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**Does the Royal Horticultural Society Campaign for School Gardening increase
intake of fruit and vegetables in children?**

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Does the Royal Horticultural Society Campaign for School Gardening increase intake of fruit and vegetables in children?

1. Aims:

The following aims apply to Trial 1 and 2:

- Can the RHS Campaign lead to increases in vegetable and fruit intake in children aged 8-9 years?
- 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)?

The effectiveness of either intervention would be determined by an increase in mean intake in one of the following; mean intake of fruit, mean intake of vegetables, or mean intake of fruit and vegetables at follow-up after adjusting for baseline.

2. Background:

The impact of poor nutrition in children is causing major public health concerns across the globe [1]. Fruit and vegetables are a fundamental component of a healthy diet[2]. Currently, children's consumption of fruit and vegetables is low in United States of America, Australia and most European countries,[3-5] with the average intake of fruit and vegetables for children in the UK being around 2.5 servings per day[6]. In British children the main source of energy intake is from chips, biscuits and crisps[6], the need for public health intervention to improve children's overall diet habits is evident[7].

Epidemiological evidence indicates that a diet rich in fruit and vegetables can decrease the risk of developing cardiovascular disease, stroke, hypertension, type 2 diabetes mellitus, obesity and several forms of cancer[1, 8]. A diet low in fruit and vegetable intake is one of the top ten risk factors for global mortality⁵. Research has also revealed that dietary habits are developed in childhood and persist throughout life; therefore it is vital that children at a young age consume adequate levels of fruit and vegetables[9, 10]. Several studies indicate that children's fruit and vegetable

intake is positively associated with their parent's intake[11].

Of particular public concern is the rise of obesity in children[12]. National surveys state that approximately one in ten children under the age of ten is obese, further estimates predict that 80% of children who are obese at the age of 10 to 14 will remain obese into adulthood[13]. Diet plays a fundamental role in weight management, having a healthy diet rich in fruit and vegetables, which are low energy density foods, could help tackle this epidemic[14].

Several different nutrition education programmes have been developed for schools, home and community settings in an attempt to improve children's diets[15-22]. Evidence suggests that the most effective interventions are multi-component with school and home based components [23, 24]. Successful intervention studies have included a variety of components; integrating teaching about fruit and vegetables into the curriculum, training teachers in theories of behaviour changing and nutritional education, increasing fruit and vegetable availability at school and in school meals, training of catering staff (verbal encouragement), hands-on exposure (tasting and preparation sessions), parental involvement through newsletters and homework activities, whole school approach (developing a nutrition policy, evening activities) and community involvement (local fruit and vegetable industry)[20, 23-30]. These intervention programmes report a moderate increase in children's fruit and vegetable consumption of approximately one third of a portion of fruit and or vegetable [22, 31, 32].

The use of school gardens as an education tool in schools is a relatively new approach to improve children's diets. The theory behind using a school or community garden to improve children's diets is that it provides children with the opportunity to learn about how fruit and vegetables are grown in an interactive manner[33], taking the focus away from classroom based nutrition education by using external or trained teacher.

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[34]. 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 and 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. 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[35-37].

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 attract further funding from external bodies to support the posts of Regional Advisers who work with 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 in the diets 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.

3. Methodology:

This study will use two parallel randomised controlled trials. Trial One; schools in the RHS Campaign for School Gardening will be randomised to receive an intensive or less intensive intervention. Trial Two; 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

All primary schools within the above London boroughs with classes in key stage 2 (years 3-6) will be invited to take part in the study.

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.

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 from the following boroughs; Wandsworth, Tower Hamlets, Greenwich, and Sutton.

Trial 2 inclusion criteria

Schools which meet all the above criteria and who have not signed up to take part in the RHS Campaign for School Gardening by the time of randomisation of schools, will be included in trial 2 from the following boroughs Lewisham, Lambeth, Merton and Newham.

Proposed sample size

Cluster randomisation will be used, randomising at the school level, because the intervention will involve whole schools and participating 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% . This 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 using 2 classes from each school. 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 the 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 appendix C for details on the intervention).

We will recruit 26 schools from four boroughs in London; Wandsworth, Tower Hamlets, Greenwich, Sutton. 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. 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

Following selection of schools into trial 1, we will contact schools from additional boroughs in London; Lewisham, Lambeth, Merton and Newham. We anticipate that these 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. A full description of the randomisation method is described in appendix A.

