EVALUATION OF THE 'CHANGE4LIFE' CONVENIENCE STORE PROGRAMME TO PROMOTE SALES AND CONSUMPTION OF FRUIT AND VEGETABLES, INCLUDING A CLUSTER RANDOMISED CONTROLLED TRIAL
Study protocol

Author: Jean Adams

Date: 21 July 2010

Version: 1

1. PROTOCOL DEVELOPMENT

This protocol has been developed using Standard Operating Procedure TM-010-00 developed by Newcastle Biomedicine Clinical Research Platforms (http://www.ncl.ac.uk/crp/assets/documents/SOP%20TM-010-00%20Protocol%20dev%20(final).pdf), the revised CONSORT statement(1) and the extension of the CONSORT statement to cluster randomised trials(2) and the list of required fields for ISRCTN registration (http://www.controlled-trials.com/isrctn/isrctn_dataset/). The protocol contains all information required for ISRCTN registration, all background and methodological information required by the CONSORT statement, plus additional information as suggested by the Standard Operating Procedure. When ISRCTN registration fields have character limits, statements meeting these character limits are provided first, followed by more detailed, 'in full' information.

2. SOURCES OF FUNDING

The study is funded in full by the UK National Institute of Health Research (NIHR) Public Health Research Programme. Total funding: £1,407,206.

3. STUDY NUMBERS

- ISRCTN registration number: (pending)
- NIHR project number: 09/3001/17
- Newcastle University MyProjects number: BH090197
- Newcastle University Account number: awaiting assignment following confirmation of ethics approval
- ClinicalTrials.gov identifier: (pending)

4. PUBLIC TITLE

Evaluation of the 'Change4Life' convenience store programme to promote sales and consumption of fruit and vegetables, including a cluster randomised controlled trial

5. SCIENTIFIC TITLE (IN PICO FORMAT)

A multi-component evaluation of the 'Change4Life' convenience store programme to promote sales and consumption of fruit and vegetables, including: a cluster randomised controlled trial of the effect of the intervention on change in fresh fruit and vegetable consumption over 12 months among regular users of intervention stores compared to regular users of control stores; an economic evaluation; and a process evaluation

6. ACRONYM

C4L c-F+VE (pronounced C4LC5)

7. STUDY BACKGROUND

7.1. Introduction

Consumption of fresh fruit and vegetables (FFV) is important for health, providing many essential micronutrients, including antioxidant vitamins, and a rich source of dietary fibre.(3) Fruit and vegetable consumption also contributes to the maintenance of healthy body weight.(3) The promotion of FFV consumption is a key government health strategy in the UK, underpinned by the 'five-a-day' message (adults in the UK are recommended to eat five, standard 80g portions, of fruit and vegetables per day, which can include up to one portion of fresh whole fruit juice; www.dh.gov.uk), yet average consumption among adults

remains at only around two to three portions per day.(4) Fruit and vegetable consumption is also known to be strongly socio-economically patterned, with lower consumption among more deprived communities.(4) Recently, governments have begun to focus on structural interventions to promote a healthier diet, including FFV intake, among poorer groups, building on the proposed, but as yet unproven, link between convenient retail access to the components of a healthy diet and consumption thereof. For example, since 2004, backed by the Scottish Executive, the Scottish Grocery Federation Healthy Living Programme has promoted FFV, as well as other 'healthier' products, in convenience stores (c-stores), with the rationale that c-stores are often found in more socio-economically deprived areas, within walking distance of people's homes, where access to a supermarket selling a wide range of products may be limited.(5)

Convenience stores are defined as small scale, local grocery stores selling food and drink for off-premises consumption as their main activity, with less than 3000ft^2 floor area, usually selling a limited range of products (typically around 3000 lines) from at least eight of 15 categories designated by the Institute of Grocery Distribution, and open long hours (more than 9am-5pm) on every day of the week.(6) Convenience stores are the most widely distributed type of food store in the UK, numbering around 50,000 in 2008, and representing approximately 20% of the total UK food and grocery market.(6) Convenience stores represent a complex retailing sector, comprising five main components:

- Co-operative Society (e.g. the Co-operative Group, Mid Counties Co-operative)
- Petrol station forecourts (dealer- and company-owned - e.g., BP, Shell, Total)
- Multiples (convenience specialists and supermarket based chains - e.g., Mills, Tesco Express)
- Symbol, franchise and fascia groups (e.g. Spar, Premier, Nisa, Londis, Lifestyle, Costcutter)
- Non-affiliated independents

More frequent shopping is a growing consumer trend across the whole population and there have been particular increases in sales of fresh foods (including FFV) and food-to-go (especially sandwiches) in c-stores in recent years.(6) More than half of the adult population uses c-stores at least once a week, both for 'top-up' shopping and non-budget-focused needs (e.g. items purchased at a premium price for convenience and quality).(6) Despite this, both anecdotally and empirically, the c-store sector has a long-standing reputation for poor availability and quality of FFV.(7) This is underpinned by a widespread belief among c-store owners and managers that their customers do not want to buy FFV in their stores and that low turnover leads to significant waste.

In England, the Department of Health (DH), working in partnership with the Association of Convenience Stores (ACS), has recently embarked on an initiative to develop and widely implement a similar intervention, as a part of the wider "Change4Life" (C4L) national health promotion programme (http://www.nhs.uk/change4life/Pages/default.aspx). Building on the methods used and lessons learned in Scotland, the c-store C4L FFV intervention has been developed and piloted in 12 demonstration stores in the North East region since October 2008. As of March 2010, the intervention has been rolled out to around 100 stores in the North East and other regions and plans are under way to roll-out to a number of additional stores in six other English regions in 2010-11. To date, in both Scotland and England, only evaluations of implementation and the commercial viability of the interventions have been conducted. These indicate that the intervention results in increased sales of FFV from participating c-stores.(8) However, this does not necessarily mean that the intervention also leads to increased FFV consumption amongst store users. Increased sales of FFV amongst c-stores may represent a displacement of FFV sales from other outlets, or may be associated with overall increased purchasing alongside increased wastage.

Working in collaboration with DH, we will conduct a rigorous outcome evaluation of the c-store C4L FFV intervention to determine the effect on FFV consumption and other markers of dietary quality at an individual level. This will be accompanied by economic and process evaluations providing in-depth insight into the costs and benefits of the intervention and how and why the intervention is or is not effective. This integrated evaluation will provide key information for the development of future UK government policy and extend the evidence base nationally and internationally on the relationship between food retailing and dietary quality.(9)

8. STUDY OBJECTIVES

The primary objective is to answer the question: does the C4L c-store FFV intervention lead to a statistically significant increase in consumption of FFV over 12 months among regular users of intervention stores, compared to regular users of control stores?

