

09/3001/19 - Does the Royal Horticultural Society Campaign for School Gardening increase intake of fruit and vegetables in children?

Protocol

Background

Little is known of the impact of projects (or interventions) involving gardening and growing programmes, on children's diet and health. There are, however a number of studies that have assessed the impact of interventions designed to increase children's intake of fruit and vegetables. The literature in this area is summarised below. The following questions were considered when reviewing this literature. Which types of interventions have been successful in terms of increasing fruit and vegetable intake? What do we know about the defining elements of successful interventions? What recommendations can be made on future interventions particularly with respect to this current proposal?

The British Nutrition Foundation conducted a review of the psychosocial basis of food choice to provide evidence to explain how to influence food choice in children (1). How children make their food choice is central to understanding whether interventions to affect diet might work. The main findings of relevance to young children were: the 'one size fits all' approach to intervention design does not seem to work well in any setting; and tailoring is necessary, particularly for different subgroups (e.g. the need to make information culturally appropriate). Tailoring interventions for different cultural settings is a key consideration. Message reinforcement appears to be important for sustained interest in the intervention/ programme. This is relevant from a school gardening perspective which requires repeated attention to prepare the ground, plant, tend and harvest. Efforts to change behaviour benefit from a supportive environment e.g. the whole school approach which involves teachers, parents, the community, canteen staff and the pupils. Successful interventions have generally combined nutrition education with

environmental support and this may extend to gardening activities. The RHS Campaign for School Gardening which is to be evaluated uses parent helpers where available to help with the garden. Several studies have shown the concept of familiarisation is important for children. Studies suggest that uptake of fruit and vegetables can be promoted if children are exposed to 'healthier' foods via teaching, through peer modelling, via the cafeteria and in vending machines. For example, children who were introduced to new foods using 'hands-on' activities in the classroom were 3-20 times more likely to subsequently choose and eat these foods in the canteen than children who did not have prior exposure (2-4).

Thomas et al undertook a systematic review of barriers and facilitators to eating fruit and vegetables (5). In this review the authors considered what kinds of interventions are effective. Some studies presented their results according to increases in fruit only and vegetables only, as well as for fruit and vegetables combined. With three exceptions, increases in portions of fruit consumed were larger than increases in portions of vegetables consumed. It appears that interventions targeting an increase in fruit and vegetables mainly increase the amount of fruit consumed – vegetable consumption does not increase by more than one third of a portion as a result of any of the interventions evaluated. Indeed our own evaluation of the School Fruit and Vegetable Scheme (SFVS) concurs with these findings (6). The reason why fruit rather than vegetables may be increased is that fruit is usually provided as a snack food for children to eat. Children therefore have more exposure to fruit and eat more of it.

Ciliska undertook a review of the effectiveness of community interventions to increase fruit and vegetable consumption in people four years of age and older (7). One study showed there was a significant increase in consumption of broccoli, carrots, spinach salad and green beans. The programme significantly improved the knowledge of students in kindergarten to grade 5, but not of those in grade 6. There was also a significant improvement in attitude towards eating nutritious foods and vegetables, but not towards eating new foods.

A further review by Contendo *et al* has shown that nutrition education programmes should be ongoing and multifaceted. The more effective programmes are those that are behaviourally- focused and based on appropriate theory and prior research. This review also found that effective programmes use a combination of contemporary models of individual, social and environmental change. Studies based on a more

didactic teaching approaches were not very effective in bringing about behavioural change (8).

A more recent systematic review by Knai *et al* synthesised data on those interventions that might lead to increasing children's intake of fruit and vegetables. Fifteen recent studies were identified. None of the studies reviewed had a detrimental effect on fruit and vegetable consumption and 10 studies had a significant effect, ranging from +0.3 to +0.99 servings/day. The authors concluded that the evidence is strongest in favour of multi-component interventions to increase fruit and vegetable consumption in children (9).

There is some evidence that interventions that include gardening and growing activities has an effect on diet. For example a study by Morris showed that including gardening in the curriculum improves children's nutritional knowledge and preference for some fruit and vegetables (10).

The implications of this review to this project are as follows. It continues to be a challenge to increase children's intake of fruit and vegetables; however, some change is possible. Interventions need to include active learning such as cooking and growing, taste testing, access to fruits and vegetables at meal times and if possible, parental involvement. Bigger effect sizes can be expected from interventions which promote a focussed health message and build on ideas for appropriate interventions derived from children's views and experiences. Behavioural modification techniques using repeated exposure to initially novel foods are successful at increasing willingness to consume the foods but only if tasting was part of the exposure. Teacher preparation time must be kept to a minimum and training and support needs to be considered to ensure successful implementation in schools. Successful interventions also depend on the enthusiasm of staff and parents.