Blinding: it will not be possible to blind schools to their intervention group because of the nature of the intervention. The fieldworkers 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 and if they still allow us to use data collected to date and to collect data at round two i.e. follow-up collection in October 2011.

Child withdrawal

A parent may request that an individual child is no longer part of the trial. 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 this will be recorded in the database. 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.

Compliance with good practice

- All statistical analyses of primary and secondary trial outcomes will be carried out under the guidance of the trial statistician.

- CONSORT guidelines will be followed for presentation of results from cluster randomised trials [38]
- Presentation of results will be informed by good practice for presentation of trials of complex interventions[39].
- 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 [40].
- Intraclass correlation coefficients from the multilevel analyses will be presented following good practice for cluster randomised trials.

Study Interventions

The RHS Campaign for School Gardening consists of two programmes. For the intensive intervention the schools known as Partner Schools receive the following:

- A day visit from the RHS regional advisor each half term to work in the garden with teachers and children (Summer Term 2010 to Summer Term 2011 inclusive).
- Follow up visits to aid lead teachers with planning (Autumn Term 2010 to Autumn Term 2011)
- General ongoing advice on the school garden, free seeds and tools
- 1 twilight teacher training session each term (Summer term 2010 to Summer term 2011 inclusive), based on seasonal tasks in the school garden (open to Partner School teachers and others from local schools)
- Free access to a wide range of teacher resources at www.rhs.org.uk/schoolgardening/

The role of the regional advisor is to assist the schools to develop a successful garden, through working directly with teachers and pupils to give them support and practical advice. They are also charged with helping schools overcome particular barriers to developing gardening within schools. Regional advisors have the expertise and experience to tie in gardening and growing activities with the National Curriculum and to run staff training sessions for teachers.

The less intensive intervention schools known as Associate Schools will work with

the RHS by attending twilight training once a term at their nearby Partner school, to help support them in developing and using their school garden. Unlike the Partner Schools the Associate schools will not have direct support from the regional advisor. The regional advisor will be running these twilight sessions for them and provide the Associate Schools with advice as needed for their school garden.

Trial One consists of schools participating in both intervention groups mentioned above, whereas for Trial Two schools involved in the less intensive intervention/Associate Schools and a group of control schools are included. These control schools will not receive any support from the regional advisor during the period of the trial, they will however, be eligible for associate intervention at the end of the study. However, it is recognised that most schools will be engaging in some activity around this topic. Baseline evaluation of all schools will assess the level of active engagement with growing by these schools.

Proposed outcome measures:

The primary outcome measure will be the following -

- Food:
 - Daily portions of fruit and vegetable intake at follow-up (15 months after baseline)
 - Daily portions of fruit intake
 - Daily portions of vegetable intake

Secondary outcomes will be the following -

- Nutrient:
 - Total energy intake (MJ/day)
 - Fat intake (g/day)
 - Saturated fat (g/day)
 - Salt intake (g/day)
 - Sugars (g/day) including non milk extrinsic sugars
 - Carotene intake (mg/day)
 - Vitamin C intake (mg/day)
 - Vitamin D intake (mg/day)
 - Iron (µg/day)

- Fibre (g/day)
 - Zinc (µg/day)
 - Carbohydrates (g/day)
 - Folate (µg/day)
- Foods:
 - high in fat, salt or sugar and sugar sweetened beverages
- Behavioural:
 - Children's attitude to fruit and vegetable consumption
- 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, 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. E.g. within 15-17 months after baseline measurements were collected. 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 by the regional advisor.

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 [40] and has been used to evaluate the national free school fruit scheme in primary school children [41] and has also been 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.

Process evaluations are useful to identify adherence level to the intervention for each school. At baseline and follow-up, schools will be asked a set of gardening questions which are based on the RHS school system that ranks schools on their gardening activity levels from 1-5. An email consisting of different questions about gardening activities within the school, will send sent to capture what fruit and vegetables each school grows and harvests. This information will be captured via email in October 2010 for trial year one and October 2011 for trial year two. For the intense intervention trial schools additional details regarding the intervention activities within each school will be captured by the regional advisor. For the less intense intervention level of involvement in the twilight sessions will be recorded. The regional advisor will keep a record of teacher's attendance. With the nature of this type of intervention, schools will naturally tailor it to their individual needs. By monitoring what activities are undertaken in the school garden and in the classroom, provides the opportunity to explore how intervention elements might be associated with dietary change.