Secondary objectives will be to answer the questions:

- What is the effect of the intervention at 12 months on change in other markers of dietary quality among regular users of intervention stores, compared to regular users of control stores?
- What are the resource consequences of the intervention at 12 months and how do they relate to intervention outcomes?
- What is the effect of the intervention on change in shopping habits at 12 months among regular users of intervention stores, compared to regular users of control stores?
- What is the effect of the intervention at 1 and 12 months on change in sales variety, cost and quality of FFV in intervention stores, compared to control stores?
- What variation is there in implementation of the intervention at 1 and 12 months?
- What is the feasibility, acceptability and unexpected consequences of the intervention at 8-10 months among key stakeholders including consumers, retail sector personnel (store managers and owners, in-store Fresh Food Champions (see section 18.1.2), and other staff) and intervention implementation professionals (decision makers from the Department of Health, the Association of Convenience Stores and the symbol groups involved in the intervention)?

9. STUDY DESIGN

9.1. A single-centre, unblinded, cluster randomised, controlled, parallel-group, superiority study conducted in the UK; with linked process and economic evaluations.

This research will comprise three linked components – a cluster randomised controlled trial (RCT), an economic cost-effectiveness evaluation, and a process evaluation. These three elements are described separately throughout.

9.1.1. Cluster RCT

Although we will measure the impact of the intervention at the individual level, it cannot be delivered at the individual level. A cluster RCT allows the effect of interventions delivered at a group level (in this case clusters of regular users of study stores) to be studied at the individual level and is, therefore, the design of choice in this instance.(10)(9)(8) The unit of randomisation will be c-stores, but data will be collected and analysed at the individual level. Stores will be randomised to either intervention or control (usual practice). We will be unable to blind stores to group allocation. We will not draw participants' or study staff's attention to group allocation, but we may be unable to prevent them becoming aware of this during the study.

9.1.2. Economic evaluation

We will assess the resource consequences and outcomes of the intervention in order to determine if it is unambiguously efficient (i.e. costs are saved and outcomes improved) or, if not, what costs are faced in the setting up of such a programme. These might involve costs being imposed on some sectors and saved by others, as well as trade-offs between costs and outcomes. Assuming that the convenience stores are driven by the profit motive and will judge the outcomes according to profit levels, we will concentrate our evaluation on the Department of Health (DH) and consumers. From the perspective of DH we will calculate the costs of initiating the intervention and, using data relating to the primary outcome, we will calculate the cost per additional portion of FFV consumed. Using secondary data and expert opinion we will also attempt to relate any changes in FFV consumption to changes in health and attempt to indicate the anticipated effect on health spending patterns. Finally, we will assess the impact on individuals of any additional FFV

consumption by comparing the additional cost of FFV *per se* and also assess any impact on total cost of purchasing FFV from a c-store as opposed to a major high street retailer.

9.1.3. Process evaluation

The process evaluation will comprise quantitative and qualitative elements. Quantitative measures will establish the impact of the intervention on the food shopping habits of cluster RCT participants; the effect of the intervention on sales, variety, cost and quality of FFV in intervention stores; and any variation in intervention implementation fidelity or standard. The qualitative element will identify and characterise intervention specific, as well as broader contextual, secular factors considered by stakeholders to have a moderating impact on the intervention, as well as psychosocial and environmental variables influencing response to the intervention. Data will be collected using focus groups with study store customers, and individual in-depth interviews with retail sector personnel and intervention implementation professionals. An ecological framework will provide a structured approach to identifying and exploring the multiple pathways from retail change to diet.

An external store mapping process at baseline and follow-up, using Institute of Grocery Distribution post-code referenced data, will ensure large scale change in the regional retail environment is fully audited and retail grocery structure is fully integrated into the analysis of study outcome measures.

10. SETTING, LOCATION AND COUNTRIES OF RECRUITMENT

The study will take place entirely in England, UK. The intervention is a community intervention provided to local c-stores. Details of recruitment and data collection are given in sections 21 and 0.

10.1. Cluster RCT

10.1.1. Stores

Participation of stores in the cluster RCT, if selected to take part, will be strongly encouraged by the C4L team. Recruitment will be by letter from the research team to store managers followed by telephone calls and in-store visits.

10.1.2. Individuals

Individual participants in the cluster RCT will be recruited in study stores and data collected from them in their homes.

10.2. Economic evaluation

Additional data for the economic evaluation not collected during other components of the study will be collected via web-search, library or other desk based research.

10.3. Process evaluation

10.3.1. Quantitative element

Data for the quantitative element of the process evaluation will be collected in-store and from cluster RCT participants during home visits.

10.3.2. Qualitative element

Participants in the qualitative element of the process evaluation will be recruited in-store (costumers) or at their place of work (retail sector personnel and intervention implementation professionals). Data will be collected from customers during focus groups in community locations. Data will be collected from retail sector personnel and intervention implementation professionals during interviews at their place of work, or other convenient location.

11. PARTICIPANTS - INCLUSION CRITERIA

Separate inclusion criteria are listed for cluster RCT stores and individual participants. The same criteria used to select individuals participants to take part in the cluster RCT will be used to select customers to take part in the qualitative element of the process evaluation. The economic evaluation will use data collected as part of the other elements of the research and no additional new participants will be recruited for it. The quantitative element of the process evaluation will rely solely on analysis of individual level data collected

from all RCT participants, sales data and in-store observations. No separate participants will be recruited for this component.

11.1. Cluster RCT

11.1.1. Stores

Stores included in the research will meet the following criteria:

- Member of one of the 'symbol' groups, e.g. Spar, Londis, Costcutter, Premier, Nisa or Mills Group
- Expressed an interest in taking part in the intervention to the DH implementation team
- Located at least 1km, network distance, from all other study stores
- Located in a lower super output area with an Index of Multiple Deprivation 2007 (IMD) score below the median for the all Government Office regions that study stores are located in
- Located in an urban area as defined by the Department for Environment, Food and Rural Affairs 'Rural Definition' of urban areas (http://www.defra.gov.uk/rural/ruralstats/rural-definition.htm#defn)

If a store is selected for the study that is less than 1km from another study store, replacement sampling will take place.

