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## Symposium on ‘Physical activity, energy expenditure and obesity’

# Physical activity interventions in the prevention and treatment of paediatric obesity: systematic review and critical appraisal

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Interventions for prevention and treatment of childhood obesity typically target increases in physical activity and, more recently, reductions in physical inactivity (sedentary behaviour such as television viewing). However, the evidence base for such strategies is extremely limited. The main aim of the present review was to update the systematic review and critical appraisal of evidence in the light of the recent rapid expansion of research in this area. Randomised controlled trials (RCT) that targeted activity or inactivity, that followed up children or adolescents for at least 1 year and that included an objective weight-related outcome measure were included. Trials were appraised using previously published criteria (Harbour & Miller, 2001), and literature search strategies described previously (Reilly *et al.* 2002) were updated to May 2002. A total of four new RCT, two new systematic reviews and one meta-analysis were identified. The evidence base has increased markedly since the completion of earlier reviews, although high-quality evidence is still lacking. The evidence on childhood obesity prevention is not encouraging, although promising targets for prevention are now clear, notably reduction in sedentary behaviour. There is stronger evidence that targeting activity and/or inactivity might be effective in paediatric obesity treatment, but doubts as to the generalisability of existing interventions, and the clinical relevance of the interventions is unclear. Further research in settings outside the USA is urgently needed, and two ongoing RCT in Scotland are summarised.

**Obesity prevention: Obesity treatment: Systematic review: Childhood: Adolescence**

### Impact of childhood obesity

The developed world has experienced an epidemic of childhood obesity in recent years (Reilly & Dorosty, 1999; Strauss & Pollack, 2001), and rapid increases in obesity prevalence have also been observed in some developing countries (Martorell *et al.* 2000). The epidemic is of great concern because of its likely clinical and public health impact (Reilly *et al.* 2003), and there is increasing recognition of the problem; at least eighteen editorials or position statements have been published in paediatric, nutrition and general medical journals since 1998 (Dorosty, 2001).

### *Role of physical activity and inactivity in the aetiology of childhood obesity*

It is widely believed that reduced physical activity and/or increasing sedentary behaviour, such as television viewing, is implicated in the aetiology of childhood obesity (Troiano & Flegal, 1998; Reilly & Dorosty, 1999). Definitive evidence of a role for reduced physical activity and energy expenditure in the causation of obesity is lacking, but the ‘circumstantial’ evidence for an important role is now substantial. First, in most developed countries increases in obesity prevalence have occurred in parallel with declines

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**Abbreviations:** CATCH, Child and Adolescent Trial for Cardiovascular Health; MAGIC, Movement and Activity Glasgow Intervention in Children; RCT, randomised controlled trials; TEE, total energy expenditure.

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in children's energy intakes (Gregory *et al.* 1995; Troiano & Flegal, 1998). Second, in both cross-sectional and longitudinal studies exposure to sedentary behaviour (television viewing) has consistently been associated with increased paediatric obesity risk (for example, see Gortmaker *et al.* 1996), and sedentary behaviour has probably increased substantially in recent years in children and adolescents. Direct evidence of reduced activity or total energy expenditure (TEE) is lacking, because the necessary cross-sectional surveys have not been carried out and most published studies have used small highly-selected samples. Our own recent work in Scottish children measuring TEE by the doubly-labelled water method and physical activity and inactivity by accelerometry has focused on larger, representative, samples. These studies indicate that levels of TEE in young children are very low (Montgomery *et al.* 2002) and levels of sedentary behaviour exceptionally high (Jackson *et al.* 2002). Third, in certain paediatric groups characterised by increased obesity risk, such as the survivors of some cancers, TEE and energy expended on activity are abnormally low and predict risk of excess weight gain prospectively (for example, see Reilly *et al.* 1998). Finally, interventions that alter exposure to activity, or inactivity, support the hypothesis that increased sedentary behaviour is implicated in the aetiology of childhood obesity (Robinson, 1999a). Interventions that change activity, or inactivity, also add considerably to the effects that can be achieved by dietary treatment alone (Epstein *et al.* 1998, 2000).