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, these events will be captured by either the RHS advisor for the intensive interventions schools, or by the NEG team through the process measures email for the less intensive schools. All adverse events will be reported to the annual TSC meetings. However, the same procedures would apply as for school or individual withdrawal detailed in section 4 above. Children who have been withdrawn from the trial 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. Participant's parents were given informed consent, with the opportunity to "opt-out" of the study if they did not wish their child to take part. If the parents wished their child not to participate in the study, they were still able to take part in the growing activities; however their food intake and child attitude and knowledge questionnaire would not be recorded.

In trial 2, a similar process will be adopted, in this instance, the study team will directly approach schools that are not on the RHS database and provide schools with information about the trial.

Statistical Analysis

This is a brief outline of the statistical analysis plan for the trial, further description of this can be found in the statistical analysis plan.

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 or fixed 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 [42] 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 [43] 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 [38].

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.

Process Measures Evaluation

Based on the results of the process measures questionnaire an efficacy subset analysis will be conducted to explore the differences between schools with different levels of adherence to the intervention programs. Whilst it is often argued that the most meaningful results are based on ITT principles, for intervention analysis such as this study, the degree that schools participate in the intervention is vital to the main outcome. It would also be necessary to compare the results from ITT and efficacy subset analysis to examine the differences in effect size generated [44]. The process measures evaluation will also identify which schools have or have not improved their gardening curriculum from baseline to follow-up using regression analysis.

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Summary of changes

Version 1.1 changes, saved as version 1.2

- Page 8, paragraph 1, line 5 the following was added "(see below appendix C for details on the intervention)."
- Page 9, paragraph 1, line 1 the following was deleted "ethnicity and deprivation to guarantee balance on these important variables. The following sentence was added ". A full description of the randomisation method is described in appendix A."
- Page 9, paragraph 4, line 6, "i.e 24 months later (CADET) was deleted. The following was added "i.e. follow-up collection in October 2011).
- Page 9, paragraph 5, line 4, the following was added "this will be recorded in the database.
- Page 11, changed reference 18 to reference 20
- Page 12, line 24, Deleted this sentence "In addition, we will consider including a more child/family orientated measure such as the Home Affluence Scale for additional information in this area."
- Page 13, paragraph 1, line 11, this sentence was modified to the following " By monitoring what activities are undertaken in the school garden and in the classroom, provides the opportunity to explore how intervention elements might be associated with dietary change. A detailed breakdown of the process evaluations methodology will be written in 2012."
- Page 13, paragraph 2, line 7, the following sentence was added "This information is stored in the folder "Adverse Events" in the excel database "Schools withdrawal details RHS""
- Page 13, paragraph 1, line 3, changed him to "regional advisor"
- Page 13, paragraph 2, line 5, from the trial was added
- Page 13, paragraph 2, line 7 the following sentence was added " This information is stored in the folder "Adverse Events" in the excel database "Schools withdrawal details RHS"
- Page 14, heading; statistical analysis, line 1 - the following sentence was added This is a brief outline of the statistical analysis plan for the trial, further description of this can be found in the statistical analysis plan document located N:\Faculty-of-Medicine-and-Health\LIGHT\Nutr-Epi\FOOD\general\1. New structure of NEG folders\NEG025 RHS Gardening\C. Protocols\SAP
- Page 16, paragraph 3, line 9, the following sentence was added "A detailed breakdown of the process evaluations methodology will be written in 2012."
- The appendix section was added to version 1.2

Version 1.2 changes, saved as version 1.3

- Page 6, Aims, the following was added The following aims apply to Trial 1 and 2:
- Page 6, Aims, line 8, the following sentences were added " The effectiveness of the intervention would be determined through identifying by an increase in mean intake in one of the following; mean intake of fruit, mean intake of vegetables, or mean intake of fruit and vegetables at follow-up after adjusting for baseline."
- Page 13, Assessment of Harm, line 3, the following sentence was added " However, these events will be captured by either the RHS advisor for the intensive

interventions schools, or by the NEG team through the process measures email for the less intensive schools. All adverse events will be reported to the annual TSC meetings."