These questions are important because recent national surveys have shown that approximately one in ten children under 10 years is obese and this figure rises to one in four by the age of 16 years (8). Obesity tracks from childhood to adulthood (8). Current trends suggest that around 8% of obese 1–2-year-old children will be obese when they become adults, while 80% of children who are obese at age 10–14 years will become obese adults, particularly if one of their parents is also obese (11). A diet rich in fruit and vegetables may offer some protection against obesity and help

in its management because these foods are low in fat and less energy dense than many other foods popular with children (7).

In addition fruit and vegetables provide a wide range of nutrients and bioactive components important for health. Evidence suggests fruit and vegetable consumption can prevent a number of chronic diseases in later life such as cardiovascular disease, cancer and a range of childhood illnesses including some cancers and respiratory conditions reference.

Recent national surveys have shown that children in the UK are not eating the recommended 5 portions of fruit and vegetables per day. On average children are only eating 2 of the recommended 5 portions of fruit or vegetable a day and 1 in 5 children eat no fruit in a day. At present only 4% of 4-6 year olds eat the recommended 5 portions a day (12).

Since the introduction of the School Fruit and Vegetable Scheme in English primary schools in 2002 three studies have shown some improvements in children's intake of these foods while they participate in the scheme during Key Stage 1. However when pupils leave the scheme their intake of fruit and vegetables falls. Other interventions and educational activities are required to help sustain and improve children's intake and interest in these foods as they progress through Key Stage 2. Without further encouragement to eat fruit and vegetables at school the important benefits derived from participating in the SFVS will be lost without accruing the wider benefits to public health.

There is evidence that children from deprived backgrounds eat less fruit and vegetables (12). However, a recent analysis by our group at the University of Leeds has shown children's consumption of fruit and vegetables increases in association with school initiatives to educate children about these foods (including growing and gardening projects) (13). We are very keen to explore this further.

This proposal would take forward and strengthen the impact that school based gardening can have on children. The RHS Campaign for School Gardening has already started in two government regions. A Regional Advisor in each region is working with 10 Partner Schools to develop teachers' practical horticultural skills, assist the development of school gardens and embed the rewarding practical activities that children enjoy so much into the curriculum whilst encouraging healthy eating and a love of the green environment.

The Campaign also offers email support from the Regional Advisor, an interactive website with Schools' Benchmarking Scheme to encourage schools to plan and chart their gardening progress. Schools are awarded prizes for each level they achieve and can access additional resources at each easily achievable level as they progress.

The RHS Campaign for School Gardening works closely with the National Healthy Schools Initiative. Findings from this research will help to strengthen and support the positive role of gardening in developing a healthy lifestyle in young children. The results could be used to help recruit more schools to the programme which is important for the national roll out of the Campaign and impact on public health. It will help to help attract further funding from external bodies to support the posts of Regional Advisers who support schools taking part in the Campaign for School Gardening. A conference would be held in conjunction with the RHS following the results of the study to disseminate the findings to a wider community of schools, health professionals and academics. The RHS has high profile publications and media representation to support dissemination alongside publications in the academic press.

This study will provide data on whether the RHS Campaign for School Gardening has an impact on fruit and vegetable intake have an impact on the diet of children. It will clarify the nature of any impact and provide important information on whether and how the diet of children may be improved.

Aims

- Can the RHS Campaign lead to increases in vegetable and fruit intake in children aged 8-9 years?
- Does a programme of practical, structured gardening education have an impact on the diet of children in KS2 (age 8-9 years)? This seems like an overall aim whereas the following points are objectives and measure something specific don't you think?
- Does the RHS Campaign affect children's intake of other food and drink e.g. savoury snacks, confectionery products, soft drinks?

- What is the effect of the RHS Campaign on intake of key nutrients (fat, carbohydrate, protein, vitamin C, carotene, iron, sodium, folate)?

Methodology

This study will use two linked randomised controlled trials. 1) Schools in the RHS Campaign for School Gardening will be randomised to receive an intensive or less intensive intervention. 2) Schools not originally part of the RHS Campaign for School Gardening will be randomised to receive the less intensive intervention or a control condition.

Study population

Inclusion criteria common to both trials

Primary maintained schools from London boroughs with classes in key stage 2 (years 3-6) will be included. List boroughs Schools should have a minimum year group size of 15 pupils.

Exclusion criteria common to both trials

Independent schools, special schools and schools without all 4 year groups in key stage 2 at primary school (years 3-6) and small schools with less than 15 pupils/year group will be excluded. Schools that have previously participated in externally supported school growing projects will be excluded from the trial.