#### *Role of intervention studies*

Intervention studies can be used, therefore, to test hypotheses in relation to the aetiology of obesity, but they have important and more obvious roles in testing strategies for prevention and treatment of obesity. However, the evidence base for treatment and prevention strategies is extremely limited at present (Campbell *et al.* 2001a; Reilly *et al.* 2002; Summerbell *et al.* 2002), and the effectiveness of all available strategies must be considered questionable. Our recent review concluded that there are no successful generalisable evidence-based intervention strategies at present (Reilly *et al.* 2002). Evidence on modifiable risk factors for obesity has also provided few evidence-based targets for prevention (Dietz, 2001; Armstrong *et al.* 2002). Recent Cochrane reviews (Campbell *et al.* 2001b; Summerbell *et al.* 2002) have drawn attention to the enormous mismatch between the scale of the clinical and public health problems presented by the paediatric obesity epidemic and the limited evidence base that informs our strategies for addressing it. However, the recent increase in interest in this area, combined with improvements in the design and conduct of intervention studies (Moher *et al.* 2001), provide some hope of an improvement in the evidence base. In addition, there is increasing recognition in nutrition that systematic review and critical appraisal provides the best approach for assessing the evidence as to the efficacy of interventions (Reilly, 2002a). The present review aims to: (a) update the process of systematic review and critical appraisal of intervention studies in paediatric obesity prevention and treatment; (b) summarise the principal weaknesses in the literature in this area to date; (c) briefly discuss the most

promising intervention strategies backed by high-quality evidence; (d) examine the clinical relevance of intervention effects; (e) make suggestions for further research; (f) briefly outline two ongoing randomised controlled trials (RCT) in paediatric obesity prevention and treatment in Scotland. Non-randomised intervention studies, and wider issues such as the conceptual basis of school-based obesity prevention, were beyond the scope of the present review. Comprehensive reviews of such topics are available elsewhere (Resnicow & Robinson, 1997; Story, 1999).

## **Methods**

### *Literature searching*

The search for systematic reviews and meta-analyses was done using Medline, Embase, Cinahl, Healthstar, the Cochrane Library and the internet. Searching from June 2000 to May 2002 provided an update on our previous review, which searched the literature up to and including May 2000 (Reilly *et al.* 2002). The search for RCT used the same databases, supplemented by manual searching of reference lists of each paper identified, and by manual searching of contents pages from thirty-nine relevant journals between June 2000 and May 2002. A recent Cochrane review on prevention of childhood obesity (Campbell *et al.* 2001b), and a Cochrane review on treatment of childhood obesity (Summerbell *et al.* 2002) were identified, and our literature search was cross-checked against these sources.

### *Evidence appraisal*

Our evidence appraisal used methodology described elsewhere (Harbour & Miller, 2001), which is widely available via the internet (Scottish Intercollegiate Guidelines Network, 2002). In summary, evidence that was relevant to the prevention and treatment of paediatric obesity was identified using inclusion or exclusion criteria given later. Two reviewers then appraised each study independently and agreed on a rating of methodological quality. This rating (Harbour & Miller, 2001) defines RCT as providing 'level 1' evidence, the highest grade of evidence available (hierarchy of evidence in descending order to level 4, expert opinion). Each published study was rated as: ++, all or most methodological criteria met, low risk of bias; +, some criteria not met or inadequately described, low risk of bias; -, few or no criteria met, high risk of bias; rejected (Harbour & Miller, 2001).

Many published studies have been given a negative quality rating (high risk of bias) in previous critical appraisal exercises in this area. For example, in our previous systematic review (Reilly *et al.* 2002) sixteen RCT of obesity treatment were identified but thirteen had major methodological flaws. This assessment may seem excessively critical, but older RCT, carried out before the emergence of the Cochrane Collaboration and the CONSORT statements (Moher *et al.* 2001) on the design, conduct and reporting of RCT, were very weak and prone to bias. This appraisal can be illustrated by listing the methodological quality criteria used by the present and the earlier review (Reilly *et al.* 2002;

Scottish Intercollegiate Guidelines Network, 2002; 1). For the thirteen of sixteen RCT of obesity treatment originally identified from our search up to May 2000 (Reilly *et al.* 2002), almost all the criteria listed in Table 1 were not met. In most cases sample size was less than twenty in each arm of the trial, and in many cases clear trial entry criteria (e.g. obesity definition used), characteristics of subjects, and outcome measures were lacking.

