PACEiOK: A Web-based Weight Program for Overweight Kids

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Abbreviated Abstract

The PACE *My*Steps program is a technology-integrated weight loss intervention program designed specifically for overweight adolescents and their supporting parents or guardians. The study's target audience was adolescents ages 12-16 who are at-risk for overweight to moderately obese (BMI $\geq$ 85th percentile for age and gender). Target behaviors addressed by the program include: increasing fruit, vegetable, and fiber intake; decreasing dietary fat intake; increasing total physical activity; and limiting inactive time spent in optional pursuits such as TV watching, video games and phone time. In addition to weekly content for teens, the program offers a comprehensive Parent web site with specific information about their teen's weekly goal and progress, as well as content specifically geared to parents wanting to support their child's efforts.

Primary Investigator

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Product Web Site: n/a at present (Research site: www.mystepsprojectinfo.com)

Research Team & Affiliations

Santech:

- Sheri Thompson, PhD, PI
- Khalisa Bolling MPH, Project Coordinator
- Ramesh Venkatraman, MS (Computer Science), MBA (Technology Mgmt.), VP of Technical Development & Commercialization

Company Founders and Project Advisors:

- Kevin Patrick, MD, MS
- Karen Calfas, PhD
- James Sallis, PhD

Total Budget

$ 846,749.00

Research Objectives

AIMS

1) To evaluate the effect, at 12 months, of the MySteps program on Body Mass Index (BMI) percentile among overweight male and female adolescents
2) To evaluate, at 12 months, the effectiveness of the intervention on behavioral measures of physical activity and diet, including:
    - total energy intake (kilocalories/day),
    - percent of calories from saturated fat,
    - fruit/vegetable/fiber consumption (servings/day or fruits/vegetables and servings/day of whole grains or legumes),
    - total energy expended (kilocalories/kg/day),
    - minutes of moderate and vigorous PA, and
    - minutes of sedentary behaviors/recreational media use.
3) To evaluate patient, parent and provider satisfaction and acceptance of the intervention
4) To conduct a pricing assessment among parents who use the program

Theory/Hypothesis

That overweight teens who utilize the MySteps web-based program will, at 12 months, have a significantly greater BMI reduction than matched peers from the Control group condition.

Experimental Design

Cohort study with non-concurrent historical control group

Final Sample Size & Study Demographics

- 63 in the experimental group that received intervention; these matched to a historical control group from an earlier study for a total of 126
- White: 51%; Black/African American 13%; Asian 3%; Hispanic/Latino 23%; Native American/Alaskan Native/Native peoples 3%; Other 7%
- 75% female; 25% males

Data Collection Methods

Height/weight assessed in office with a calibrated scale and electronic surveys and questionnaires administered in the office; telephone administration of NDS surveys.

Outcome Measures

Primary measurement points are baseline and 12 months, with a subset of measures also administered at months 4 & 8.

- BMI percentile – primary outcome
- NDS (Nutritional Dietary Surveys)
- YAQ (Youth-Adolescent Questionnaire)
- PAR (Physical Activity Readiness)
- MTM questions related to Staging, Change Strategies, Pros & Cons, & Confidence for:
- Physical Activity, Sedentary, Fruits & Vegetables, & Dietary Fat

Evaluation Methods

The intervention group will be compared to overweight and obese adolescents from the SunSmart cohort from the PACE+ study of over 878 adolescents. As stated in the primary aim of this study, we will evaluate the impact, at 12

months, of the intervention on changes in BMI. The primary outcome will be tested using an intention to treat assumption, where missing endpoint data are replaced by carrying forward the value from the last completed assessment. The statistical model will be a repeated measures ANOVA with a 2 (treatment condition) by 2 (time) within-subject design. The full model will include tests for the two main effects and the treatment by time interaction effect. Covariates (e.g. age, education, and ethnicity) and first order interaction terms can be added to this model in further analyses.

Research Results

Analyses just commencing – last participant completed the intervention on July 17, 2008

Barriers & Solutions

- Sophisticated UI development and features/functionality on a tight budget – had to simply prioritize and generate a long "wish list" based on teen, parent and staff input
- Compliance (novelty wearing off long before 12 mo. mark) – very intensive case mgmt & support efforts when compliance slipping
- Recruitment very slow – direct to consumer not effective - resorted back to our proven network of medical providers
- Less than optimal parent involvement and compliance – attempted to encourage w/ email and phone support and reminders, and in person during measurement visits

Product(s) Developed from This Research

Currently PACE MySteps™, but most likely to be licensed as a private label application