Evidence Analysis Worksheet

Question	What is the evidence to support that a school-based intervention based on social cognitive theory (SCT) compared to an intervention not based on SCT results in change in health eating, BMI or markers of cardiovascular risk in children aged 7 to 18 years old?
Date of review	August 7, 2014
Reviewer	Candace Richards, Caitlin Mondelli

Author/Year: Leupker/1996

Complete Reference: Leupker R, Perry C. Outcomes of a Field Trial to Improve Children's Dietary Patterns and Physical Activity. JAMA 1996;275:768-776.

Design Type: Cluster Randomized Controlled Field Trial

Class: A

Quality: +

Purpose/Population Studied/Practice Studied

Purpose
To assess the outcomes of health behavior interventions, focusing on the elementary school environment, classroom curricula, and home programs, for the primary prevention of cardiovascular disease.

Inclusion Criteria
- Inclusion criteria at the school level included distance from one of the four study centers, the ethnic diversity, the food service's potential for intervention at the school, and commitment to offering at least 90 minutes a week of physical education (PE) and to participating in a 3-year study. Additionally, schools also were required to cooperate with random assignment to treatment or control status.

- Schools were included if they were within a reasonable distance to the field centers: The University of California at San Diego, La Jolla; University of Minnesota, Minneapolis; University of Texas at Houston; and Tulane University School of Public Health and Tropical Medicine, New Orleans, LA.

- The CATCH interventions also involved a coordinating center (New England Research Institute, Watertown, Mass.), and the National Heart, Lung and Blood Institute Project Office, Bethesda, Md.

Exclusion Criteria
Exclusion criteria was not described.

Study Protocol
Recruitment:

Recruitment was not described in detail, but was based off of the inclusion criteria.

Design –
This was a cluster randomized controlled trial in which 56 ethnically diverse schools were randomized to one of three groups if they met the criterion being within a reasonable distance to the field center.

School and student measurements were taken. Measurements of school- and student- level outcomes were made at the beginning of third grade (fall 1991). Follow-up measurements were made in spring 1994.

Randomization:
The 96 schools were randomized to either intervention (56 schools [14 per field center]) or control (40schools[10 per field center]). Randomization occurred after all baseline measurements were completed. The intervention schools were further randomized into two equal subgroups. One group received a school-based program consisting of school food service modifications, PE interventions, and the CATCH curricula (28 schools [seven per field center]); the other group received the same school-based program plus a family- based program (28 schools [seven per field center]).

Blinding:
Blinding was not described.

Description of what was done in intervention group(s) and control group(s):
1. **Intervention subgroup 1 (CATCH curricula without family-based programs)**:
   Classroom curricula, food service, and physical activity changes were made to the school. Classroom curricula addressed by teachers at that school included lessons on eating habits, physical activity, and cigarette smoking. The cafeteria changes included adjusting the meals to be lower in fat (30% of energy), saturated fat (10% of energy), and sodium (600-100mg per serving). The physical activity component sought to increase moderate-to-vigorous-physical-activity (MVPA) to 40% of the PE class.

2. **Intervention subgroup 1(CATCH curricula with family-based programs)**: The above interventions occurred in addition to a home intervention that included activity packets with classroom curricula that required adult participants. 19 activity packets over the 3 schools years. There were also "family fun nights" during grades 3 and 4 to culminate the classroom activities in a fair-type atmosphere.

3. **Control:** Received the usual health curricula, PE, and food service programs, but none of the CATCH interventions.

Timing of measures

Outcome measures were taken at baseline at the beginning of the third grade in the fall of 1991 and follow-up measures were made in spring 1994. Additional follow-up measures were taken to observe fidelity.

Measures description
School-based outcome measures

Recipe and menu analysis: measured using Nutrition Data System of the University of Minnesota

Nutrition Coding Center.

PE intervention: measured using System for Observing Fitness Instruction Time (SOFIT), and provided a quantitative measure for lesson and length and type of physical activity

Individual outcome measures
Dietary, exercise, and smoking habits, social reinforcements, and self-efficacy of students: The Health Behavior Questionnaire (HBQ) was a class-administered 45-minute instrument designed to evaluate factors associated with diet, exercise, and smoking at baseline, in the spring of grades 3 and 4, and at follow-up. It included psychosocial data on dietary knowledge, intentions, usual food choices, social reinforcement and support, and self-efficacy. The reliability and validity of the instrument, assessed during the pilot phase of CATCH and with the baseline data, were found to be adequate.