#### *Inclusion and exclusion criteria in present review*

Only the RCT that followed up children or adolescents for at least 12 months from the start of the intervention were included. This condition is a common and important inclusion criterion (Campbell *et al.* 2001b; Reilly *et al.* 2002; Summerbell *et al.* 2002). The rationale is that almost all interventions in this area are grounded in lifestyle changes and the behavioural change literature shows consistently that short-term lifestyle changes can be made relatively easily, but are difficult to sustain. Short-term studies in this area are therefore prone to bias. Indeed, a number of high-quality studies with 1–2 year follow-up periods have concluded that their studies were limited in this respect, and that even longer follow up would have been desirable (for example, see Luepker *et al.* 1996; Gortmaker *et al.* 1999; Epstein *et al.* 2000; Sahota *et al.* 2001). Short-term studies can usefully test hypotheses in relation to the role of activity or inactivity in the causation of obesity, and can be of high methodological quality (for example, see Robinson, 1999a), but do not provide definitive evidence on the long-term efficacy of intervention strategies. For inclusion, studies on prevention had to have included non-clinical groups of subjects (recruited from nursery, school or community). Studies on obesity treatment had to have children defined as obese using objective criteria. Both studies of prevention and treatment had to have included objective outcome measures of body weight, BMI or body composition. All papers that met our entry criteria were appraised, but studies that were given a negative quality rating in the present review have not been summarised.

**Table 1.** Criteria for evaluation of randomised controlled trials\* (adapted from Scottish Intercollegiate Guidelines Network, 2002)

Does the study address a clear question or aim?
Were subjects allocated randomly to treatment groups?
Was allocation concealed?
Were subjects and/or investigators kept 'blind' to treatment allocation?
Were treatment and control groups similar at the start of the trial?
Apart from the treatment being investigated, were groups treated equally?
Were relevant outcomes measured in valid and reliable ways?
How high was dropout rate?
Were subjects analysed in the groups to which they were randomly allocated?
Was a power calculation carried out?
Was sample size adequate?
What is the likely direction of study bias?

Studies rated as 1– meet few or any of these criteria adequately.

## Results

### *Evidence appraisal and summary: obesity prevention*

The present literature review identified three papers that met the inclusion criteria and were appraised (Epstein *et al.* 2001a; Muller *et al.* 2001; Sahota *et al.* 2001). The recent Cochrane review on paediatric obesity prevention was also noted (Campbell *et al.* 2001b).

The studies reported by Muller *et al.* (2001) and Epstein *et al.* (2001a) were given a quality rating of '–' on the grounds that they failed to meet most of the criteria listed in Table 1. It was unclear whether the study by Muller *et al.* (2001) was truly an RCT, and for both studies important issues of trial design were either not addressed or not reported. These limitations included: whether (Muller *et al.* 2001) and how randomisation took place (both studies): the failure to address concealment and blinding: no 'intention to treat' analysis was used: no power calculations were reported. In addition, Muller *et al.* (2001) failed to report drop out, and these studies were heavily dependent on outcome measures (e.g. fruit and vegetable consumption) that may not be measurable. The Cochrane reviewers downgraded both these trials (Campbell *et al.* 2001b).

The study by Sahota *et al.* (2001) was characterised by stronger design, conduct, and reporting, and was based in England. Ten schools (*n* 636 children at baseline, mean age 8.3 years) were randomised to intervention or control by the toss of a coin, although no blinding of the researchers was possible. Pairs of schools were matched and had similar characteristics before the 1-year intervention, which focused on modifying the school environment. Sahota *et al.* (2001) described their primary aim as modifying the risk factors for obesity (education, attitudes and behaviours such as fruit and vegetable consumption and physical activity). These outcomes were assessed largely by self reporting, although an objective index of obesity (BMI SD score) was also included as an outcome. The drop out for the behavioural measures was high (e.g. dietary intake, 37 % of subjects lost to follow up at 1 year), but much lower (6 %) for BMI. Despite a favourable process evaluation, Sahota *et al.* (2001) reported no significant effects on BMI SD score, or overweight or obesity prevalence, and negligible impact on the other variables. However, Sahota *et al.* (2001) also commented that their study may have been underpowered, and the intervention under-resourced.

