The West Midlands ActiVe lifestyle and healthy Eating in School children (WAVES) study: a cluster randomised controlled trial testing the clinical effectiveness and cost-effectiveness of a multifaceted obesity prevention intervention programme targeted at children aged 6–7 years

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Scientific summary

The WAVES RCT

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Scientific summary

Background

Childhood obesity is associated with adverse health and psychosocial outcomes, which continue into adulthood. Obesity prevalence doubles during the primary school years, suggesting that this period presents an important opportunity for delivering interventions aimed at preventing obesity. Systematic reviews show some evidence that school-based multicomponent interventions could effectively reduce obesity prevalence, but methodological weaknesses in existing studies suggest a need for further trials with a stronger design, reporting longer-term outcomes. Other limitations of previous trials include a lack of detailed process and implementation measures, the infrequent consideration of differential intervention effects in subgroups, the neglect of potential harms and the absence of cost-effectiveness analyses.

Objectives

1. How effective is the theory-based WAVES (West Midlands ActiVe lifestyle and healthy Eating in School children) intervention package, delivered at school level, in reducing adiposity in children, compared with usual practice?
2. For how long do any observed effects persist after active intervention has ceased?
3. What is the incremental cost-effectiveness ratio (ICER) of supplying the WAVES study obesity prevention intervention?
4. How effective is the intervention package at improving diet and increasing physical activity (PA), compared with usual practice?
5. What is the effect of the intervention on quality of life and body image dissatisfaction?
6. Does the intervention work differently by sex, ethnicity, level of deprivation or baseline weight status?

Methods

Design

The WAVES study was a cluster randomised controlled study, split across two randomisation groups, with an economic evaluation.

Setting

State primary schools in the West Midlands, UK, including pupils from a range of backgrounds, varying in terms of ethnicity, socioeconomic status and geographical location.

Participants

Eligible schools were within 35 miles of the University of Birmingham, included children in school years 1–5 (aged 5–10 years), had a minimum class size of 17 and were not in 'special measures'. Schools with a higher proportion of pupils from minority ethnic populations (South Asian and Black African Caribbean) were oversampled (ratio 3 : 1) to enable subgroup analyses. In participating schools, all year 1 pupils (aged 5–6 years) were eligible. Parents provided consent (mainly 'opt in') and children gave verbal assent for the study measurements.

Baseline assessment

Baseline data were obtained at the end of year 1 (pupils aged 5–6 years) prior to randomisation. Data were collected by the direct assessment of participating children in school by trained researchers using validated instruments and standard protocols, as well as from parent questionnaires. The primary

measure was assessment of height and weight, used to derive body mass index z-score (BMI-z). Other anthropometric assessment included measures of waist circumference, skinfold thickness (at five sites) and body fat percentage by bioelectrical impedance. Dietary intake was assessed using the Child And Diet Evaluation Tool 24-hour tick list, and PA was assessed over 5 days using Actiheart® monitors (CamNtech Ltd, Papworth, UK). Psychosocial measures included quality of life (Pediatric Quality of Life inventory), social acceptance (KIDSCREEN-52) and body image dissatisfaction. Preference-based utility was assessed using the Child Health Utility 9D (CHU9D) measure (© University of Sheffield 2008). Data on pupils' date of birth, sex, ethnicity and postcode were obtained from the parent questionnaire or school records.

Randomisation

A blocked balancing algorithm was used to randomise participating schools to either the intervention or the comparator arm. The algorithm randomly selected one of a number of allocation designs that minimised the imbalance between a set of prespecified covariate means (percentage of pupils who were eligible for free school meals; percentage of South Asian, black African Caribbean, white or other ethnic group background; school size). The first 27 schools [group 1 (G1) schools] were randomised within the first block, and 1 year later the remaining 27 schools [group 2 (G2) schools] were randomised within the second block, conditioning the balancing algorithm for the first block allocations.

Intervention and comparator

The 12-month intervention, targeting the school and family environment, encouraged healthy eating and PA through four inter-related components:

1. Helping teachers to provide opportunities for additional moderate to vigorous physical activity (MVPA) during the school day (aiming for an additional 30 minutes per day).
2. Participation in the 'Villa Vitality' programme, delivered through an iconic sport institution (Aston Villa Football Club) over 6 weeks. This programme promotes healthy lifestyles, in particular increased PA and healthy eating, and includes practical opportunities for PA and cooking skills, interactive learning and home-based activities.
3. Termly (three over the school year) healthy cooking workshops in school time for parents and children, focusing on healthy eating (with the key messages of increasing fruit, vegetable and fibre intake, and reducing fat and sugar intake) and practical skills.
4. Two information sheets to families signposting local PA opportunities.

Schools allocated to the comparator arm continued with their usual healthy lifestyle activities.

Outcome measurements

The primary outcomes were the difference in BMI-z between the trial arms at 3 and 18 months post intervention (clinical outcome), and the cost per quality-adjusted life-year (QALY) (cost-effectiveness outcome). The secondary outcomes included further anthropometric measurements; dietary, PA and psychological assessment; and difference in BMI-z between arms at 27 months post intervention in G1 schools. Outcome assessments were undertaken at 3 months (follow-up 1) and 18 months (follow-up 2) after the end of the intervention period (pupils aged 7–8 and 8–9 years). For half of the participating schools (G1 schools), children were further assessed 27 months (follow-up 3) after the end of the intervention (pupils aged 9–10 years).

