NIHR Public Health Research programme

NHS National Institute for Health Research

PHR Protocol - project ref: 09/3005/04
Version: Version 1
Date: 03/05/11

Active for Life Year 5: A cluster randomised controlled trial of a primary school-based intervention to increase levels of physical activity, decrease sedentary behaviour and improve diet.

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Sponsor	University of Bristol
Funder	NIHR Public Health Research Programme
NIHR Portfolio number	09/3005/04
ISRCTN registration (if applicable)	ISRCTN50133740

Active for Life Year 5: A cluster randomised controlled trial of a primary school-based intervention to increase levels of physical activity, decrease sedentary behaviour and improve diet.

1. Aims/Objectives:

The aims of AFLY5 are to determine the effectiveness of the intervention in children aged 9-10 years to improve the following primary outcomes:

1. Daily time spent in, and amount of, physical activity.
2. Daily time spent in sedentary behaviour.
3. Portions of fruit and vegetables consumed per day.

And secondary outcomes:

1. Time spent screen-viewing per day.
2. Portions of: snacks; high fat foods; and high energy drinks consumed per day.
3. Body mass index (BMI).
4. Waist circumference (WC).
5. Whether overweight/obese.

The aim is to determine whether the intervention affects these outcomes in the short-term (i.e. immediately at the end of the intervention) and in the longer term (i.e. 12 months after the end of the intervention).

2. Background:

Low levels of physical activity, high levels of sedentary behaviour and low levels of fruit and vegetable consumption, all of which are associated with adverse health outcomes, are common in children in the UK and other high income countries.[1-7] Since almost all children attend school, school-based interventions have the potential to efficiently change behaviours to be more health promoting. However, current evidence for the effectiveness of school-based interventions is limited by important sources of bias.

A Cochrane systematic review of school-based physical activity programmes in children and adolescents identified 26 relevant studies (15 randomised controlled trials (RCTs) and 11 quasi-experimental studies).[8] The majority (16/26) of studies were from the US, with none from the UK. In all but one study the intervention included curricular-based activities that provided physical activity during school hours. Of nine outcomes assessed, school-based physical activity interventions showed a beneficial effect on four: duration of physical activity (achieved largely by increased activity in school), television viewing, cardio-respiratory fitness and blood cholesterol.[8] Two key weaknesses of most studies included in the review were noted. First, the vast majority used self- or parental-report of physical activity and sedentary behaviours and there was some evidence that the use of self-report biased results towards a more beneficial impact of the intervention.[8] Second, all but one study examined outcomes only at the end of the intervention. This is an

important weakness since a key effect was likely to be the direct result of increased class-based physical activity, which to some extent the children are compelled to do. Whilst this is likely to be beneficial in the short term it is also important to know whether healthy behaviours continue beyond the period of the intervention.

A systematic review of controlled studies with interventions to reduce sedentary behaviour identified 12 studies (11 RCTs and 1 quasi-experimental); 6 were in clinical obese populations and 6 were general population prevention studies.[9] All of the general population prevention studies were school-based, of which 5 were curriculum-based with health promotion activity lessons; one was extracurricular only (after school dance classes and home visits). In all 6 studies screen viewing time declined markedly in children from the intervention schools (decline ranging from 43% to 16%) and either decreased only slightly or increased in the control groups (ranging from 14% decline to 12% increase).[9] Outcomes were only assessed at the end of the intervention and parental/child report of sedentary behaviour was used for the key outcome measure in all six studies.

At least ten published systematic reviews of school-based intervention studies aimed at preventing childhood overweight/obesity have been published.[10] Differences in the reviews include the time periods of the reviews, the inclusion and exclusion criteria, whether meta-analysis was undertaken and how outcomes were assessed. Two included meta-analyses and these both reported a protective effect of school-based interventions: odds ratio of overweight or obesity of 0.74; 95% CI: 0.60 to 0.92[11] and a standardised mean difference in weight of -0.29; 95% CI: -0.45 to -0.14.[12] There is some evidence that the quality of trials has improved over time.[10] However, the vast majority of trials are from the US, most assessed outcomes only at the end of the intervention and few used objective measurements for assessing changes in physical activity and sedentary behaviour.[10]

We have completed feasibility and pilot work of a school-based intervention – Active for Life Year 5 (AFLY5) – which is aimed at increasing physical activity, reducing sedentary behaviour and increasing consumption of fruit and vegetables in 9-10 year olds.[13][14] The intervention is adapted for the UK school context from the Planet Health and Eat Well Keep Moving intervention from the US.[15] Our feasibility and pilot work demonstrates that AFLY5 is acceptable and feasible to deliver, and appears to have beneficial effects on physical activity, screen viewing and fruit and vegetable consumption.[13][14]

Although the underlying causes for the pattern are unknown, recent evidence suggests that most childhood weight gain occurs in mid-childhood (age 7-11 years) in UK children.[16][17] If further research confirms that changes in diet, physical activity and sedentary behaviour around this age are related to this increase in weight gain, the AFLY5 intervention (aimed at 9 to 10 year olds) may be particularly important to improving public health should it turn out to be effective in generating healthy changes in these behaviours.