11.1.2. Individuals

Cluster RCT participants will be recruited in-store and will meet the following criteria:

- Have used the study store on average at least twice per week over the past three months
- Member of a household from which no other member has already been recruited to take part
- Able and willing to give consent to take part in the research
- Age 18 years or older
- Able to communicate in English

11.2. Process evaluation (qualitative element)

Members of three stakeholder groups will be selected to take part in the qualitative element of the process evaluation: study store customers, retail sector personnel, and intervention implementation professionals. Customers and retail sector personnel will be recruited from a small number of cluster RCT study stores (both intervention and control).

11.2.1. Stores

Stores will be purposively sampled for inclusion in the qualitative element of the process evaluation from all study stores. They will, therefore, meet the following criteria:

- Study store in cluster RCT
- Purposively sampled to represent different socio-economic locations and sizes of all stores in cluster RCT

11.2.2. Customers

Customers taking part in the qualitative element of the process evaluation will meet the same criteria as cluster RCT individual participants, and will be purposively sampled to reflect the socio-demographic composition of individual participants in the cluster RCT recruited from the same store. To avoid drawing cluster RCT individual participants' attention to the intervention, they will be excluded from the qualitative process evaluation. Thus, there will be no overlap between cluster RCT individual participants and those in the qualitative element of the process evaluation. Customer participants in the qualitative element of the process evaluation will, therefore, meet the following criteria:

- Have used a cluster RCT study store on average at least twice per week over the past three months
- Member of a household from which no other member has been recruited to take part in cluster RCT
- Able and willing to give consent to take part in the research
- Age 18 years or older
- Able to communicate in English
- Not taking part in the cluster RCT
- Purposively sampled to reflect the socio-demographic composition of individual participants in the cluster RCT recruited in the same study store

11.2.3. Retail sector personnel

Members of staff at study stores selected to take part in the qualitative element of the process evaluation will be purposively sampled to reflect store managers and owners, in-store Fresh Food Champions (see section 18.1.2 for definition), and other staff. They will, therefore, meet the following criteria:

- Work at study store selected for inclusion in the qualitative element of the process evaluation
- Able and willing to give consent to take part in the research
- Age 18 years or older
- Able to communicate in English
- Purposively sampled to reflect store managers and owners, in-store Fresh Food Champions, and other staff

11.2.4. Intervention implementation professionals

This group will include members of the DH implementation team, key decision makers from symbol groups, symbol group regional managers involved in the intervention (see section 18.1.3 for definition) and any other professionals involved in intervention implementation.

- Member of key stakeholder group
- Able and willing to give consent to take part in the research
- Age 18 years or older
- Able to communicate in English

12. PARTICIPANTS - EXCLUSION CRITERIA

None, beyond inclusion criteria listed.

13. PARTICIPANT INFORMATION MATERIAL

See appendices (section 40).

14. TARGET NUMBER OF PARTICIPANTS AND SAMPLE SIZE CALCULATIONS

Cluster RCT: 2660 individuals across 28 stores. Also: 18 focus groups with consumers, 32 interviews with retail sector personnel and 10 interviews with implementation professionals.

Sample sizes are described for stores and individual participants taking part in the cluster RCT and the qualitative element of the process evaluation. Sample size for the economic evaluation and quantitative element of the process evaluation will be as for the cluster RCT.

14.1.1. Cluster RCT

The sample size calculation was based on a t-test of the mean difference between groups in change in FFV consumption between baseline and 12 months. As the data are clustered at the c-store level, individual level sample size was multiplied by a design effect to retain statistical power. The study is powered to detect a mean difference in change of FFV intake of 40g (0.5 portions) per day. This represents an increase of around 20% above current population levels(4) and is similar to the change seen in other community intervention studies.(11, 12)

There are two published UK studies which provide data on change in FFV intake from baseline to 12 months following retail changes.(13-15) Both were used to provide estimates of the standard deviation of change in FFV intake from baseline to 12 months for intervention and control groups. The pooled estimates of the standard deviations of the change were 1.8 (95% CI: 1.66-1.96) and 2.2 (95% CI: 2.06-2.37). We were also able to access unpublished data, supplied by the MRC Human Nutrition Research Centre in Cambridge, from a method comparison study of four day food diaries and repeated 24hr recalls conducted over four consecutive days.(16) From this study the standard deviation for FFV intake at a single time point was 2.1 (95% CI: 1.98 -2.23). There are no published data on the intraclass correlation (ICC) for the change in FFV intake at the c-store level. However, data from Newcastle provide an ICC for actual FFV intake at the postcode level of 0.01(7) and 'typical' values of ICCs in community randomised trials have been found to be small (usually less than 0.01 and often near 0.001).(17) Given most of the unexplained variation in FFV intake in the Newcastle study was at the individual level, and since similar observations were made for all

dietary outcomes,(7) this ICC has been used as a guide in the calculation of possible design effects. Further, the c-stores included in this study will be sampled from locations with IMD scores below the median for the study region, thus restricting the variation between clusters in terms of IMD – associated with FFV intake in the Newcastle study.(7) Given these considerations, sample size calculations were performed using standard deviations across the range 1.6 to 2.4 with ICCs of 0.005, 0.01 and 0.02.

We calculate that a total achieved sample size at follow up of 692 individual participants and 28 c-stores (14 intervention and 14 control) is required to detect as statistically significant a mean difference in the change in FFV intake between study groups of 40g (standard deviation of the differences 2.1 portions, 80% power, 5% significance level, two-sided test, ICC 0.01). This equates to 25 individual participants per store. Assuming 35% attrition between baseline and follow up,(15) the total number of individual participants recruited at baseline per c-store increases to 38 and the total sample size at baseline to 1064. Assuming a recruitment rate of 40%, (similar to that in previous work; S Cummins, personal communication), the total number of individuals that we will invite to take part will be approximately 2660.

14.1.2. Process evaluation(qualitative element)

We will select eight intervention and eight control stores from which consumers and retail sector personnel recruited to take part in the qualitative element of the process evaluation will be selected. One focus group discussion with customers will be conducted per store, and two for any store with a particularly heterogeneous customer base, giving a total of around 18 focus groups. We will conduct individual interviews with two retail sector personnel per selected store – 32 interviews in total. We envisage 5-10 individual interviews with intervention implementation professionals.

