barriers Track lunch foods over 2 days, rate and improve quality of lunch choices	Creating and promoting a new healthy snack	Pencil case and supplies (peer and teacher recognition; pen for task completion)
Fall eighth grade	Energy balance: energy in/energy out	Let's be balanced	Basic principles of energy balance: calories ingested from food vs calories spent in activity	Monitor food and activity, set goals, problem solve about barriers Track specific number of calories burned in physical education class, fruits/vegetables eaten at lunch, snacks $\leq 200$ cal, days screen time $\leq 1$ h	Energy balance artwork	Energy balance cards and game pieces (peer and teacher recognition); medals for goal achievement)
Winter/spring eighth grade	Strength, balance, and choice for life	Healthy for life	Consolidation of previous learning	Look back and forward, take charge of healthy lifestyle choices and behaviors, problem solve barriers, identify sources of support Write a letter to self in high school reflecting on personal goals and challenges	Movement routine set to music	Message cube (peer, teacher and school-wide recognition)

Abbreviation: FLASH, Fun Learning Activities for Student Health.

structured to progress from individual work, to pairs, to small group interactions of 3–5 students. Teachers were directed to adhere to this designated progression of student groups, but were given discretion on regrouping students if misconduct posed barriers to the completion of the session. Typically, at the start of the session, teachers shared the delivery of instructions with students, who either read aloud from the workbook or responded interactively to questions and prompts from the teacher. Activities, such as cryptograms, true-false questions and interactive games, were conducted in pairs and small groups, and permitted students to gain knowledge while having fun. The middle sessions of FLASH, which targeted individual self-monitoring and other challenges, incorporated group problem solving so that students worked together to overcome barriers to healthy eating and activity. Students were provided with a theme 'enhancer,' such as a water bottle or pedometer, to assist them in carrying out the behavioral assignments. Participation in these efforts and eventual goal attainment resulted in social recognition and other rewards. In the final sessions, students worked together in their small groups to engage in a creative process that resulted in the production and presentation of group projects, including posters, mock public service announcements, commercials, songs, raps, poems, movement and dance routines. Creative products were presented and acknowledged in the classroom and in other school venues as possible to enhance self-confidence and social competence for healthy behavior change.

Overall, the FLASH modules were designed to build cognitive and cooperative social skills, such as listening, communicating, working together and sharing ideas about health and health behavior change.

#### *Behavioral skills training and practice*

Behavioral skills practice, as well as using goal setting, self-monitoring and problem solving, was an important aspect of the FLASH behavior intervention component (see Table 1). These methods were adapted from procedures commonly used in obesity prevention and treatment for broad application to all students as they considered their options to enhance health. Tasks were initiated in the classroom but were aimed at teaching students skills for self-awareness in all environments. Students were initially taught to track pertinent behaviors at school and later away from school, always bringing information back to the small peer group. Self-monitoring tasks began with a simple self-observation (for example, 'how many cups of water do you drink during one school day?' or 'how many steps does it take you to go from your classroom to the gym?'). A more complex self-monitoring assignment was not used until the fourth FLASH module in the first semester of the eighth grade. A tracking booklet introduced a series of four challenges, and social recognition and rewards for these tasks were based on documented attainment of specific behavior change goals.

### *Implementation of FLASH*

The overall HEALTHY intervention was designed as a collaborative effort between centrally trained and supervised study staff interventionists for physical education, school food service and behavior, as well as key school personnel. For the behavior intervention, classroom teachers were selected in concert with school administration, then trained and supported by the staff of the HEALTHY study. Peer-selected student leaders in each classroom (known as student peer communicators) had an integral role in intervention delivery. The principal at each participating school assumed the final discretion in selecting the classrooms and teachers for FLASH implementation. Given the need for standardization of delivery, each FLASH session was formulated to be a self-contained learning unit with specific objectives. The FLASH teacher manual provided explicit, scripted instructions for each section of the lesson with major talking points outlined. The remainder of the session was mainly peer led, but facilitated by the teacher with assistance from the designated HEALTHY study staff.