3. News:

4. Methods:

a. Setting
State-run primary / junior schools in the areas covered by Bristol City and North Somerset Councils. Both of these are located in the South West of England.

b. Design
School-based cluster randomised controlled trial.

c. Recruitment and randomisation
All state primary and junior schools with children in Years 4-6 (aged 8-11) in the area covered by Bristol City Council and North Somerset Council will be invited to participate. Both of these areas are in the South West of England and include a range of levels of deprivation, as well as urban and rural areas. Special schools (that is, those for children whose additional needs cannot be met in a mainstream setting) will be excluded because they are unlikely to be teaching the standard national curriculum and the children may not be able to take part in all the measurements. Participants will be children in Year 4 at the recruitment stage. Baseline assessment (prior to intervention) will be undertaken when these children are in the final terms of Year 4. The intervention will take place when the children are in Year 5. Figure 1 shows the planned flow of participants through the study.

Randomisation procedure
Prior to inviting schools to participate we will identify all local and national initiatives that currently target primary/junior schools and are aimed at increasing physical activity, decreasing sedentary behaviour and improving diet. We will include a brief questionnaire with the letter of invitation to schools requesting information on involvement of the school in any initiatives to change the children's behaviour that our intervention is aimed at influencing. We will use this information to define recruited schools as high or low involvement in current initiatives. We will define recruited schools as high, mid or low-deprivation by thirds of English Government's school deprivation indicator.[18] We will group schools by level of involvement in current initiatives and thirds of deprivation score (total of 6 groups/strata) and randomly allocate them within these strata to control or intervention. Randomisation will be undertaken by a researcher unaware of any characteristics of the schools and will be concealed by using the Bristol Randomised Trials Collaboration's automated (remote) system.

d. Data collection
Children will be assessed on three occasions, planned to take place at the following times:

1. Baseline, between April-July 2011, when the children are in school Year 4.
2. Immediate follow-up, between April-July 2012, when the children are in school Year 5 and at the very end of the intervention.
3. 12 months long-term follow-up, between April-July 2013, when the children are in school Year 6.

At each assessment the following will be measured/collected.

Outcome measurements

The **primary outcomes** are:

1. Accelerometer assessed mean time per day spent doing moderate/vigorous physical activity (MVPA).
2. Accelerometer assessed mean time per day spent in sedentary activity.
3. Self-reported (validated questionnaire) portions of fruit and vegetables consumed per day.

The **secondary outcomes** are:

1. Self-reported (validated questionnaire) mean time spent screen-viewing.
2. Self-reported (validated questionnaire) portions of: snacks; high fat foods; and high energy drinks consumed per day.
3. BMI determined from weight and height measured in classrooms by two study fieldworkers.
4. WC measured in classrooms by two study fieldworkers.
5. Overweight/obesity, determined by appropriate gender and age specific thresholds from BMI and WC growth charts.

We do not see the timing of follow-up (immediate or 12 month long-term follow-up) in terms of primary or secondary outcomes, but rather as having equal importance in assessing the primary and secondary outcomes (as above) at these two different time points.

A cost consequence analysis will be conducted in which the costs to society of the intervention will be compared with both primary and secondary outcomes.

The potential **mediators** (based on Social Cognitive Theory [19]), that we will assess among children are:

1. Physical activity and sedentary behaviour self-efficacy.
2. Fruit and vegetable consumption self-efficacy.
3. Report of parental support for physical activity.
4. Report of parental support for consuming healthy levels of fruit and vegetables.

Assessments will be undertaken by trained fieldworkers who will have completed enhanced criminal records bureau (CRB) checks as required for those working with children in the UK. The fieldworkers will not be told which schools have been allocated to which arm of the trial. At each stage of assessment (baseline, immediate- and 12 month long-term follow-up) the following will be measured on the children in both intervention and control

schools:

Accelerometer assessment of physical activity and sedentary behaviour. We will use ActiGraph accelerometers[21] and the same protocol that we used in our feasibility/pilot work. Accelerometers will be set to record at 10-second epochs on the day after the accelerometers are handed out. Where possible, accelerometers will be given out on a Wednesday and will be collected the following Tuesday, downloaded, recharged, reinitialised and taken to the next school the following day. The accelerometers will be shown to the children and verbal instructions provided in the class room with all children together. Each child will be given their accelerometer individually at the time of the anthropometric measurements and the child will be asked what they remembered about when the accelerometer should be worn and removed. They will be asked to wear them during the day (except when bathing or swimming or participating in contact sports such as karate) until the fieldworkers return to collect them. This will allow data collection on three weekdays (Thursday, Friday and Monday) and both weekend days. We will use established procedures for analysing the accelerometer data and calculate time spent in MVPA and sedentary behaviour.