15. ANTICIPATED START DATE

01/08/2010

16. ANTICIPATED END DATE

31/01/2013

17. DISEASE, CONDITION OR STUDY DOMAIN

Public health nutrition, public health policy, food retailing, diet. In particular, the effect of a specific policy led food retailing intervention on fresh fruit and vegetable intake.

18. INTERVENTIONS

18.1. Intervention arm

The c-store C4L FFV intervention implemented in development stores involves an in-store 'toolkit', an in-store Fresh Food Champion, and regular support from the DH implementation team. As retailers make a substantial financial contribution to the cost of the intervention, it also involves the presence of a committed retailer. Although the main intervention components are consistent across stores, there will naturally be store-to-store variation in implementation, as expected in a pragmatic trial.

18.1.1. In-store toolkit

The in-store toolkit comprises C4L branded chiller cabinet, impulse stand, ambient shelving, on-street A-stand, and vinyl window display. The total cost of this is in the region of £15-20,000 per store depending on size and any alterations required to accommodate the new materials. DH contributes an average of £3000 per store, and retailers make up the difference.

18.1.2. Fresh Food Champion

The in-store Fresh Food Champion is a member of staff who takes responsibility for the C4L branded units and product lines sold from them. This is the main point of contact between the DH implementation team and individual stores. The champion receives a DVD tutorial, and is responsible for ensuring that all branded units are used as intended and that the freshness of produce is maintained.

18.1.3. Support from the regional managers and DH implementation team

Symbol groups maintain contact with individual stores through regional managers. This network of individuals visit stores around fortnightly in order to maintain the branding of the group, pick up store managers' orders, and provide an informal support mechanism. This established network will be used by the DH implementation team as liaison workers. In addition to their ongoing duties, regional managers will provide information on use of the C4L toolkit, help retailers manage bulk purchasing and in-store product placement, and provide on-going informal support. This additional role for regional managers is facilitated by the presence of key decision makers from each of the symbol groups involved in the programme on the C4L c-store FFV intervention steering group.

18.2. Control arm

The control condition will be usual practice. Stores will be free to make any changes to layout and inventory they wish. Control stores will not have access to financial support from DH, or specific C4L related support from the DH intervention team, or symbol group regional managers during the 12 months of the intervention period. The intervention will be made available to control stores, should they wish it, following final data collection.

18.3. Duration of treatment

The in-store toolkit will not be withdrawn once it is in place in study stores– although it is possible that DH may provide updated in-store materials in the future. As DH has earmarked funding for the intervention until 2011, we envisage that support from the DH implementation team will last at least until 2011. Use of the in-store toolkit and in-store Fresh Food Champion is likely to vary from store-to-store, and with time.

18.4. Duration of follow up

18.4.1. Cluster RCT

Data will be collected from individual cluster RCT participants at baseline and 12 month follow up.

18.4.2. Process evaluation

Quantitative process evaluation data will be collected from study stores at baseline immediately before intervention implementation, and 1 and 12 months after intervention implementation. Qualitative process evaluation data will be collected around 8 months after intervention implementation.

19. PRIMARY OUTCOME MEASURE(S)

The primary outcome (change in FFV consumption) amongst individual cluster RCT participants will be measured as change in mean grams of FFV consumed per day using two-day food diaries, based on the methods used in the National Diet and Nutrition Survey (NDNS). Diet will be recorded over two consecutive days, with study days at baseline and follow up varying between, but not within, participants. Approximately equal numbers of individuals per store will begin recording their diet on each day of the week.

20. SECONDARY OUTCOME MEASURE(S)

Secondary outcomes will be measured at the individual level in the cluster RCT. Additional store level measures will be used in the economic evaluation and in the quantitative element of the process evaluation.

20.1. Cluster RCT

The secondary outcome measured in cluster RCT participants will be change in other markers of dietary quality – in particular, percent of dietary energy derived from fat, for which there is a clearly defined UK recommendation,(18) and energy density of food intake, which would be expected to reduce with increased consumption of low energy dense foods such as FFV.(19) These will also be derived from two-day food diary data as per primary outcome measurement.

20.2. Economic evaluation

The customer centred outcome measures to be used in the economic evaluation will be the same as those in the cluster RCT. We will seek to gauge the impact of the intervention on stores' revenues using electronic point of sales (EPOS) data. Data will be collected at 12 months from the intervention stores and regional managers and DH on the specific costs of intervention implementation. Estimates of costs to consumers of any changes in diet will be made using food diary data and contemporary price data for specific foods and

food categories. We will then derive summary measures of costs associated with the intervention as they fall on DH, on stores and on individual consumers.

20.3. Process evaluation

The quantitative element of the process evaluation will allow consideration of a number of markers of process at the store and individual level.

20.3.1. Stores

At the store level, the primary quantitative marker of process will be change in sales of FFV measured as total turnover from FFV per week using EPOS data provided by store managers over one week at baseline, one month and 12 month follow up. These data are collected by electronic bar-code scanners already installed in stores. Secondary markers of process measured using EPOS data will be change in range of FFV sold, change in proportion of total sales accounted for by FFV, and change in proportion of baskets that include FFV. Secondary markers of process, measured from data collected during in-store observations at baseline, one month and 12 month follow up, will be change in:

- variety of FFV available, measured as the number of different FFV lines on sale
- cost of FFV, measured as the proportion of FFV lines on sale at below the median price for that line across all stores in the study
- quality of FFV, measured as proportion of FFV lines on sale judged by appearance to be of good quality

In intervention stores we will also assess fidelity and standard of the implementation of the intervention at baseline, one month and 12 month follow up, using in-store observations and a data collection instrument covering key aspects of intervention implementation derived from the guidance and documentation provided to store managers with C4L materials. We will also take digital photographs of the inside and outside of study stores to keep a permanent visual record of the use of C4L branded materials and FFV displays.

20.3.2. Individuals

At the individual level, the primary quantitative marker of process will be change in shopping habits as measured by number of weekly visits to the study store around which individuals are clustered, and total weekly spend and proportion of weekly food spend spent at the study store. This will be assessed using a shopping habits questionnaire at baseline and follow up.

21. SAMPLING & RECRUITMENT

The sampling and recruitment procedures will vary across the three components of the research. The National Centre for Social Research (NatCen) will be responsible for recruitment of individual cluster RCT participants.

21.1. Cluster RCT

The cluster RCT will involve recruiting stores as well as individual participants who are regular users of those stores, and assessment and follow up of individual participants.