Trial 1 inclusion criteria

Schools which meet all the above criteria and have signed up to take part in the RHS Campaign for School Gardening (and who have undertaken the benchmarking process).

Trial 2 inclusion criteria

Schools which meet all the common criteria and who have not signed up to take part in the RHS Campaign for School Gardening by the time of randomisation of schools in trial 1.

Proposed sample size

Cluster randomisation will be used, randomising at the school level, because the intervention will involve whole schools and classes. Based on results from our previous work on schools in a national sample using CADET in Project Tomato, we

estimate the standard deviation for the amount of vegetables eaten to be 85g and for fruit 143g. The associated intraclass correlation coefficient for total vegetables from Project Tomato was 12.5% and for fruit 11.4% (12). This A sample of 50 children (one year 3 class and one year 4 class) from each school, will give a design effect of approximately 6.6 for vegetables and 7.1 for fruit to take account of the cluster randomisation. To have 90% power to detect a 0.5 portion difference in vegetable intake, 627 per group are required, i.e. about 13 schools. To have 90% power to detect a 1 portion difference in fruit intake, 482 per group are required, i.e. about 10 schools. Based on results from our evaluation of the SFVS, 75% who completed CADET at baseline also completed the final follow up CADET. To allow for this margin of safety, 16 schools per group will be selected in each group apart from the intensive intervention group where it is only possible for 10 schools to be involved. The size of effect the study is powered to detect, (one half of a portion of vegetables or one portion of fruit) was chosen because it was considered the smallest improvement in intake that was worthwhile detecting with an achievable sized sample, and considering the nature of the intervention.

Trial 1 – Schools in the RHS Campaign for School Gardening

The RHS plan to establish their Campaign for School Gardening to schools in the London region in the autumn of 2009. The RHS Campaign provides intensive support in each region to 10 schools through support from an RHS School Gardening Regional Advisor (the intensive intervention). The remaining schools, have access to support through twilight training sessions for staff and other activities (see below for detail of intervention).

We will recruit 26 schools from five boroughs in London. This will be done through the RHS contacting all schools in these boroughs with a letter about the trial and asking for their permission for the school to be contacted directly by the study team.

The schools will represent a range of geographical locations and urban/rural sites. Of the 26 schools we will randomly allocate 10 schools to receive the intensive intervention and 16 schools to receive the less intensive intervention. Schools will be randomly allocated to the intensive intervention or the less intensive intervention using block randomisation within strata defined by geographical area and measures of ethnicity (% non-white) and deprivation (% free school meal index). For ethnicity and deprivation, these will be split at the median or could use tertiles which NFER did for %FSME. Block randomisation uses blocks of two because allocation will take

place in one go, so there will be no opportunity for prediction of which group the schools will be in. This approach will guarantee balance on these important variables. The allocation sequence will be generated by the trial statistician. All schools will be allocated at the same time. Time between notification of allocation and the start of the intervention will be as short as possible. It will not be possible to randomise schools to receive no intervention at all since the RHS is committed to providing support to all schools who register an interest in the Campaign. As a consequence of this, we will recruit a second set of schools into a linked trial.

Trial 2 – schools not originally in the RHS Campaign for School Gardening

In order to avoid volunteer bias in a non-randomly allocated comparison group we will undertake a second linked trial. Following selection of schools into trial 1, we will contact schools from two additional boroughs in London. We anticipate that these two boroughs will have approximately 130 primary schools. We will aim to recruit 32 schools into the second trial. Of these schools, 16 will be randomly allocated to sign up to the RHS Campaign for School Gardening and to receive the less intensive intervention and 16 schools will act as comparison schools. As in trial 1, schools will be randomly allocated to the associate intervention or the comparison group using block randomisation within strata defined by geographical area, ethnicity and deprivation to guarantee balance on these important variables.

Blinding: it will not be possible to blind schools to their intervention group because of the nature of the intervention. The fieldworker will be blinded to the allocation of schools to the intervention (more or less intensive) and comparison arms of the study.

Discontinuation criteria

Schools analysis will follow the principle of intention-to-treat as far as possible. We will therefore include in analyses all schools and children initially randomised, including them for analysis purposes in the intervention group originally allocated to them. To this end, all reasonable and ethical steps will be taken to ensure completeness of follow-up of outcome measures.

School withdrawal

If a school wishes to withdraw from the trial, the study team will post a data collection form to the head/class teacher along with a freepost envelope. The data collection form will record the following: reasons for withdrawal; whether anything could have been done to make taking part in the study easier; if they no longer want to take part in the intervention and receive information/training/materials would they still allow us to collect data at round two i.e. 24 months later (CADET).