Weight, height and waist circumference. All anthropometric measurements will be completed with children in a private room with both CRB checked trained fieldworkers present. Weight will be measured without shoes in light clothing to the nearest 0.1kg using a Seca digital scale. Height will be measured, to the nearest 0.1cm, without shoes using a portable Harpenden stadiometer. Fieldworkers will be trained to ensure correct position for height assessment. WC will be measured the nearest 1mm at the mid-point between the lower ribs and the pelvic bone[22] with a flexible tape. BMI and WC will be used to define whether a child is generally overweight/obese (using BMI) or centrally overweight or obese (WC), using appropriate gender and age specific thresholds from BMI and WC growth charts.[23-25] For BMI we will use both international obesity task force thresholds and those based on the UK 1990 growth charts[23] and will compare results using these two different definitions.

Questionnaire assessment of diet, physical activity and sedentary behaviour. Fruit and vegetable consumption and other dietary outcomes will be assessed using the “A Day in the Life Questionnaire” (DILQ),[26] which was used in our feasibility/pilot studies.[14] The DILQ provides information about the children’s entire food and drink intake the previous day. To improve recall the questionnaire is structured with sequential questions in a 24 hour segmented school day. Fruit and vegetable consumption and other dietary outcomes will be assessed using an established scoring scheme.[14][27][28] As in the pilot study, allocation of foods written in text to categories will be undertaken independently by two individuals with discrepancies checked by a third independent individual, and a random 5% further coded by another researcher to check for accuracy. In the pilot/feasibility work there were very high levels of agreement (>97%).[14] An abbreviated and updated version of a

previously validated screen viewing questionnaire was used to assess self-report sedentary behaviour in our feasibility/pilot study and this will be used here.[29] The questionnaire asks about the length of time spent doing screen based activities on the previous weekday and Saturday. The changes that we made (with the author's permission) included adding new media, such as Xbox and Play Station, and removing detailed questions about the number and location of TVs in the house and eating whilst watching TV, in order to reduce the length of the questionnaire.

Mediators assessment. We hypothesise that change in physical activity and fruit and vegetable consumption will be mediated by change in the child's self-efficacy. As the study is designed to increase parental support for physical activity we also hypothesise that parental support will function as a mediator of behaviour change. Increasing our understanding of the mechanisms of behaviour change is essential for designing and delivering more effective interventions and establishing how to disseminate a complex intervention that has been shown to be effective in one setting to another setting.[30] Therefore, we will assess four hypothesized mediators using well-established scales that have been shown to have good reliability among primary school aged children. Specifically, physical activity and screen-viewing self-efficacy will be assessed using the 9-item scale of activity and sedentary behaviour self-efficacy[31] and fruit and vegetable self-efficacy will be assessed using an 18-item scale that assesses child's self efficacy for this behaviour.[32] Parental support for physical activity will be assessed using the 18-item, child completed Activity support questionnaire which provides information on parental logistic support (that is, transport to activity venues, facilitating participation in organised activities), parental modelling of physical activity behaviours and parental support for reducing screen-viewing.[33][34] Perceived parental modelling for consuming fruit and vegetables will be assessed using a 15-item scale.[35]

All questionnaires will be combined into one document and administered in the classroom (self-completed by the school children) with a fieldworker and teacher present to answer any queries and to assist the children with reading and writing as necessary. The fieldworkers and teachers will be instructed only to help with reading and spelling specific words and not to suggest answers to any questions.

Collection of information on resource use and costs. Resource use related to the administration of the intervention in the form of time, travel and materials will be collected through trainer and teacher time and resource logs completed over the intervention period. A parental completed postal questionnaire will be administered at the end of the intervention. The parents will be asked about their time spent in helping children with relevant homework, and taking children to and attending out of school activities, as well as any cost involved. They will also be asked about health service use in relation to exercise related injury in their child. To facilitate the completion of this questionnaire resource use logs, in which they can record this information,

will be given to parents at the beginning of the year in which the intervention takes place. In order to compare costs between intervention and control schools the same questionnaire will be sent to parents at all schools.

d. Data analysis

The presentation of findings from the trial will be in accordance with CONSORT guidelines for cluster RCTs.[34] Descriptive statistics (comparisons of means, medians or % as appropriate) will be used to assess any marked differences between intervention and control schools at baseline in terms of the outcome measurements, gender, age, school deprivation, participation of schools in other initiatives to promote healthy behaviours and neighbourhood characteristics.