21.1.1. Sampling of stores

A sampling frame of all stores meeting the inclusion criteria, except the distance criterion (see section 11.1.1), will be supplied by relevant individuals at DH & ACS. All stores in the sampling frame will be stratified according to Government Office Region, socio-economic deprivation and store size. The exact nature of the deprivation and size strata will be determined once data on these stratifying variables have been examined. Pairs of stores (which are more than 1km from each other or other pairs) will then be randomly selected from each stratum for inclusion in the research. If stores are selected that are within 1km of previously selected stores, re-sampling will take place. Within each pair one store will be randomised to the intervention arm of the study and one to the control arm.

21.1.2. Recruitment of stores

Stores selected to take part in the research will be informed in a letter and information sheet sent to store managers and during a follow-up telephone call and visit to stores from a researcher. During this visit the research process will be described and full informed consent to take part in the research will be obtained

from managers. Any stores that refuse to participate will be replaced by resampling until the required sample size is achieved. Stores will be informed of the trial arm to which they have been randomised in a letter following baseline data collection.

21.1.3. Sampling of individual participants

The target population will be all those who meet the inclusion criteria (see section 12.1.2). However, as it will not be possible to compile a complete sampling frame, we will use systematic-, rather than simple-, random sampling to select individuals to be invited to participate. The distribution of adult visitors by day and time to each study store ('footfall') will be estimated using baseline EPOS data. Days will be split into five three hour shifts from 7am-10pm across the seven days of the week and individuals will then be selected, proportional to footfall, from a sample of 12 shifts per store balanced across days and times within and between stores. This should ensure that those invited to take part are reasonably representative of all store users, in terms of day and time of store use.

21.1.4. Recruitment of individual participants

Based on previous research, we estimate that around 40% of individuals invited to take part in the study will agree. Potential participants will be recruited in-store by trained NatCen fieldworkers who will approach adult shoppers and invite them to take part in a short screening questionnaire to confirm the inclusion criteria. If these are met, the research will be explained and individuals will be invited to take part. Those who express interest will be given a written information sheet and asked to provide contact details so a home visit from a trained NatCen fieldworker can be arranged.

21.2. Economic evaluation

The individual and store level data used in the economic evaluation will be collected as part of the cluster RCT and process evaluation. Sampling and recruitment will, therefore, be as per those components.

21.3. Process evaluation

The qualitative element of the process evaluation will involve recruiting stores as well as individual participants who are regular users of those stores, alongside retail sector personnel working at those stores, and intervention implementation professionals.

21.3.1. Sampling of stores

A sub-sample of study stores taking part in the cluster RCT will be purposively sampled to reflect the same sampling strata used to select stores for the cluster RCT and to include most of the symbol groups participating in the intervention. Customers and retail sector personnel participants in the qualitative element of the process evaluation will be selected from around these study stores.

21.3.2. Sampling and recruitment of customers

Regular users of selected study stores will be recruited using the same techniques as described for the cluster RCT, although recruitment will be by trained researchers from Stirling University, not NatCen. That is, a trained researcher will approach adult shoppers and invite them to take part in a short screening questionnaire to confirm the inclusion criteria. If these are met, the research will be explained and individuals will be invited to take part. Those who express interest will be given a written information sheet and asked to provide contact details so telephone calls can be made to arrange focus group sessions.

Individuals will then be purposively sampled to reflect the socio-demographic profile of individuals participants in the cluster RCT from amongst those who express interest in taking part in the research. These individuals will be telephoned and invited to attend focus groups at convenient community locations.

21.3.3. Selection and recruitment of retail sector personnel and intervention implementation professionals

Retail sector personnel will be purposively sampled to reflect store owners, store managers, Fresh Food Champions, and other members of staff. Key people involved in the implementation of the intervention will be purposively sampled and include members of the DH implementation team, key decision makers from symbol groups taking part in the intervention, and symbol group regional managers. Potential participants will be invited to take part in interviews via a telephone call to their place of work introducing the research and explaining the research process. Interviews will take place at participants' place of work, or other convenient locations.

22. RANDOMISATION

Randomisation will take place only at the store level within the cluster RCT. We will employ simple randomisation within pairs of stores (the digital equivalent of tossing a fair coin) to allocate one of the two stores to the intervention. Randomisation will be performed by the trial statistician at Newcastle University.

23. ASSESSMENT AND FOLLOW-UP

23.1. Cluster RCT

23.1.1. Baseline assessment of individuals

Individual participants will be contacted by telephone soon after in-store recruitment to arrange a home visit from a trained NatCen fieldworker. During these telephone calls, participants will be asked whether they would prefer reminders the day before home visits are due to take place to be made via telephone or SMS text message, and to provide an appropriate telephone number to facilitate this. Participants will be telephoned, or sent SMS text messages, as appropriate, the day before home visits are due to take place as a reminder and to confirm arrangements.

During home visits, participants will be given a further verbal explanation of the research process and the opportunity to ask any questions they have of the researcher. They will then be invited to confirm their willingness to proceed by completing a written consent form. Next, a socio-demographic questionnaire will be completed and the process of the two-day food diary explained. Finally, the researcher will explain that a questionnaire collecting information on household grocery shopping habits will be completed at the follow-up visit when the food diary is collected and that participants may want to discuss the issues that this questionnaire will cover with the main household grocery shopper (if this is someone other than the respondent) in the interim. A card describing the main topics in the shopping habits questionnaire will be left with participants.

Participants will be provided with a food diary in which to record all food and drink consumed with time of consumption and approximate weights over two consecutive days, with the first day of recording chosen using a quota method to ensure approximately equal numbers of individuals per store begin recording on the same day of the week. When placing the diary, interviewers will use a protocol to explain it to the respondent, going through the different sections including the instruction page, information on describing details of food and drink and portion sizes and an example day. The diary will provide photographs of frequently consumed foods as small, medium and large portion sizes which respondents can use for identical or similar foods. Otherwise portion sizes will be in household measures or, for packaged foods, the weight indicated on the packet. Respondents will also be asked to collect the food label information/wrappers for any unusual foods and ready meals consumed to help coders identify or clarify items consumed.

