

Invited commentary

Achieving physiological change in school-based intervention trials: what makes a preventive intervention successful?

In this issue of the *British Journal of Nutrition*, Manios *et al.* (2002) describe a 6-year, school-based intervention programme using health and nutrition education to reduce cardiovascular disease (CVD) risk. The study was conducted among 1st to 6th grade students (6–12 years old) in Crete. Among the positive outcomes, statistically significant changes in serum lipids, particularly LDL-cholesterol (LDL-C), total cholesterol:HDL-C ratio and LDL-C:HDL-C ratio were achieved. Net reduction in total serum cholesterol (TSC) was 3%, 0.15 mmol/l (60 mg/l), while net reduction in LDL-C was 8%, 0.22 mmol/l (85 mg/l) and net increase in HDL-C was 6%, 0.1 mmol/l (40 mg/l).

School-based intervention studies in Europe and the USA have had mixed results in their ability to achieve physiological changes. The Oslo Youth Study (Tell & Vellar, 1987) and the North Karelia Youth Project in Finland (Puska *et al.* 1982) both achieved lipid changes. The Oslo Youth Study (Tell & Vellar, 1987) showed a 4% mean reduction (0.15 mmol/l or 60 mg/l) in TSC after a 2-year intervention study in 5th to 7th grade students and the North Karelia study showed a 2% mean reduction (0.08 mmol/l or 30 mg/l) in TSC after a school and community intervention targeting 7th and 8th graders. Two US studies are comparable to the Manios *et al.* (2002) study: the Child and Adolescent Trial for Cardiovascular Health (CATCH; Luepker *et al.* 1996); the Know Your Body (KYB) study (Walter *et al.* 1988). CATCH was a 3-year school-based CVD risk reduction study conducted in ninety-six schools in four states involving students in 3rd through to 5th grade. At the end of the 3-year intervention, there were no statistically significant differences between intervention and control school students in their blood lipids or other physiological outcomes. While students in the intervention group achieved a reduction of 0.03 mmol/l (12 mg/l) in TSC between baseline and the end of the intervention, students from the control group realized a similar reduction of 0.02 mmol/l (8 mg/l) in TSC.

The Walter *et al.* (1988) KYB study evaluated the effects of a 5-year health education curriculum targeting reduction in CVD risk factors in two samples. One sample included students from fifteen schools in Westchester County, New York and the other included students from twenty-two schools in the Bronx, New York. At the end of the 5-year study, a statistically significant net decrease in TSC between control and intervention group (0.045 mmol/l or 17 mg/l) was seen in the sample from

Westchester but statistically significant changes were not seen in the sample from the Bronx (0.025 mmol/l or 10 mg/l net decrease). Other USA-based studies have had mixed or disappointing results, particularly when school, rather than the individual, is used as the unit of analysis (Harrell *et al.* 1999).

Why have the European studies (Puska *et al.* 1982; Tell & Vellar, 1987; Manios *et al.* 2002) been able to show larger changes in serum lipids through school-based interventions than have the US studies? The success of the Oslo Youth Study (Tell & Vellar, 1987) and the North Karelia study (Puska *et al.* 1982) may be partially attributed to additional, personalized intervention activities for high-risk children, deviating from the purely primary prevention approaches of the Crete, CATCH and KYB studies. Manios *et al.* (2002) suggest that their success in Crete can be attributed to: (1) high levels of risk factors in the children; (2) high degree of parental participation in intervention activities; (3) a health education programme that was combined with physical education classes, allowing more hours spent on intervention than in the US studies, and providing less emphasis on competition, fostering a greater enjoyment of activity; (4) the relatively long duration of the intervention and high level of teachers' compliance in programme delivery.

Do these attributes distinguish the Crete study from US studies and account for the differences in their success? Considering level of risk factors, in the Manios *et al.* (2002) study, 29% of the sample had baseline TSC values greater than 2000 mg/l, while in CATCH, the proportion of boys and girls with baseline TSC levels of 2000 mg/l or greater was 11.1% and 15.6%, respectively (Webber *et al.* 1995), supporting their contention. Baseline mean TSC of students (taken in the first grade) from the Crete study was 4.91 mmol/l in the intervention group and 4.49 mmol/l in the control group while in CATCH mean baseline TSC (3rd grade) was 4.39 mmol/ml in the intervention group and 4.41 mmol/l in the control group. Baseline levels of TSC in the KYB samples, taken in the 4th grade, ranged from 4.29 to 4.47 mmol/l. Higher or similar levels in the Manios study might be reflective of the generally higher TSC levels in childhood that begin to decline at pubertal onset; still, mean levels of TSC were not markedly different between studies.

The other speculations by Manios *et al.* (2002) regarding their success pertain to the implementation and effectiveness of the intervention strategies. Unfortunately, they

reported no process data, so we cannot evaluate the dose, fidelity or completeness of the intervention as designed. Process data from the CATCH intervention indicate that there was excellent implementation of the programmes; still no physiological changes were noted (Perry *et al.* 1997).