A brief summary of the two high-quality RCT identified in our previous review and appraisal is appropriate (Table 2). Both RCT were large-scale long-term studies based in the USA, and both employed complex interventions that targeted diet, activity and inactivity (Child and Adolescent Trial for Cardiovascular Health (CATCH), Luepker *et al.* 1996; 'Planet Health', Gortmaker *et al.* 1999). Both studies employed cluster randomisation in which the 'unit of randomisation' was the school rather than the individual subject or family. The primary outcome in the study by Gortmaker *et al.* (1999) was change in obesity prevalence (defined as BMI and triceps skinfold both > 85th percentile). Luepker *et al.* (1996) used change in serum cholesterol as their primary outcome, with change in BMI as a secondary outcome. Both studies carried out process evaluation of the intervention. Both RCT aimed to alter the

**Table 2.** Summary of obesity prevention trials rated 1+\*

Trial	Subject characteristics at baseline			Nature of intervention or target	Drop-out rate (%)	Primary outcome(s)	Duration of follow up
	Age (years)	<i>n</i>	Location				
Gortmaker <i>et al.</i> (1999)	11.7	1295	USA	↓ Television viewing ↓ Fat consumption ↑ Fruit and vegetable intake ↑ Physical activity	17	Obesity prevalence and remission	Approximately 17 months
Luepker <i>et al.</i> (1996)	8.8	5106	USA	↑ Intensity of physical education ↓ Fat consumption in school ↑ Physical activity	21	Serum cholesterol	Approximately 30 months

↓, Reduce; ↑, increase.

\*These studies were rated as 1+ and met all or most of the criteria listed in Table 1 (Scottish Intercollegiate Guidelines Network, 2002).

school environment, although one arm of CATCH tested the impact of a home-based intervention. Results of these large-scale long-term interventions are not encouraging. CATCH reported no marked change in BMI at follow up, although data were not presented in terms of changes in BMI SD scores, or changes in overweight or obesity prevalence (Luepker *et al.* 1996). There was some evidence of increases in intensity of physical education classes in the intervention schools relative to control schools and the process evaluation of CATCH indicated that implementation of the intervention was good, and was sustained over three school years. Despite these positive changes, the impact of the intervention on primary and secondary outcomes was limited. The authors concluded that this result could reflect a combination of factors, including inadequate power, insufficient duration of follow up and the difficulty of making effective changes to the environment. The Planet Health Study (Gortmaker *et al.* 1999) reported significant declines in obesity prevalence in girls in the intervention groups (adjusted odds ratio 0.47, 95 % CI 0.24, 0.93,  $P < 0.05$ ) and significantly greater remission of pre-existing obesity in girls (adjusted odds ratio 2.16, 95 % CI 1.07, 4.35,  $P < 0.05$ ). There was some evidence that the intervention effects were mediated by reductions in television viewing targeted by the intervention. The obesity outcomes did not change significantly in boys, although sample size or power may have been a limiting factor. Process evaluation indicated that the Planet Health intervention was generally implemented well and was sustained by schools.

#### *Evidence appraisal and summary: obesity treatment*

The literature review for the present study identified two papers that met our inclusion criteria: one new RCT (Warschburger *et al.* 2001) and one meta-analysis on the impact of exercise as a treatment (Le Mura & Maziekas, 2002). The recent Cochrane review was also noted (Summerbell *et al.* 2002).

The study by Warschburger *et al.* (2001) provided no information on the randomisation process, and the issues of blinding and concealment were not addressed. Subject drop-out rate was not reported, and there was no evidence of an 'intention to treat' analysis. Subjects varied widely in age

at trial entry and it is unclear whether there were differences in treatment (other than the intervention) between groups. There was some evidence of differences between groups at baseline. The study was also dependent on some outcome measures that are not readily measurable.