Dietary intake: A 24-Hour Dietary Recall measured total daily food and nutrient intake in a random subsample of 30 students per school were taken at baseline and follow-up (using a prompt of a none-qualified food record completed by students on the previous day).

Activity level: The Self-administered Physical Activity Checklist (SAPAC) was developedand validated during CATCH. It was administered in grade 5 only to assess type, duration, and intensity of selected leisure time physical activities, television watching, and video games.47Children reported the number of minutes they had spent during the previous day in various common physical activities and selected sedentary activities.

Physiological Measures
All physiological measures were taken at baseline and the fifth-grade follow-up and were taken in 45% of randomly selected individuals.

Non-fasting venipuncture samples: taken for analysis of total cholesterol, with high-density lipoprotein cholesterol and apo-lipoprotein
Blood pressure: the average of the three readings was used
Tricep and subscapular skin folds: measured used Lange calipers, with skinfold thickness measured 3 times at each site
Height: measured using a portable stadiometer, measured to nearest 0.1
Weight: measured using a balance scale, measured to nearest 0.1 kg
Aerobic fitness: measured using group times 9-minute run in a test-retest format

Statistics
All end points were analyzed by the single-stage, mixed-model strategy to take advantage of the fact that some measurements were taken as a school level (where randomization occurred) while others were taken at an individual level (where randomization did not necessarily occur). Individual measurements were analyzed by ANCOVA and included all physiological measures, the 24-hour food recall, and the 9-minute run. School-level measurements were analyzed using ANCOVA and included school menu data, school-mean responses to the HBQ, and PE class observations using the SOFIT.

Data Collection

Independent variables:

CATCH interventions – school foodservice modifications, enhances physical education (PE) and classroom health curricula. Also, 28 additional schools received these components plus family education.

Dependent variables

- Primary end-points at the school level: changes in the fat content of food service lunch offerings and the amount of moderate-to-vigorous physical activity in the PE programs.
- Primary end-points at the individual level: serum cholesterol change
- Secondary outcomes at the individual level: psychosocial factors, recall measures of eating and physical activity patterns, and other physiologic measures.

Confounding variables

ANCOVA was controlled for sex, race, CATCH field site, and the random effect of school within site and intervention group. Additional covariates were included as appropriate were age, height, and body mass index as predictors of risk factors and weather conditions as a predictor of distance in the 9-minute run. Each end point was also tested for interactions of the CATCH intervention group with site, sex, and race. The SOFIT analysis was additionally controlled for the location of the lesson (indoors or outdoors) and the specialty of the teacher classroom or PE).

Primary Outcome(s) /Results & Significance

Actual Sample

- Total n=5106 (60.4% of the third-grade students enrolled)
- The CATCH cohort was defined as those for whom lipid assessment was completed at baseline and follow-up: n=4019
- There was no significant difference by site, sex, or ethnic group among those who did and did not participate.

Participation and Implementation Fidelity

- n=3651 (72%) of the 5106 students at baseline were in CATCH schools and 28% (n=1455) were not in CATCH schools.
- No significant baseline differences in conditions for any of the primary or secondary endpoints between participants and those who were lost to follow-up. Also no significant differences to follow-up participation by intervention assignment or sex.
- Participation in intervention programs was consistently high across 56 intervention schools.
- Training session attended by 86% school food service cooks, 94% PE specialists, 86% teachers.
- 90% school food service guidelines were met during Eat Smart intervention and 80% CATCH PE activities implemented, 88% curriculum sessions were completed w/out modification and teachers completed 90% of all activities in the four curricula. 70% families participated in home curricula during each grade level and 63% attended family fun night.

Results – focus should be on the dependent variable or primary outcome of interest to the evidence question; only include other variables or secondary outcomes if important to putting your results and conclusions in context; tables are actually easier to understand and communicate; DO NOT copy exactly tables from the article

Primary

School-level endpoint:

- % energy intake from total fat, saturated fat and total energy intake in the meals significantly reduced in intervention school lunches compared with the control school lunches:

Value	Group	Baseline	Follow-up	P Value compared
Total energy content	C	2.97	3.12	<.001
	I	3.01 (719kcal)	2.86 (683kcal)	
Energy from total fat %	C	38.9	36.2	<.001
	I	38.7	31.9	
Energy from saturated fat %	C	15.1	13.7	.007
	I	14.8	12.0	