Food diaries will be collected at a second visit no later than three days after the last diary day. Interviewers will review the diary with the respondent to identify and edit possible omissions and missing detail. The shopping habits questionnaire will then be administered. At this visit, participants will also be given a form and return envelope to inform the study team of changes of address or change of circumstance (including where a study participant has died) between baseline and follow up. All participants who complete a food diary will be given a £20 shopping voucher as a 'thank you' gesture. As soon as possible after this follow-up visit, fieldworkers will complete an evaluation of food diaries indicating their assessment of the quality of data collected.

In any cases where participants are not at home when a fieldworker arrives for a home visit, efforts will be made to re-arrange by telephone on a maximum of five occasions on different days of the week and at different times of day. This will occur after a maximum of two broken appointments.

23.1.2. Follow up assessment of individuals

All individuals who complete baseline assessments will be sent a 'thank you' letter around six months after baseline that also reminds them of follow up assessments at 12 months. A further change of address and change of circumstance form and return envelope will be included with this letter. Twelve months after baseline participants will be re-contacted, via letter and then telephone, to arrange another home visit from a trained NatCen fieldworker and the preferred method of sending confirmation details determined. The

procedure for data collection will be largely as at baseline, although written informed consent will not be collected again. Additional questions concerning awareness of the intervention will be included in the shopping habits questionnaire at follow up. Each participant will complete a food diary for the same two days of the week at follow up as they did at baseline.

Following complete of final data collection at follow-up, all participants will be given a further £20 shopping voucher as a "thank you" gesture.

In any cases where participants are not at home when a researcher arrives for a home visit, efforts will be made to re-arrange by telephone on a maximum of five occasions on different days of the week and at different times of day. This will occur after a maximum of two broken appointments.

Whenever data is collected the researchers will adhere to good practice in maintaining confidentiality of information given and data will be anonymised as soon as practicable. The Newcastle University Institute of Health and Society, Code of conduct on confidentiality (in appendix A) will be used to guide appropriate procedures.

23.2. Economic evaluation

The majority of the data used in the economic evaluation will be collected as part of the cluster RCT and process evaluation components and assessment will, therefore, be as per those components. The topic guide for the qualitative element will incorporate topics relevant to the economic evaluation such as time taken up by the initiative and impact on staff. In addition, costs of the intervention associated with DH and individual c-stores will be assessed, including any labour, consumables and any other costs. Where necessary this additional data will be accessed by telephone calls to the store managers and regional managers. Data from the cluster RCT and process evaluation (e.g. food diary data and shopping habits questionnaire, in store observation and contemporary web data) will be used to estimate costs to consumers associated with changing consumption patterns.

23.3. Process evaluation

23.3.1. Quantitative element

Collection of shopping habits data is detailed in sections 23.1.1 and 23.1.2. The other aspects of the quantitative process evaluation are analyses of EPOS data and in-store observations. Information on sales of FFV over one week at baseline, one month and 12 month follow up will be provided by store managers from their EPOS records.

Information on available FFV will be assessed by direct observation by researchers visiting individual stores. An in-store observation instrument will be used to collect data at baseline; one and 12 month follow up to assess variety, cost and quality of FFV and to assess how the intervention has been implemented in intervention stores at one and 12 month follow up. With store managers' permission, we will also take digital photographs of the inside and outside of study stores to keep a permanent record of use of C4L branded materials and FFV displays. Cost comparison data will be accessed via web based searches of a major high street retailer's on-line store for the costs of a comparable range of FFV to that currently available in the study c-store within eight days of each individual c-store visit.

Although researchers will make themselves known to managers on arrival for observations and seek permission to conduct observations, these visits will be unannounced.

23.3.2. Qualitative element – focus groups with customers

Arrangements for attendance at focus groups made during recruitment telephone calls will be confirmed in a letter sent with a further copy of the information sheet. During recruitment telephone calls, participants will be asked whether they would prefer reminders the day before focus groups are due to take place to be made via telephone or SMS text message, and to provide an appropriate telephone number to facilitate this. Participants will be telephoned, or sent SMS text messages, as appropriate, the day before focus groups are due to take place as a reminder and to confirm arrangements.

Consumers will be welcomed to focus groups with light refreshments and a brief verbal description of the research process and discussion of the ground rules for focus groups. Participants will then be invited to ask

any questions they have of the researchers and to complete a written consent form. Following focus groups, participants will be thanked for their input and given £20 shopping voucher as a "thank you" gesture.

Focus group discussions will be guided by a topic guide developed during pilot work, and with participants' consent, will be audio recorded. Recordings will be transcribed verbatim for analysis.

No attempts will be made to recontact participants who do not attend focus groups as arranged.

23.3.3. Qualitative element – one-to-one interviews with retail sector personnel and intervention implementation professionals

Arrangements for one-to-one interviews made during recruitment telephone calls will be confirmed in a letter sent with a copy of the information sheet. During recruitment telephone calls, participants will be asked whether they would prefer reminders the day before interviews are due to take place to be made via telephone or SMS text message, and to provide an appropriate telephone number to facilitate this. Participants will be telephoned, or sent SMS text messages, as appropriate, the day before interviews are due to take place as a reminder and to confirm arrangements.

Interviews will begin with a brief verbal description of the research process. Participants will then be invited to ask any questions they have of the researcher and to complete a written consent form. Following interviews, participants will be thanked for their input and given £20 shopping voucher as a "thank you" gesture.

Interviews will be guided by a topic guide developed during pilot work, and with participants' consent, will be audio recorded. Recordings will be transcribed verbatim for analysis.

In any cases where participants are not available when a researcher arrives for a one-to-one interview, efforts will be made to re-arrange by telephone on a maximum of five occasions on different days of the week and at different times of day. This will occur after a maximum of two broken appointments. If arranging a face-to-face interview proves impossible, telephone interviews will be conducted.

24. BLINDING

Blinding will only be of importance in the cluster RCT – participants in the qualitative element of the process evaluation will be actively encouraged to discuss the intervention. At baseline, we will not inform fieldworkers or individual cluster RCT participants what the intervention being studied is, nor whether stores have been allocated to the intervention or control group. By 12 month follow up it is possible that both individual cluster RCT participants and fieldworkers will have noticed local C4L branded c-stores. However, again we will not specifically tell either participants or fieldworkers what the intervention being studied is. There will be some questions concerning awareness of the intervention at follow up so. For these reasons, we will not be able to prevent awareness of the intervention or group allocation by 12 month follow up in all cases and the cluster RCT technically falls within the definition of an 'unblinded' RCT.