The meta-analysis (Le Mura & Maziekas, 2002) also received a negative quality rating, largely on the grounds (Scottish Intercollegiate Guidelines Network, 2002) that the search strategy was incomplete, and there was no attempt to formally appraise the quality of studies included in it. The meta-analysis was heavily dependent on short-term studies, and a number of study designs were entered, including non-randomised trials and uncontrolled trials. Biases in this meta-analysis are likely to inflate the apparent efficacy of treatment, and its conclusions may have been more positive about the effect of exercise in obesity treatment than is warranted by current evidence.

A brief summary of the high-quality obesity treatment RCT identified in our previous review (Reilly *et al.* 2002) is appropriate, in view of the absence of new high-quality evidence. The RCT employed complex interventions (Table 3) that were fairly intensive in terms of their resource utilisation (clinic and therapist time, access to specialist groups of health professionals), and were from the same research group in the USA. Epstein *et al.* (1995) compared the 'traffic light' diet with one of three randomly-allocated treatments: (1) targeted reductions in sedentary behaviour; (2) targeted increases in aerobic activity; (3) combination of treatments 1 and 2. There were significant differences in outcomes between the three groups ( $P < 0.05$ ), with the greatest change in percentage overweight at +4 and +12 months in the group targeted for reductions in sedentary behaviour (e.g. mean -20 % change in percentage overweight at +12 months *v.* -12 % in the group targeted for increases in activity). The clinical relevance of these changes is unclear, but this study highlights the potential value of targeting sedentary behaviour in the treatment of childhood obesity. It may also be a more practical and realistic target than aerobic activity for health professionals to focus on. A more recent high-quality RCT by the same research group (Epstein *et al.* 2000), which involved twenty treatment sessions over a 6-month period, provided further support for the treatment effects of controlling sedentary behaviour (Table 3).

**Table 3.** Summary of obesity treatment trials rated 1+\*

Trial	Subject characteristics at baseline			Nature of intervention or target	Drop-out rate (%)	Primary outcome(s)	Duration of follow up (months)
	Age (years)	<i>n</i>	Location				
Epstein <i>et al.</i> (1995)	8–12	61	USA	Traffic light diet plus ↓ sedentary behaviour or ↑ physical activity, or both	10	Percentage overweight, aerobic capacity, dietary intake, activity (self reported)	12
Epstein <i>et al.</i> (2000)	10.5	90	USA	Traffic light diet plus: ↓ Sedentary: Low dose (<10 h/week) High dose (<20 h/week) ↑ Activity: Low dose (16 km/week) High dose (32 km/week)	16		24

↓, Reduce; ↑, increase.

\*These studies were rated as 1+ and met all or most of the criteria listed in Table 1 (Scottish Intercollegiate Guidelines Network, 2002).

## Discussion

### *Major implications of present review*

The present study represents the most up to date systematic review in this area. Increasing awareness of the problem of paediatric obesity, combined with the associated increase in funding opportunities for research, has led to a rapid increase in the amount of evidence available in recent years. However, the increase in evidence over the past 2 years has consisted largely of studies that did not meet our entry criteria (particularly short-term studies, which remain common). Of those that were eligible for inclusion, most were prone to bias as a result of limitations in their design, conduct and/or reporting (Moher *et al.* 2001). Systematic reviews must be updated, and this process is particularly important in the rapidly-developing field of obesity prevention and treatment (Campbell *et al.* 2001b; Summerbell *et al.* 2002). An important strength of the present review was the formal critical appraisal of published evidence. Published evidence should be formally appraised and graded if it is to inform clinical and public health approaches adequately (Harbour & Miller, 2001).

There remains serious doubt as to the long-term efficacy, clinical relevance, and generalisability of published interventions in this area. The clinical relevance of treatment interventions is difficult to address and perhaps, as a result, rarely addressed. Most of the published interventions of high quality are from the USA, and most of these (at least for obesity treatment) are from the same research group. There is an urgent need to test the efficacy of treatment and prevention strategies in other settings; can the principles of successful treatment be adapted for use in other circumstances? In the UK, for example, the amount of health professional time available for treatment of paediatric obesity is limited, and access to other professional groups that have been important in published studies (e.g. clinical psychologists) is even more limited. There are also training needs; most health professionals involved in treatment of childhood obesity in the UK are unaware of recent evidence in this field, and there is confusion over basic issues such as diagnosis of obesity (Reilly, 2002b).