- Page 11, proposed outline measures, line 3, the following was added " at follow-up (15 months after baseline)."
- Page 12, Assessment and follow-up, line 2, the following was added "E.g. within 15-17 months after baseline measurements were collected."
- Moved the appendix C Study Intervention to page 10

Appendices

Appendix A: Randomisation

Cluster randomisation with school location and borough to identify each “cluster” was used to randomise the schools. The schools were randomised by location, ie. their London borough. They were randomly assigned using Stata (Stata Corporation, 2005) to (for trial one) the intense RHS intervention or the less intense RHS intervention, for trial two the less intense intervention. The Stata command for each borough was “*sample x, count.*” If the schools had more than one year 3 or year 4 class the same statistical method was used to determine which class was involved in the trial.

References

Stata statistical software: Release 9.2. College Station, TX. Stata Corporation, 2005.

Appendix B: Baseline and Follow-up Measurements

The main outcome measurements will be collected at baseline in May-June 2010 when the children are in years 3 and 4. The follow-up measurements will be collected in September-October 2011 when the children are in years 5 and 6. This means the intervention will take place over two growing seasons and will be 15 months long in total.

Dietary Assessment Tool: School Food Diary and Home Food Diary

For this trial diet will be assessed using a modified version of the Child And Diet Evaluation Tool (CADET) questionnaire. CADET is a prospectively completed tick list of all foods consumed over a period of 24-hours. Part one of CADET consists of different food and drinks which have been categorised (e.g. cereal, chicken and turkey, and fruit) with appropriate sub-headings under each category, such as apples, pears, and banana. Each item in the diary has seven tick boxes related to different meal time options “morning break, lunch time, afternoon tea.” Part two consists of food related questions to identify daily milk, bread, sugar, spreads, and fruit juice, general demographic questions about the family household, and 10 questions about attitude towards fruit and vegetables and availability of fruit and vegetables at home. The availability of fruit and vegetables at home questions, is a new section added for this study and is based on the existing literature by Kristjandorrit et al 2006.

To complete the diary, participants tick each item consumed, under the appropriate meal time heading within the 24-hour period. In previous research trained field workers have filled in

the CADET diary during the school day hours, and parents were asked to complete the evening and morning food consumption. However, not all children returned the CADET diary back to school, which led to all nutrition data collected on that child being lost. For this trial, CADET was improved and split into two diaries, a School Food Diary for all school time meals, and a Home Food Diary for children to take home for their evening snacks, meals and breakfast the next day. This meant that any data collected at school, remained at school and was not lost if the home section was not returned. Another improvement that has been incorporated into this trial is that the field workers went back to the school to collect the Home Food Diary, and went through the diary with the children. This meant all Home Food Diaries could be checked, to see if parents had completed the diaries. In addition, any children who did not return their diaries did a retrospective recall of what they ate the previous evening. It was noted in previous studies, that sometimes the children aged 7-8 years filled in the CADET diary themselves, and they didn't fully understand the requirements. One of the common mistakes was ticking everything that they "liked" to eat, not what they "actually" ate that evening. Having a field worker go through the diary the next day could potentially improve the data collected, and reduce the amount of inaccurate and incomplete data.

Accurately measuring children's energy and nutrient intake is challenging, especially in a large trial such as this as there are always benefits and limitations with any nutritional assessment tool. Research suggests that children are aware of what they consume from around 8 years old. With primary school aged children parents are often used to collect the dietary information as children are considered too young to collect accurate dietary data. However, dietary analysis is prone to many form of measurement error (Bryant et al., 2008). CADET has been validated in an ethnically diverse population (Cade et al., 2006) and has been used to evaluate the national free school fruit scheme in primary school children (Ransley et al., 2007) and in a large national RCT of an intervention to maintain fruit and vegetables eating in year 3 children once they are no longer eligible for free fruit. The style of CADET using a simple tick box list is considered an appropriate tool for people with low literacy that struggle to record or weigh what they eat. The main benefit of using a 24-hour tool is it is easy to implement at a relative low cost in a large sample (Gibney et al., 2006). This style of nutrition analysis will capture the mean intake of a population, and is the standard method used for intervention evaluation. The disadvantage with 24-hour data is it cannot be used to analyse individual intake, as the instrument is not sensitive enough to identify individual differences in dietary patterns (Gibney et al., 2006 & (Evans et al., 2010). A more appropriate tool for individual analysis would be to use a weighed record or a food diary over a number of days or repeated recall data to capture the random variability of a person's food intake (Cade et al., 2006). Including 17 the interview with the children on the second day will assist with

consistency and accuracy of the data (Cade et al., 2006). However, it does rely on children's memory and ability to recall their previous food, which can be difficult for some children, and also lead to socially desirable answers (Somerset et al., 2004).