- Sodium content increased in both groups, not significant
- Potassium increased significantly in intervention school lunches (330mg/1000MJ to 357.9mg/1000MJ) compared to the control groups (325.3mg/1000MJ to 326.6mg/1000MJ): P<.01
- PE lesson length did not change significantly, but the intensity increased significantly more in the intervention group
- The curves of the intervention and reference conditions diverges significantly for both MVPA (F=2.71, df=5,1979, P=.02) and vigorous activity (F=2.35, df=5,1979, P=0.04)

Student-level outcomes

- Response scores for dietary knowledge, intentions and self-reported food choice changes on HBQ were significantly greater in intervention schools at follow-up:

Scale	Group	Baseline	Follow-up	P-value between groups
Dietary Knowledge	C	4.0	5.5	<0.001
	I	4.8	9.4	
Dietary Intention	C	1.4	-0.8	<0.001
	I	1.8	1.1	
Usual Food Choice	C	0.8	-1.1	<0.001
	I	0.8	0.2	

- Social reinforcement for healthful eating patterns: significantly higher in interventions groups
- Self-efficacy: no significant difference at follow-up
- Fat intake: significantly reduced in intervention schools at follow-up compared to control groups (P<0.01)
- Polyunsaturated and monounsaturated fat intake significantly reduced in intervention compared with control (P<0.02)
- Cholesterol (diet) was significantly reduced among children in intervention group compared to controls (P<0.05). Blood cholesterol concentrations declined in the intervention groups and the control groups.
- Apolipoprotein B declined in both groups, but differences were not statistically significant.
- Measures of body size, pulse rate and blood pressure did not differ at baseline or follow-up between groups.

Conclusions

Author's Conclusions

- The CATCH study was the largest and most rigorous school-based health promotion field trial at the time of publishing. Ninety-six public elementary schools maintained involvement, all with ethnic and geographic diversity.
- Two of the three primary outcomes were met in the study:
  1) Cafeterias in intervention schools were able to significantly modify lunch offerings to approach 30% of total energy from fat and 10% saturated fat energy intake
  2) The percentage of PE class time devoted to MVPA significantly increased in intervention schools compared with control schools.
- However, decreased in serum cholesterol levels among students in the intervention compared with the control group were not significant.
- This study demonstrates that policies and practices of schools can be changed without substantial new school resources and time. These changes seen with this study have the potential to produce long-term CV health benefits.
- The CATCH provides an important model of a school-based health promotion program for the primary prevention of CVD.

Reviewer's Comments – limitations of research; items listed in the rubric ; did the author over extend the data; was the author's conclusions linked to the original objective of the study and methods use; was the design appropriate for the study objective and why or why not; what the design appropriate for the evidence questions and why or why not.

Author mentioned the following limitations:

- Statistical power of the study – The targeted end point for power calculations was a differential between conditions of 0.13 mmol/L (5.1mg/dl) of cholesterol, which may not have been attainable with a population intervention, or even with children at high risk.
- Participation rates – at baseline, 60.4% of third-grade populations in 96 schools agreed to participate. Participation required written consent by the child and parent – moderate rates of participation could be expected.
- Amount of intervention that was feasible in public elementary schools – students had a 3-month summer vacation, during which there was no communication – recidivism could have occurred.
- The CATCH intervention did not encompass community members, mass media, grocery stores, parks and recreational facilities, or other resources that may have been important in the maintenance of children's health behaviors.

The original objective (To assess the outcomes of health behavior interventions, focusing on the elementary school environment, classroom curricula, and home programs, for the primary prevention of cardiovascular disease) was linked to the author's results and conclusions.

The design was appropriate for the study objective and the evidence question – It was a cluster, randomized field trial, indicating a class A study.

Conclusion Statement

Leupker et al (1996) found in a cluster, randomized control field trial of + quality that a intervention focusing on the elementary school environment, classroom curricula, as well as a sub-study with the addition of home programs, was able to modify the fat content of school lunches, increase moderate-vigorous physical activity in PE, and improve eating an physical activity behaviors in children during 3 school years from 3rd grade to 5th grade. This was found in a sample of ethnically diverse cohort of 3rd

graders. All analyses were controlled for sex, race, CATCH field sit and the random effect of school within site and intervention group. Major limitations include the statistical power of study for cholesterol reduction not being clinically significant for improving other physiological measures and participation rate (60.4%) in 96 schools, but overall there were few limitations that significantly affected the outcomes of the study. It appears that the CATCH intervention provides an important model of a school-based health promotion program for diet modifications in school lunches.