### *Potential for adverse effects of interventions*

Concern is often expressed that paediatric obesity prevention or treatment may produce adverse effects (particularly on psychological health), but studies that have included adverse outcome measures, such as measures of psychological health or growth retardation, have generally failed to find evidence of adverse effects (Mellin *et al.* 1987; Epstein *et al.* 2001b; Muller *et al.* 2001; Sahota *et al.* 2001). If handled sensitively, interventions may not exacerbate the existing stigmatisation of obese children (Reilly *et al.* 2003), and may not increase health risks for non-obese children. However, all interventions should consider the possibility of causing harm and should quantify this factor if possible (Scottish Intercollegiate Guidelines Network, 2002).

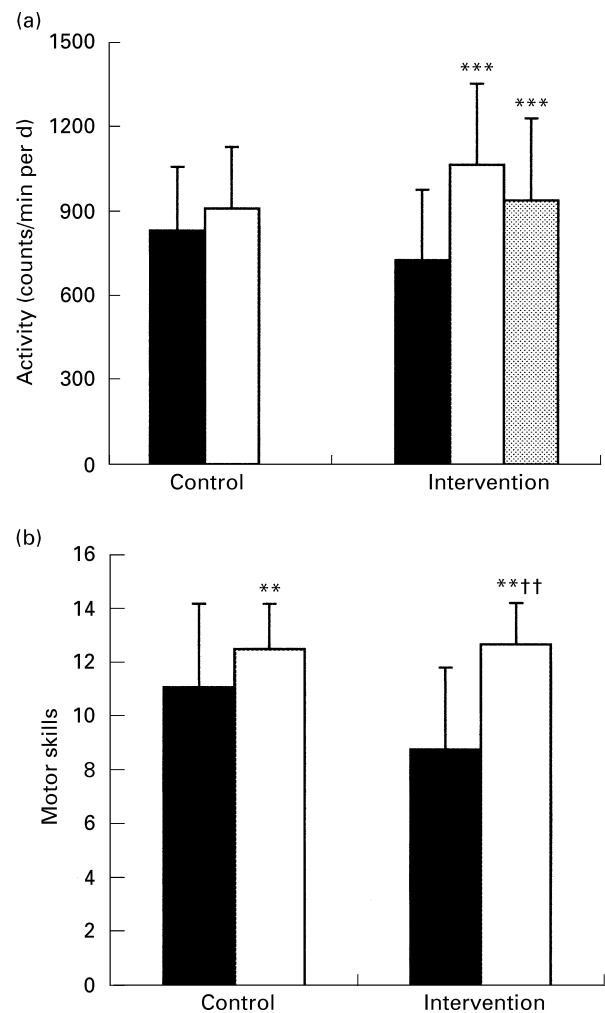
### *Suggestions for further research: prevention*

As noted earlier, high-quality 'long-term' RCT on paediatric obesity prevention have produced promising targets for intervention (notably control of sedentary behaviour), although doubt remains as to the long-term efficacy of current strategies. One promising approach is to focus the intervention wholly on inactivity. At present this approach has been limited to short-term studies (for example, see Robinson *et al.* 1999a), but it does appear to produce benefits. One attraction of the approach is that the intervention 'effort', which is usually limited by time and/or financial considerations, can be concentrated at a single target. Interventions that target a wider range of behaviours may experience an extent of dissipation of intervention effort in each of the behaviours and so reduce the overall impact of the intervention (for example, see Sahota *et al.* 2001). In addition, a number of published RCT in obesity prevention, and increasingly in obesity treatment, have targeted behaviours that are peripheral to the aetiology or management of obesity, such as consumption of fruit and vegetables (for example, see Epstein *et al.* 2001a; Sahota *et al.* 2001). Focusing on sedentary behaviour is more likely to target the intervention effort on the factor that is causally linked to obesity development and maintenance (reduced physical activity). This approach would also bring