The primary aim of this trial is to collate daily portions of fruit and vegetable intake, daily portions of fruit intake, and daily portions of vegetable intake derived from the School and Home Food Diaries. The secondary analysis will be key nutrients:

- Total energy intake (Mj/day)
- Fat intake (g/day)
- Salt intake (g/day)
- Intake of sugars (g/day) including non-milk extrinsic sugars as total sugars will increase with increase of fruit
- Carotene intake (mg/day)
- Vitamin C intake (mg/day)
- Iron and folate (mg/day)

Home Food Diary Instruction DVD

To improve accuracy and completion of the Home Food Diary MK wrote a script and had a short cartoon DVD developed. Previously there were two pages of instructions for parents to read on how to complete the diary. The DVD was designed for children and parents to watch together before completing the Home Food Diary, with the aim of helping parents and children with low literacy ability or English as a second language to understand how to complete the diary.

Knowledge and Attitudes towards fruit and vegetables questionnaire

A short questionnaire was developed to identify children's knowledge and attitude towards fruit and vegetable consumption, and assess gardening activity levels. The knowledge questions assessed children's ability to recognise different fruit and vegetables. Children were presented with a list of fruit and a list of vegetables (and a few herbs), with a colour picture for each, and they have to draw a line connecting the name with the right picture. The attitude questions were based on previously validated research by Miller et al. 2007 and Somerset et al 2004. The gardening questions assessed the children's gardening experience (Cullen, et al., 1998); what they have grown and what they have tasted. This questionnaire was read out to the children as a class, to help them with any difficult words.

Process Measures

School Gardening Questionnaire

Process evaluations are useful to identify adherence level to the intervention for each school. At baseline and follow-up, schools will be asked a set of gardening questions which are based on the RHS school system that ranks schools on their gardening activity levels from 1-5, with

The School Garden		Yes	No
1	We are already growing some plants inside or outside the classroom.		
1	We are conducting an audit of our school grounds.		
1	We are planning to do a risk assessment for our growing activities.		
2	A plan has been produced and an area identified for a school garden.		
2	Preparation work on the site has begun e.g. clearing the site, providing containers or raised beds, improving the soil.		
2	We have done a risk assessment for all activities carried out in the school garden.		
3	We grow a range of plants in our garden such as flowers, shrubs, trees, fruits and vegetables.		
3	We demonstrate care for the environment in our garden by gardening organically, reducing water use, using mulches and composting.		

1 identify low gardening involvement or no gardening involvement and 5 indicating high gardening involvement in the school. These questions address different aspects of school gardening such as school culture and ethos, the school garden, teaching and learning, and the community. The schools are asked a series of questions for each area (e.g. school garden, teaching and learning) each question has been ranked by the RHS to indicate involvement level (1-5). Once the schools have completed the interview the score is calculated to identify gardening level. Below is an example of a few of the school garden section questions.

Growing and harvesting in your school email

Another process measure is to identify what fruit and vegetables each school has grown and or harvested. Each year in October (2010 and 2011) all schools will be sent an email asking them the following questions about their school garden.

- Do you have a school garden (e.g. garden at the school, a few pots for growing plants in or an allotment)?
- Which year groups are involved in gardening at your school?
- Do you have a growing club or environmental club? If yes, which year groups are involved?
- What fruit and vegetables has your school grown/tried to grow this summer?

- What did you harvest?
- What were your success/failure stories in the school garden this summer?

Intervention details process measure

For trial one the process information will be captured by the regional advisor and be used by him to outline changes in school gardening. For trial two, another process measure that will be captured is level of involvement in the twilight sessions, whereby the regional advisor will keep a record of teacher's attendance. With the nature of this type of intervention, schools will naturally tailor it to their individual needs. By monitoring what activities are undertaken in the school garden aspects of the intervention that may be associated with dietary change will be identified.

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