Child withdrawal

A parent may request that an individual child is no longer part of the intervention. This request may go either to the school, the RHS or the study team at the University of Leeds. Whoever is the first point of contact with the parent must inform the other relevant groups (school/RHS/University of Leeds) by telephone or letter. On receipt of this information the study team will send a letter to inform the class teacher that the child is to be withdrawn from the study. A data collection form and freepost envelope will be sent via the class teacher to the parent. A covering letter will make clear to the parent that while the child will not receive any self-study or home based materials, the child will not be left out of whole class activities as to do so would involve taking the child out of the class whilst these activities were occurring. The parent will be asked to complete the data collection form and post back to the Nutritional Epidemiology Group in the freepost envelope.

Interim analysis and stopping rules

No interim analyses of trial outcomes are planned. The trial will stop when the identified sample size required for adequate power have been achieved.

Compliance with good practice

- All statistical analyses of primary and secondary trial outcomes will be carried out by the trial statistician. No – they will be carried out by you and supervised/managed by statistician!
- CONSORT guidelines will be followed for presentation of results from cluster randomised trials (14).
- Presentation of results will be informed by good practice for presentation of trials of complex interventions (15).

- The flow of both clusters and individuals through the trial, from assignment to analysis, will be presented using a flowchart, in accordance with CONSORT guidelines.
- Intraclass correlation coefficients from the multilevel analyses will be presented following good practice for cluster randomised trials.

Study Interventions

The intervention package is the RHS Campaign for School Gardening. There are two main levels at which schools can be involved – more intensive and less intensive.

Trial 1

The more intensive intervention involves support from the RHS Regional Schools Advisor (RA). The role of the RA is to help schools develop a successful garden, work directly with teachers and pupils to give them support and practical advice. They are also charged with trying to help schools overcome particular barriers to developing gardening within schools. RA have the expertise and experience to tie in gardening and growing activities with the National Curriculum and to run staff training sessions for teachers.

Trial 2

The associate intervention schools do not have direct support from the Regional Advisor but do have access to training from teachers in the partner (more intensive) schools in twilight teacher training sessions. They will be able to have e-mail contact with the RA and access to the RHS resources on the Internet as well as potential for a one-off training event at the school. The comparison schools in trial 2 will not be provided with additional support regarding growing fruit and vegetables. However, it is recognised that most schools will be engaging in some activity around this topic. Baseline evaluation of the schools will assess the level of active engagement with growing by these schools.

The nature of the intervention allows schools to tailor their engagement with the intervention according to their needs. We will monitor which activities are undertaken by the schools during the growing year and assess, through process measures, how compliant schools have been with the different aspects of the intervention undertaken. Schools in the study will be encouraged to keep a diary of the activities they undertake as part of the intervention and complete a questionnaire detailing these activities. The process measures will allow us to identify aspects of the Campaign which have influenced the effectiveness of the activities.

Our previous work with school interventions has shown a high level of follow up at 75%, meaning that likely loss to follow up will be in the region of 3-4 schools and 150-200 children. This has been taken into account in our recruitment strategy.

Proposed outcome measures:

The primary outcome measure will be the following -

- Dietary:
 - Daily portions of fruit and vegetable intake derived from CADET.

Secondary outcomes will be the following -

- Dietary:
 - Daily portions of fruit intake derived from CADET
 - Daily portions of vegetable intake derived from CADET
 - Intake of key nutrients derived from CADET:
 - Total energy intake (MJ/day)
 - Fat intake (g/day)
 - Salt intake (g/day)
 - Intake of sugars (g/day) include NMES as total sugars will increase with increase of fruit
 - Carotene intake (mg/day)
 - Vitamin C intake (mg/day)
- Behavioural:
 - Children's attitude to fruit and vegetable consumption – using a validated psychological questionnaire (17)
- School level:
 - Involvement of schools in promoting consumption of fruit and vegetables (number of lessons devoted to school gardening and growing or learning about fruit and vegetables, school food policy, resources, involvement in other national/local food related initiatives).
 - Involvement by schools of parents in promoting consumption of fruit and vegetables among pupils.
- Process measures concerning the practicality of the intervention, timing, delivery, used and not used elements of the intervention.

Assessment and follow up:

All measures will be taken at baseline and then at the end of the intervention, after two growing seasons. Schools will have baseline measures taken when children are in the spring term of year 3 and 4 (2010) and then again when these children are in years 5 and 6, in the autumn term of that year (2011). The RHS Campaign will take place in schools over two growing seasons which will include the summers of 2010 and 2011. Support will be provided throughout the year to schools.