the benefit of focusing trial outcomes on more measurable variables such as activity or inactivity. Most dietary outcome measures are not measurable with any confidence, and the practice of comparing one dietary assessment method of unknown validity against another of unknown or doubtful validity to provide a 'validation' remains common. An additional consideration is that the burden that dietary assessment places on subjects tends to increase drop out. Targeting sedentary behaviour may also have effects on a range of behaviours; there is some evidence that it can reduce energy intake, by changing eating habits, in both obesity prevention and treatment (Robinson, 1999a; Epstein *et al.* 2000). Evidence-based targets of prevention efforts are limited at present (Dietz, 2001), and it seems appropriate to focus interventions on those modifiable variables that are evidence based and most closely associated with the development of positive energy balance. Finally, it should be noted that inactivity is best considered as a distinct construct from activity. Determinants of activity and inactivity are likely to be different, and the more traditional model of targeting physical activity is not essential for paediatric obesity prevention (Dietz, 1996; Robinson, 1999a).

#### Ongoing research: obesity prevention

A major British Heart Foundation-funded obesity prevention RCT is now underway in Scotland, the Movement and Activity Glasgow Intervention in Children (MAGIC) Study. The intervention consists of a 24-week programme of structured physical activity that aims to both increase activity levels and improve basic motor skills. The intervention is delivered three times per week (90 min/week) in 3–4 year olds who attend nursery schools. The nursery-based intervention is supplemented with a home-based health education element that targets the reduction of sedentary behaviour. As noted earlier, our previous studies of TEE and physical activity (and inactivity) in representative samples of Scottish preschool children have shown that TEE is extremely low (Montgomery *et al.* 2002) and engagement in inactivity high (Jackson *et al.* 2002). These behavioural risk factors for obesity seem appropriate, therefore, for modification, particularly with the short- and long-term benefits that school-based interventions may bring (Story, 1999). Approximately 220 children have been randomised to the intervention and 220 to the control group, using a cluster randomisation design. The primary outcome is change in BMI SD score measured at baseline, +6 months and +12 month follow up. Secondary outcomes include the measurement of physical activity (Fairweather *et al.* 1999) and inactivity (Reilly *et al.* 2001a) by accelerometry, body fat distribution, body composition, blood pressure and motor skills. Researchers blinded to trial allocation will measure all outcomes. A pilot study for MAGIC, conducted over 12 weeks in sixty children, indicated that the intervention was associated with a significant improvement in both total activity (40 % increase in accelerometry output, as an index of total physical activity, on days on which the intervention was delivered, and 29 % increase on days on which it was not,  $P < 0.001$  in both cases; Fig. 1). The intervention was also associated with a significant ( $P < 0.01$ ) improvement in



**Fig. 1.** (a) Total activity as measured by accelerometry (counts/min per d) and (b) motor skills measure at baseline (■) and follow up (□) in control and intervention groups in the pilot study for the Movement and Activity Glasgow Intervention in Children Study, an obesity prevention randomised controlled trial underway in Scotland. Total activity was assessed at follow up on days on which the activity programme was implemented for the intervention group (□) and on which it was not (▨). Values are means and standard deviations represented by vertical bars. Mean values for total activity at follow up for the intervention group for both treatment days were significantly different from that for the control group: \*\*\*  $P < 0.001$ . For both the control group and the intervention group the mean value for motor skills measure at follow up was significantly different from that at baseline: \*\*  $P < 0.01$ . The magnitude of the difference from baseline for motor skills measure for the intervention group was significantly greater than that for the control group: ††  $P < 0.01$ .

motor skills (Fig. 1). Furthermore a process evaluation was encouraging: the intervention was easily implemented in the nursery school, well attended, enjoyed by nursery staff and pupils, and available at low cost. First results on the efficacy of the intervention from the MAGIC study should be available in 2005. The MAGIC study was intended to avoid the design problems that have affected older RCT in obesity prevention, and the aim was to test the efficacy of a simple low-cost intervention that could be implemented

more widely with minimal logistical problems. The secondary outcomes included in the design were intended to address the problems of outcome measurement noted in previous Cochrane reviews (Campbell *et al.* 2001b; Summerbell *et al.* 2002), to provide information on compliance with the intervention and the mechanisms underlying any effects. Major methodological difficulties have hampered research in this area and these issues are discussed later.