We suggest that the effectiveness of the school-based intervention studies conducted in Europe may have more to do with study design, the homogeneity of the populations targeted in the intervention, and the length of time of the interventions than it does with risk factor levels or implementation or effectiveness of the intervention strategies. Study design and analysis issues have been evolving in this field over the past two decades making direct comparisons between studies very difficult. Although Manios *et al.* (2002) selected schools within counties at random, they did not randomize counties and used school as the unit of analysis. Current study design standards in the USA demand randomization of schools and/or communities with the unit of randomization also used as the unit of analysis. If Manios *et al.* (2002) were to use county as the unit of analysis, level of statistical significance would probably be reduced, but the estimated net reductions would not be changed.

In the sample of students from Crete, 99% of the children and their families were Christian Orthodox Greek and, at the county level, there were no differences in education, income or employment (Manios *et al.* 2002). Contrast these demographics with the sample from CATCH where the 5100 children in the sample came from four different geographical regions; 69% of the sample was White, 13.2% African-American, 13.9% Hispanic and 4% classified as 'Other'. There was notable diversity in parental occupation, education and employment associated with the geographical and ethnic differences. In the KYB study reported by Walter *et al.* (1988) the sample with significant TSC results was from Westchester, a middle- to upper-income suburb of New York City where 90% of intervention students were White, 2.8% were Black and 7.4% were classified as 'Other.' However, the sample of students from the Bronx, a lower-income borough of New York City, included 43% Black, 31.7% White and 25.3% students classified as 'Other'; no statistically significant changes in TSC were seen with this diverse sample. Walter *et al.* (1988) speculated that the differences between the samples were due to teachers in Westchester being more skilled in programme delivery or perhaps parents in Westchester being more supportive of curriculum objectives. However, no process data were presented to confirm or refute this assertion.

Both the KYB and the CATCH studies used the same intervention in multiple communities, attempting a 'one size fits all' intervention model. However, effective behavioural interventions must be relevant within the social and cultural context of the target audience. Using appropriate role models and norms, and understanding cultural expectations and culturally influenced beliefs and values are important considerations in designing intervention channels, strategies, and activities that are relevant and effective in influencing change (Perry, 1999). When diversity abounds, creating interventions that are relevant to all

targeted groups is a challenge. In particular, dietary choice and physical activity behaviours often targeted by our CVD risk reduction programmes are laden with cultural expectations and affected by family customs and structures that may differ group to group.

Heterogeneity of samples may also affect the stability of populations under study. In the Manios *et al.* (2002) study, 80% of the original cohort was still participating at the end of the 6 years intervention study. In CATCH, after 3 years of intervention, 72% of the original sample was available for follow-up measures. In the KYB study (Walter *et al.* 1988), of those students eligible to participate in the baseline sample, 66% of the Westchester sample and 45% of the Bronx sample were eligible for the follow-up analysis, reflecting differences in baseline participation and loss to follow-up. A more diverse study population may also be less geographically stable. For a school-based study this means that students may move between control and intervention schools resulting in contamination; students may not receive a full dose of the intervention; teachers and school staff may have trouble delivering the intervention as students and families move in and out of their classes during and between school years; and attrition may limit the power and generalizability of the results.

The length of interventions is also likely to be important in the effectiveness of school-based studies. Longer intervention periods allow for increased student exposure to positive role models, practice with problem-solving behaviours, establishment of healthier norms, and more opportunities for reinforcement of healthful behaviours. The longer exposure may also beneficially influence the lifestyles of the teachers, though this conjecture has not been studied. CATCH and other school-based studies have been able to show statistically significant and maintained changes in student diet and activity behaviours (Luepker *et al.* 1996; Lytle *et al.* 1996; Nader *et al.* 1999). Perhaps a greater intervention dose during childhood and adolescence might have resulted in lipid changes.

In the past decade in the USA, federal funding for school-based intervention studies in a single geographical location results in, at most, a two to three school-year intervention period. Larger, longer studies are generally multi-centre, where sample diversity is a key objective. Researchers in the USA are encouraged to design studies that target diverse populations in order to reflect the population, enhance external validity of studies and address the needs of populations at risk. But do these efforts, combined with a 'one size fits all' intervention, compromise our ability to show physiological changes? Diversity is a valued characteristic of US culture and to suggest creating unique interventions for each cultural group in schools would be impractical, ineffective and inappropriate. However, even within our multi-centred, school-based community trials, interventions must be designed to be flexible and responsive to the social and cultural environments within which they occur. Active participation by community members during the formative assessment period of intervention is essential to determine cultural factors that affect student health behaviour; continued engagement of community members will enhance the implementation of the intervention. While the primary intervention objectives

and strategies need to be determined by the investigators, how those strategies are manifest within a given school or community should be tailored to local characteristics.

We believe that school-based intervention studies require long intervention periods. In addition, our intervention models need to be theoretically strong, use the most potent intervention objectives and strategies available, but also be designed so that they may be operationalized within the local, cultural context within which the students' behaviours will occur. The reporting of process data is essential to understand how the intervention was implemented. Finally, our school and community interventions will be more successful if they occur in healthful environments (Richter *et al.* 2000). Creating school and community environments, both physical and social, that support and encourage healthful eating and activity behaviours in youth will do much to transcend the inherent challenges in diversity that is experienced in the USA and that are becoming worldwide challenges through globalization.

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