The primary effectiveness analyses will be conducted on an intention to treat basis, with secondary (explanatory) analyses conducted first comparing outcomes in all control schools to outcomes only in those schools that completed at least 70% of the lessons, and secondly employing instrumental variables regression models to address the question of causal effect if the intervention were applied as intended.[37] For the instrumental variables regression analyses we will use the method proposed by Greenland for cluster RCTs.[37] Comparisons of means for the primary and secondary continuously measured outcomes will be presented as mean differences or ratios of geometric means with 95% confidence intervals. Odds ratios and 95% confidence intervals will be presented for binary outcomes. Estimates will be obtained from linear (or logistic) regression with adjustment for baseline measurements of the outcomes as well as age and gender in order to improve precision. Clustering will be accounted for by using random effects regression models.

In secondary analyses we will compare effects stratified by gender and then by thirds of deprivation. Here we will focus on marked differences in point estimates. Although we will employ interaction terms to formally investigate differences in effects between these subgroups in the relevant regression models, their power will be limited given the primary research aim (and focus of the sample size calculation) on the main effect of the intervention.

Economic evaluation

The economic evaluation from a societal perspective will take the form of a cost consequences analysis. This approach is chosen given the number of important primary and secondary outcomes. Resources will be valued as reported by researchers, teachers and parents and using routine data sources. The differences between the two arms in terms of mean cost will be calculated, adjusting for variables and accounting for clustering as in the main analysis and using bias corrected confidence intervals, derived using bootstrapping techniques if necessary. Any methodological or parameter uncertainty will be examined through a series of one way sensitivity analyses.

5. Project Management:

The **programme manager** (S Wells) will be responsible for the day-to-day management of the study, including managing data collection, entry and analysis and the project budget. She will line-manage the study administrator and fieldworker staff.

The **trial administrator** (J Brown) will support the applicants and all staff with administrative tasks. They will organise appointments with the schools for outcome and audit data collection; will organise and take minutes at meetings of the Trial Management Group, Local Advisory Group and Trial Steering Committee and will ensure all information (electronic and paper) sources are appropriately labelled and stored.

The full-time study **fieldworkers** (A Blackett and D Hucker) will write standard operating procedures (SOPs) for all aspects of data collection and will be responsible for implementing these as they collect data from study participants. They will update SOPs as necessary and log any changes as data collection proceeds.

We have formed a **Trial Management Group (TMG)** which will is chaired by Professor Lawlor and includes all of the investigators, the trial coordinator and all other study staff. Currently, the TMG meets every two months to discuss all key issues relating to the conduct of the study and to note action points and ensure that these are all implemented. Monthly meetings have been scheduled for the first 12 months of the study. If appropriate, these will be reduced to every two months after the first 12 months and the frequency will be monitored according to needs.

We will form a **Local Advisory Group (LAG)** of teachers, school administrators and parents (including a head-teacher and parents from the pilot/feasibility study schools) to advise on the delivery of the intervention and provide guidance on any school-related issues that might arise during the course of the intervention. The LAG will meet once per term during the intervention year and immediately before the follow-up assessment.

We are forming a **Trial Steering Committee (TSC)** for the study. The TSC will include an independent chair plus three other independent external members and senior members (all applicants and the programme manager) of the study team. Prof Janet Cade, University of Leeds, has agreed to be the independent chair of the TMC. Prof Naveed Sattar, University of Glasgow has agreed to be one of the other members of the TSC and Dr Chris Bonnell, London School of Hygiene & Tropical Medicine, and Prof Sandra Eldridge, Queen Mary's London, have been invited to be the other two members (their responses are still awaited). The TSC will have its first meeting September 2011 and will meet annually thereafter. If any concerns arise during conduct of the study – for example, problems with recruitment / loss to follow-up / difficulties arranging measurements in the schools – we will arrange additional ad-hoc meetings of the TSC, which may be face-to-face of via teleconferencing depending on the chair after initial discussion regarding the problem between the PI and the chair.

6. Service users/public involvement:

Parents from the schools involved with the study will be represented on the LAG (see above) and information about the trial and eventually the results will be disseminated to teachers and parents in the school via their newsletters. We will also involve the DECIPHer youth advisory team (http://www.decipher.uk.net/YouthAdvisoryGroup.html) in development of the protocol for dissemination of the results to all school children (both those involved in the study and more broadly across the UK). The School of Social and Community Medicine, University of Bristol, where the trial is based currently run a number of school based trials and cohort studies of school aged children. We are also involved with a number of international collaborations of studies in children. We will use experience across studies in the School and our international collaborations to obtain information on involvement of children in research and for developing protocols for best practice for appropriately doing this.

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This protocol refers to independent research commissioned by the National Institute for Health Research (NIHR). Any views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NHS, the NIHR,
the PHR programme or the Department of Health.