24.1. Cluster RCT

24.1.1. Stores

It will be impossible to blind store staff to the group they have been allocated to, and no attempt will be made to do this. Store managers will be informed whether they have been allocated to the control or intervention group after baseline data collection via a letter.

24.1.2. Individuals

Individuals will not be informed of the specific intervention that the study is evaluating or the specific outcome of interest. However, if they regularly use an intervention group study store it is unlikely that they will not notice changes made as a result of the intervention. Participants will be asked at follow up if they are aware of the intervention in general, or in a store they regularly shop at.

24.1.3. Research staff

NatCen fieldworkers will not be informed of the specific intervention that the study is evaluating, the specific outcome of interest, or the study group that stores have been allocated to at baseline. However, it is possible that they will become aware of the intervention being studied and the study group that stores have

been allocated to at follow up during travels in the local area and during administration of questions on awareness of the intervention. No steps will be taken to avoid this.

25. RETENTION AND MINIMISATION OF LOSS TO FOLLOW UP

As the primary outcome of interest is the effect of the intervention at the individual, rather than store, level, we will be most concerned with loss to follow up of individual cluster RCT participants, but drop out of stores is also possible. Loss to follow up will not be a concern in the qualitative element as participants will not be followed up.

25.1. Cluster RCT

25.1.1. Stores

We will not make any specific attempts to minimise loss to follow up amongst study stores. If any stores do drop out from intervention implementation, we will identify this during 12 month in-store observations.

25.1.2. Individuals

We will take a number of steps to minimise loss to follow up, including:

- Ensuring participants understand the full research process when they agree to take part at baseline
- Arranging all home visits at a time convenient to participants
- Reminding participants of home visits the day before they are due to take place by telephone or SMS text message – as preferred by the participant
- Offering financial incentives to all individuals who complete the research
- Making substantial efforts to rearrange any missed home visits
- Leaving change of address notification forms with participants at the end of baseline data collection
- Sending updates to participants around 6 months after baseline reminding them of the research, the financial incentive, and providing a further change of address notification form

The majority of data collection will take place in-home after making initial contact with individuals in-store and then arranging a home visit by telephone. There is further potential for drop-out between initial contact and baseline data collection. It will be the responsibility of NatCen fieldworkers to take account of this and the contract with NatCen will be to recruit and collect baseline data from a minimum of 38 individual participants per store.

26. DEBRIEFING

At the final contact with researchers, all participants in all components of the research will be asked if they would like to be informed of the study results when these become available. All those who indicate that they would, will be asked to provide their name and address (should this not already be on file). A written summary of the research aims and results will be sent to all those who indicate they would like this. This will occur as soon as possible after completion of all data collection.

27. STOPPING RULES

We do not propose any stopping rules or discontinuation criteria. Data will only be collected from individual cluster RCT participants at one follow up point and we will not be able to assess interim effects. We do not anticipate any serious negative impacts on individual cluster RCT participants of taking part in the research.

28. ANALYSES

28.1. Cluster RCT

28.1.1. Coding of food diaries

Food diaries will be coded by trained coders and editors at the MRC Human Nutrition Research Unit, Cambridge (HNR). Food intakes will be entered into a modified version of HNR's dietary assessment system (Diet In Nutrients Out - DINO), an all-in-one dietary recording and analysis system. The food composition data in the FSA's NDNS nutrient databank will be used. Coders will assign food and portion codes from DINO to each item recorded in food diaries. Wrappers and labels collected by individual cluster RCT participants will also be used when coding. Within DINO, each food code is linked to appropriate portion size descriptors, mainly household measures, which are then linked to the correct weight for that food. Coding of portions,

described as small, medium or large, is based on the FSA's reference book.(20) In addition, where portion size is described as a weight, the weight can be entered directly in grams.

28.1.2. Statistical analysis

For the primary outcome measure, the null hypothesis is that there is no difference in mean change in FFV intake from baseline to 12 months between individuals clustered around intervention and control stores. The alternative hypothesis is that the mean difference in the change between the two groups is not equal to zero. The null hypothesis will be tested using a multilevel model with random components for individuals and c-stores, and will be adjusted for baseline FFV intake and randomisation stratification variables. The multilevel model takes account of the clustering of individuals at the c-store level and adjusts standard errors appropriately. The result of this analysis will be presented as a 95% CI for the (adjusted) mean difference in the change in FFV intake between the two groups.

A multilevel modelling approach also allows variation in change in FFV intake to be partitioned in to store and individual levels. It permits the inclusion of characteristics of individuals and stores that are known (or hypothesised a priori) to be associated with the outcome of interest. Inclusion of such terms may reduce the estimate of the standard deviation of the effect and hence provide a more precise estimate of the effect of the intervention. The primary analysis will be by intention to treat. If necessary, a per-protocol analysis will also be performed, only including data from those stores that have complied with the intervention.

Exploratory analyses that incorporate interaction terms within and between levels and random coefficient terms at the store level will attempt to tease out "what works for whom, in what circumstances". However, formal hypothesis testing will be restricted to the primary outcome for which the study has been powered. All other hypothesis testing will be informal and interpreted as such.

28.2. Economic evaluation

Given that most of the economics data will be collected in disaggregated form, the statistical analyses will follow those for the cluster RCT data - taking account of the cluster design of the trial and of any further skewness in the costs. Beyond this, the approach will be to assess whether the intervention is unambiguously efficient - leading to improvements in dietary behaviour with no impact on net costs (or profits) in the different sectors concerned. If this is not the case, the trade-offs between sectors in terms of costs and outcomes will be made explicit along with an assessment of their magnitudes.

28.3. Process evaluation

28.3.1. Quantitative element

The EPOS data will be analysed using standard data mining measures for basket analysis – a modelling technique that identifies products commonly purchased together.(21)

28.3.2. Qualitative element

Focus group and interview transcripts will be electronically organised according to themes specified in the topic guides and emergent from the data. Transcript tables will then be examined in-depth to identify key patterns of, and divergent, responses. At least two researchers will be involved in the analysis, and any differences of interpretation will be resolved through discussion or involvement of other members of the research team. Verbatim anonymous quotes will be used to illustrate findings.