### *Family outreach newsletter and break take home challenge packages*

The family outreach component of the behavior intervention aimed at providing parents with information and tools for promoting sound nutrition and increased physical activity in the home environment, and for involving families in supporting behavior changes being made by the student. The newsletter content corresponded with the progression of themes and targeted behaviors that characterized the FLASH intervention. Seven one-page, double-sided color newsletters were produced centrally with local customization through photographs by each center. Newsletters were distributed at strategic times, such as during breaks, for maintaining intervention messaging.

Newsletters featured vignettes about parent efforts to promote children's healthy behavior, specifically illustrating the means by which parents had successfully modified nutrition practices or increased physical activity. These vignettes were collected from parent focus groups and interviews conducted at all study centers before the start of the HEALTHY intervention. Each of the first three newsletters contained 'role model' stories derived from interviews and written as first-person narratives that depicted, in their own words, the manner by which the parents overcame barriers to raising a healthy family. The newsletters also contained recipes, lists of available opportunities for community activity programs and advice columns aimed at decreasing impediments and increasing self-efficacy for parental support of healthy lifestyle behavior. A Spanish language translation was produced as needed.

In addition to the newsletters, students received two packages of materials intended to be used by the entire family to sustain behavior change during school-break periods. One package was produced for the summer break

between the seventh and eighth grades and one for the eighth grade for the winter holiday break. The packages contained instrumental items intended to facilitate healthy behavior outside school (for example, behavior self-monitoring calendars, t-shirts, a heart healthy cookbook, a vegetable cutting board, a 'TV turn-off' decal and both a teen- and family-oriented aerobic exercise DVD (digital versatile disc)). Accompanying instructions challenged students and their families to set and meet behavior goals.

### **Discussion and summary**

A major challenge for the HEALTHY behavior intervention was to provide appropriate learning tools for a diverse array of US middle school students to develop and implement skills for a healthy energy balance. Reported research and pilot testing documented that changes to the total food service and physical education environments were enhanced by the inclusion of an extended (peer and family influenced) behavior change program. In addition, it was essential that the behavior integration component be delivered with fidelity to the maximum number of students without jeopardizing the primary instructional mandate of the middle schools.

Thus, HEALTHY study group members with expertise in health behavior change and school-based interventions designed a behavioral learning sequence with the following key elements: (1) peer-led classroom interactions that were both enjoyable and engaging and fostered self-awareness and responsibility for lifestyle choices; (2) multi-semester learning opportunities that acknowledged and addressed the increasing cognitive and social complexity of the middle school students; (3) training and practice of behavioral skills, such as goal setting, self-monitoring and problem solving to minimize less healthy behavior and increase more healthy behavior; and (4) sustaining behavior change and involving parents and families through outreach vehicles, such as newsletters and school-break materials.

The HEALTHY behavior intervention component was developed both before and during intervention implementation. Process evaluation procedures in the form of surveys, interviews and observations were built into the overall conduct of the study, and this information was processed on an ongoing basis.<sup>41</sup> The feedback was used to improve delivery of the intervention, including modifications to FLASH training and teacher instructions, and the provision of extended learning activities that could be used to fill an entire class period. The summer and winter break challenges were not part of the original behavior intervention plan, but were developed to address the need to involve parents and families and to provide ways to maintain behavior change during school breaks.

The behavior intervention component is the only aspect of the HEALTHY intervention to address family outreach. The

HEALTHY behavior experts recognized the importance of involving the family in the effort to make and retain behavior change. The HEALTHY study was primarily intended to be a school-based intervention, although prevention of risk factors for type 2 diabetes is a community and nationwide public health concern. Continued development of ways to involve families, parents and communities is encouraged.

### Conflict of interest

The authors declare no conflict of interest.

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