#### *Suggestions for further research: treatment*

Many of the comments made earlier in relation to interventions aimed at preventing childhood obesity apply equally to interventions aimed at treatment. Targeting sedentary behaviour appears to provide a treatment benefit that is greater than targeting lifestyle activity, and both strategies add considerably to the benefits of dietary treatment (Epstein *et al.* 1995, 1998, 2000; Robinson, 1999b). In addition to the major study design problems in older RCT in this area, there is a serious methodological problem; practical valid outcomes for many of the variables of interest are lacking, or need further methodological evaluation (Summerbell *et al.* 2002). Measurement of dietary energy intake in children is generally less prone to bias than in adults (Hill & Davies, 2001), but a wealth of evidence has shown that obesity produces similar reporting bias to that in adults, and this conclusion is true even in relatively young children (for example, see Maffeis *et al.* 1994). In addition, even the best available dietary assessment methods are time consuming, yet fairly imprecise, and accurate only at the group level (Reilly *et al.* 2001b). Further research on dietary assessment methodology may be of limited value if the attainable limits of precision and accuracy have been reached (Reilly *et al.* 2001b), and dietary intake data from obese children must be regarded as misleading. Other outcomes are also problematic; there is good evidence that body composition is more informative for intervention studies than proxies for body composition (such as body weight or BMI) in paediatric research (Reilly, 1998). However, methodology available is of limited accuracy (Wells *et al.* 1999), and can present practical problems (Reilly, 1998). At present, no simple method has been validated against a multicomponent reference (Reilly, 1998; Wells *et al.* 1999).

Methodological research on the measurement of physical activity and inactivity is more promising. Limitations in older self-report methodology have seriously weakened research in this area (Robinson, 1999a; Summerbell *et al.* 2002). The advent of objective methods such as accelerometry provides the possibility of valid and precise measurement of both activity (Fairweather *et al.* 1999) and inactivity (Reilly *et al.* 2001a), which is practical even in young children and in large-scale interventions.

#### *Ongoing research: obesity treatment*

A major Scottish Executive Health Department-funded obesity treatment RCT, the Scottish Childhood Obesity Treatment Trial, is underway in Scotland. The trial is intended to test the hypothesis that the behavioural change

strategies that have been shown to be successful in high-quality studies in the USA can be successfully adapted to the typical clinical setting in the Scottish Health Service, and can be delivered by a single health professional (a dietitian). The intervention consists of a 24-week programme that targets sedentary behaviour and employs a modified version of the 'Traffic Light' diet (Epstein *et al.* 2000), using the principles of behavioural change outlined in previous studies (for example, see Mellin *et al.* 1987; Epstein *et al.* 2000). The primary outcome of the study is change in BMI SD score, measured at baseline, +6 and +12 months. Secondary outcomes include measurement of physical activity and inactivity (by accelerometry), blood pressure, body fat distribution, body fatness and adverse effects (on growth and psychological health). Researchers who are blinded to trial allocation will measure all outcomes. The trial aims to enter approximately 110 6–10-year-old children to treatment or (typical care) control groups. Typical care consists of the low-intensity very general dietetic advice on healthy diet and increasing physical activity. First results from the Scottish Childhood Obesity Treatment Trial should be available in 2005.

### Conclusions

The evidence base for interventions in childhood activity, with the aim of prevention or treatment of obesity, remains limited. Simple, effective and generalisable interventions are lacking. This position reflects a combination of factors: the recent emergence of the childhood obesity epidemic, which was not obvious in the UK until 1999 (Reilly & Dorosty, 1999); limitations in trial design before the advent of the Cochrane and CONSORT processes; the major difficulties (methodological, financial, practical, ethical) presented by carrying out long-term research in this area. A wealth of new research is likely to improve our ability to address the childhood obesity epidemic, but this research should attempt to build on previous evidence and employ the most rigorous trial design available.

A number of previous studies have noted the possibility that the large-scale societal changes that have driven the obesity epidemic may be beyond the reach of interventions aimed only at the family or school environment (Luepker *et al.* 1996; Gortmaker *et al.* 1999; Sahota *et al.* 2001). Large-scale policy or strategic initiatives, employing macroenvironmental or 'ecological' approaches, may be essential if the public health impact of the childhood obesity epidemic is to be addressed (Koplan & Dietz, 1999; Swinburn *et al.* 1999). However, any such initiatives should also be evidence based and should be evaluated rigorously.

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