Effectiveness

Diet will be assessed using a validated questionnaire known as CADET (Child And Diet Evaluation Tool). CADET has been validated in an ethnically diverse population (17) and has been used to evaluate the national free school fruit scheme in primary school children (6) and is currently being used in a large national randomised controlled trial of an intervention to maintain fruit and vegetable eating in year 3 children once they are no longer eligible for free fruit. Measures of socio-economic position are also included on the CADET. This includes a record of postcode, ethnic background and highest educational level of parents – these questions to be completed by the parent. In addition, we will consider including a more child/family orientated measure such as the Home Affluence Scale for additional information in this area.

Process measures will include regular collection of datasheets recorded by schools to indicate what activities have taken place with regard to growing fruit and vegetables and learning about them in each half term.

Assessment of harm

On rare occasions, children or schools may need to discontinue the randomised intervention. This may, in most cases, be only a temporary withdrawal, for example, if a child injures themselves with a spade. Minor adverse reactions would not be grounds for discontinuing. However, the same procedures would apply as for school or individual withdrawal detailed in section 4 above. Children who have been withdrawn due to an adverse reaction of some sort (eg. allergy etc) will be followed up 3 months by the study team after withdrawal to assess their condition.

Ethical considerations

The ESRC Research Ethics Framework will be followed since participants are school children and not directly associated with the NHS. Ethical approval will be sought from the University of Leeds Research Ethics Committee. Informed consent to

participate in the trial will be obtained, firstly from all schools and secondly from all parents whose children are in the classes chosen to be involved in data collection for the trial. Schools will be informed about the trial for trial 1 initially by the RHS since they hold the database of schools who are registered for their Gardening Campaign. If schools consent to be approached with regard to the trial, schools will then be contacted by the study team firstly by letter and then followed up with a telephone contact. The team will provide details of the trial, potential benefits and any possible risks. Once a school has consented to take part, then parents will be informed about the trial, risks and benefits, by an information sheet and letter from the study team delivered by pupil post. Parents will be asked to provide signed consent to their child taking part in the trial. If parents did not provide positive consent this would not preclude children being involved in growing activities at school – rather children would not be asked to record their food intake using CADET. In trial 2, a similar process will be adopted, in this instance, the study team will directly approach schools who are not on the RHS database and provide schools with information about the trial.

Statistical Analysis

Statistical analysis:

Balance of school/class and child-level variables between the two intervention groups will be assessed for the following variables:

School/class level:

- % children with English as an additional language
- % non-white children
- % children with free school meals eligibility
- % children defined as having special educational needs

Child level:

- Sex
- Age
- Each of the primary and secondary outcomes

Primary analyses

A random intercepts model of primary and secondary outcomes will be used allowing for hierarchical structure of data caused by cluster randomisation: child within class within school. MLwiN (18) will be used for this analysis. The single covariate for the intervention group will be included in the model (treated as a random effect since schools in the trial are themselves a sample from the population of schools).

Secondary analyses

The models from the primary analyses will be repeated, each including one additional covariate from the list of variables assessed for baseline balance. Where adjustment for this covariate changes the estimate by more than 20%, this will be reported.

Unadjusted analyses originally performed in MLwiN will be repeated in Stata 10 (19) using Sandwich estimates to take account of the cluster randomisation to assess robustness of conclusions to the methodology used.

Analysis of children's attitude towards eating fruit and vegetables derived from CADET. The ten items relating to children's attitudes to fruit and vegetables will be analysed using factor analysis to identify the underlying structure of their responses. Tests for Kaiser-Meyer-Olkin and Bartlett's test of sphericity will be carried out to verify the assumptions for factor analysis are correct. The number of factors extracted will be based on a screeplot of Eigenvalues greater than 1. For each factor, internal consistency will be measured using Cronbach's alpha. In view of the fact that there will be a number of potential outcomes assessed with possibly more than one identified factor, repeated at two time points, we will use multivariate analysis of variance (what is this exactly?! Not sure that I know! Need to think who will supervise this type of analysis to determine whether the intervention has a differential effect on children's attitudes over time.

Subgroup analyses

There are no planned subgroup analyses.

Multiple comparisons

No adjustment will be made for multiple comparisons of these pre-specified secondary analyses. All tests will use a 5% significance level, and use 95% confidence intervals.

Exploratory analyses

Other non-key nutrients (e.g. Iron intake, carbohydrate intake) and dietary components will be investigated in an exploratory manner using the same modelling procedure above. These will be tested at the 1% significance level.

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