Sample size

The sample size calculation was based on the primary outcome (BMI-z), taking into account repeated measures (estimated correlation between before and after measures = 0.9), varying cluster size (assuming mean cluster size of 25, standard deviation = 23) and probable estimates of the intracluster correlation coefficient (0–0.04). In order to detect a difference of a 0.25 BMI-z between intervention and comparator groups with 90% power, a two-sided alpha level of 0.05 and an estimated pupil dropout rate of 20%, a follow-up sample of 1000 children from 50 schools was needed. Allowing for school dropout of 8%, we recruited 54 schools to take part in the study.

Economic evaluation

The cost-effectiveness of the intervention compared with no intervention was assessed from a public sector perspective using a trial-based cost–utility analysis. Costs were based on cluster-level resource use for intervention delivery, and the primary outcome was QALYs using CHU9D at 18 months post intervention. In the base case, missing data were imputed to estimate the incremental cost per QALY gain. A secondary analysis was based on cost per obesity case prevented. All costs were expressed in the year 2014. Missing data were addressed using multiple imputation methods and the uncertainty surrounding the cost-effectiveness estimates was examined through the use of the net benefit regression framework.

Results

Twenty-seven schools ($n = 650$) were randomised in 2011 (G1), and another 27 ($n = 817$) were randomised in 2012 (G2). At first follow-up (3 months) and second follow-up (18 months) for the primary outcome, data were available for 1249 and 1145 pupils, respectively, from 53 schools. The mean difference (MD) in BMI-z between control and intervention arms was –0.075 [95% confidence interval (CI) –0.183 to 0.033] at 3 months and –0.027 (95% CI –0.137 to 0.083) at 18 months post intervention. There was no significant difference in any of the secondary outcomes between the arms for the main analyses for the first two follow-up periods.

The third follow-up (27 months) included data on 467 pupils from 27 G1 schools and showed a statistically significant difference in BMI-z in favour of the intervention group (MD –0.20, 95% CI –0.40 to –0.01, in partially adjusted models; MD –0.18, 95% CI –0.34 to –0.02, in fully adjusted models). Post hoc analysis in response to this finding showed heterogeneity between G1 and G2 schools, with a significant difference in mean BMI-z at baseline. School group-specific analyses showed an intervention effect in G1 schools, at 3 and 18 months, of a similar size to that observed at 27 months. However, there was no significant effect in G2 schools. There was no statistically significant intervention effect for the other anthropometric measures, although the direction of effect for all, apart from the sum of four skinfolds, favoured the intervention. There was no difference between groups in terms of quality of life, self-perception or body image dissatisfaction, suggesting that there was no evidence of harm from the intervention.

Subgroup analyses showed no evidence of heterogeneity of effects by sex, ethnicity, household deprivation or baseline weight status. Sensitivity analyses did not alter the findings.

Results of economic analysis

For the primary economic analysis, the mean cost of the intervention was £155.53 per child, taking account of all of those who received the intervention, or £266.35 per child when including only those who were included in measurements. The incremental cost-effectiveness of the intervention compared with no intervention was £46,083 per QALY in the base case (including only children with measurements) or £26,804 per QALY if we assume that the sample with measurements was representative of the wider population who received the intervention. There is much uncertainty around both estimates because of the lack of significant intervention effect in terms of QALY gains. The intervention is, therefore, not cost-effective using National Institute for Health and Care Excellence-recommended willingness-to-pay threshold levels of £20,000–30,000 per QALY. It was not possible to report the secondary outcome of cost per obesity case prevented, as the primary analyses showed no evidence of effect.

Conclusions

The primary analyses show no evidence of effectiveness of the WAVES study intervention in reducing BMI-z at 3 or 18 months. The lack of cost-effectiveness is mainly due to the lack of clinical effectiveness, which led to a high level of uncertainty around the ICERs.

The exploratory post hoc analysis, driven by findings at third follow-up, suggests a clinically important difference in BMI-z between arms in favour of the intervention, which was sustained over 27 months in G1 schools. Baseline imbalance in the main outcome in G2 schools may have contributed to the observed group difference. This interpretation needs caution, given the absence of evidence of effectiveness in terms of behavioural outcomes.

Detailed process evaluation suggests variation in delivery and perceived impact of intervention components. The WAVES study intervention was well received and valued at various levels by schools, children and their parents. The Villa Vitality, daily PA and cooking workshop components were particularly appreciated and relatively well implemented. Given the acceptability and feasibility of delivery and the lack of evidence of harm, the last two components, which have a lower overall cost, could be taken up by schools to fulfil their mandatory functions in relation to healthy lifestyles.

Future work

Schools are important settings for accessing children and their families, but are one of several levels of environments that influence behaviour. The delivery of knowledge and skills to support healthy lifestyles is one of the mandatory functions of schools and is recognised by school staff as a contributor to children's wider well-being. Future school-based interventions need to be integrated within a wider societal framework and supported by upstream interventions. This includes having supportive policies to promote social and environmental change. Interventions at multiple levels are needed to tackle the complex set of interacting factors that contribute to childhood obesity.

In terms of methodology, future cluster randomised controlled trials need to include appropriate steps to ensure a balanced allocation of intervention and control across key characteristics, to reduce the risk of chance bias.

Trial protocol

The trial protocol is available at www.ncbi.nlm.nih.gov/pubmed/?term=adab+pallan+waves+protocol.

Trial registration

The trial is registered as ISRCTN97000586.

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