28.4. Integration of results and final interpretation

Results from the cluster RCT, the economic evaluation and the process evaluation will be considered together in order to judge the impact of the intervention on c-stores and their users. Three sources of quantitative data will be used to explore changes at store level between and within study arms: EPOS data, showing changes in FFV sales and FFV costs; difference in intervention implementation using in-store observations; and retail mapping using Institute of Grocery Distribution data (to demonstrate any major changes in local retail landscape). Data from a number of sources will contribute to the economic evaluation. In particular, data will be integrated from food diaries, the food shopping questionnaire and EPOS data on food cost. The qualitative data will be used to explore our findings from the quantitative and economic analyses, including any differences in effects between stores and areas.

29. ETHICS APPROVAL

Ethics approval will be sought from Newcastle University Faculty of Medicine Ethics Committee for all components except the qualitative process evaluation. Ethics approval for the qualitative process evaluation will be sought from Stirling University.

30. RESEARCH GOVERNANCE

Newcastle University will act as the sponsor for this research. The research will be overseen by a Independent Trial Steering Committee (ITSC) in line with the MRC Guidelines for Good Clinical Practice in Clinical Trials.(22) The composition of the ITSC will be:

- Prof. John Norrie (independent expert chair)
- Prof. Annie Anderson (independent member)
- One further member, to be confirmed (independent member)
- Dr. Jean Adams, Newcastle University (co-applicant, research manager)
- Prof. Ashley Adamson, Newcastle University (co-applicant, lead for analysis of nutritional data)
- Ms. Georgina Cairns, Stirling University (co-applicant, lead for qualitative aspects of the process evaluation)
- Dr. Sam Clemens, National Centre for Social Research (co-applicant, NatCen liaison and lead for cluster RCT participant recruitment and assessment)
- Prof. Cam Donaldson, Glasgow Caledonian University (co-applicant, lead for economic evaluation)
- Ms. Anne Findlay, Stirling University (co-applicant, lead for quantitative aspects of the process evaluation)
- Dr. Alison Lennox, Cambridge University (co-applicant, HNR Cambridge liaison and lead for input of nutritional data)
- Ms. Stephanie Rice, Association of Convenience Stores (implementation manager of the c-store C4L FFV intervention programme for DH and ACS)
- Dr. Alison Ross, Department of Health (budget holder for the c-store C4L FFV intervention programme within DH)
- Ms. Vicky Ryan, Newcastle University (co-applicant, trial statistician and representative of Newcastle Trials Unit)
- Prof. Martin White, Newcastle University (principal applicant, chief investigator)
- Representative of the public recruited through INVOLVE

Observers from the funders will be invited to all ITSC meetings and all ITSC papers and reports will be copied to them.

Management of the study will be overseen by a study management committee, including all investigators and representatives of the intervention team.

Both the ITSC and study management committee will meet on four occasions during the course of the study.

Day-to-day management of the study will be guided from the team based at Newcastle University meeting at least monthly.

31. TRIAL WEBSITE

None. As we do not want to alert individual cluster RCT participants to the intervention being evaluated, we will not develop a trial website aimed at participants.

32. PUBLICATIONS

None as yet.

33. PUBLICATION POLICY

All applicants, and study researchers, will be eligible for authorship of all papers but final authorship will be determined using the Vancouver criteria. In addition to a final report to the funders, we envisage the

following publications in peer-reviewed journals (with responsibility for leading, or identifying a lead, as indicated):

1. A protocol paper (Jean Adams, co-applicant and project manager).
2. A results paper describing the effect of the intervention on the primary and secondary dietary outcomes (Martin White, principal applicant).
3. A results paper describing the quantitative process evaluation (Anne Findlay, co-applicant and lead for quantitative process evaluation).
4. A results paper describing the qualitative process evaluation (Georgina Cairns, co-applicant and lead for qualitative process evaluation).
5. A results paper describing the economic evaluation (Cam Donaldson, co-applicant and lead for economic evaluation).

34. PERSONNEL

34.1. Principal applicant

Prof. Martin White, expertise in evaluation of complex interventions, will lead integration of the three research strands and will provide overall leadership for the full research team. As principal applicant and overall lead, he will be a member of the ITSC.

34.2. Co-applicants

Dr. Jean Adams, expertise in socio-economic inequalities in health and analysis of large datasets. She will lead reporting and act as research manager.

Prof. Ashley Adamson will bring expertise in nutritional epidemiology and collection of dietary data.

Ms. Georgina Cairns will lead and manage the qualitative retail aspects of the process evaluation. She will also act as liaison between the retail and qualitative research teams.

Dr. Steven Cummins will bring expertise in geographical and socio-environmental determinants of health and will contribute to store sampling for the cluster RCT using geographical information systems techniques.

Prof. Cam Donaldson will bring expertise in economic evaluation and lead the economic evaluation.

Ms. Anne Findlay will lead the quantitative retail evaluation, conduct the retail mapping, design and analyse the in-store monitoring, and supervise EPOS data input and conduct analysis.

Dr. Amelia Lake will bring expertise in assessment of the food retail environment and nutritional epidemiology and will contribute to analysis of nutritional data.

Dr. Alison Lennox is based at HNR Cambridge and has substantial experience in collection of dietary data through involvement with NDNS, she will oversee food diary coding.

Prof. Sally Macintyre will bring expertise in the evaluation of complex interventions and the socio-environmental determinants of health.

Prof. Mark Petticrew will bring expertise in evaluation of non-health sector policy interventions.

Ms. Vicky Ryan will bring expertise in statistical analysis, as well as leading sampling, randomisation and data quality control. She will conduct the statistical analysis of the cluster RCT data and act as a representative of the Newcastle Trials Unit and as the trial statistician.

Prof. Leigh Sparks will bring expertise on retail research and its application in dietary monitoring.

Ms. Martine Stead will bring expertise in qualitative process evaluation, and will also contribute to completion of the consumer aspects of the process evaluation.

34.3. Collaborators

Alison Ross is the budget holder for the c-store C4L FFV intervention programme within DH and a member of the cross-government obesity unit. Her colleague *Mark Hennis* will deputise as necessary.

Stephanie Rice project manages the c-store C4L FFV intervention programme for DH and ACS.

Sam Clemens at NatCen will co-ordinate and manage data collection for the cluster RCT. Her colleague *Tracey Anderson* will deputise as necessary.

34.4. Research staff

Linda Penn will be based at Newcastle University and will contribute to project management and lead in-store observations.

Further researchers, to be identified, will be based at Glasgow Caledonian University (economic evaluation), Stirling University (qualitative and quantitative aspects of process evaluation), NatCen (in-store recruitment and data collection from cluster RCT participants), and HNR Cambridge (coding of food diaries).

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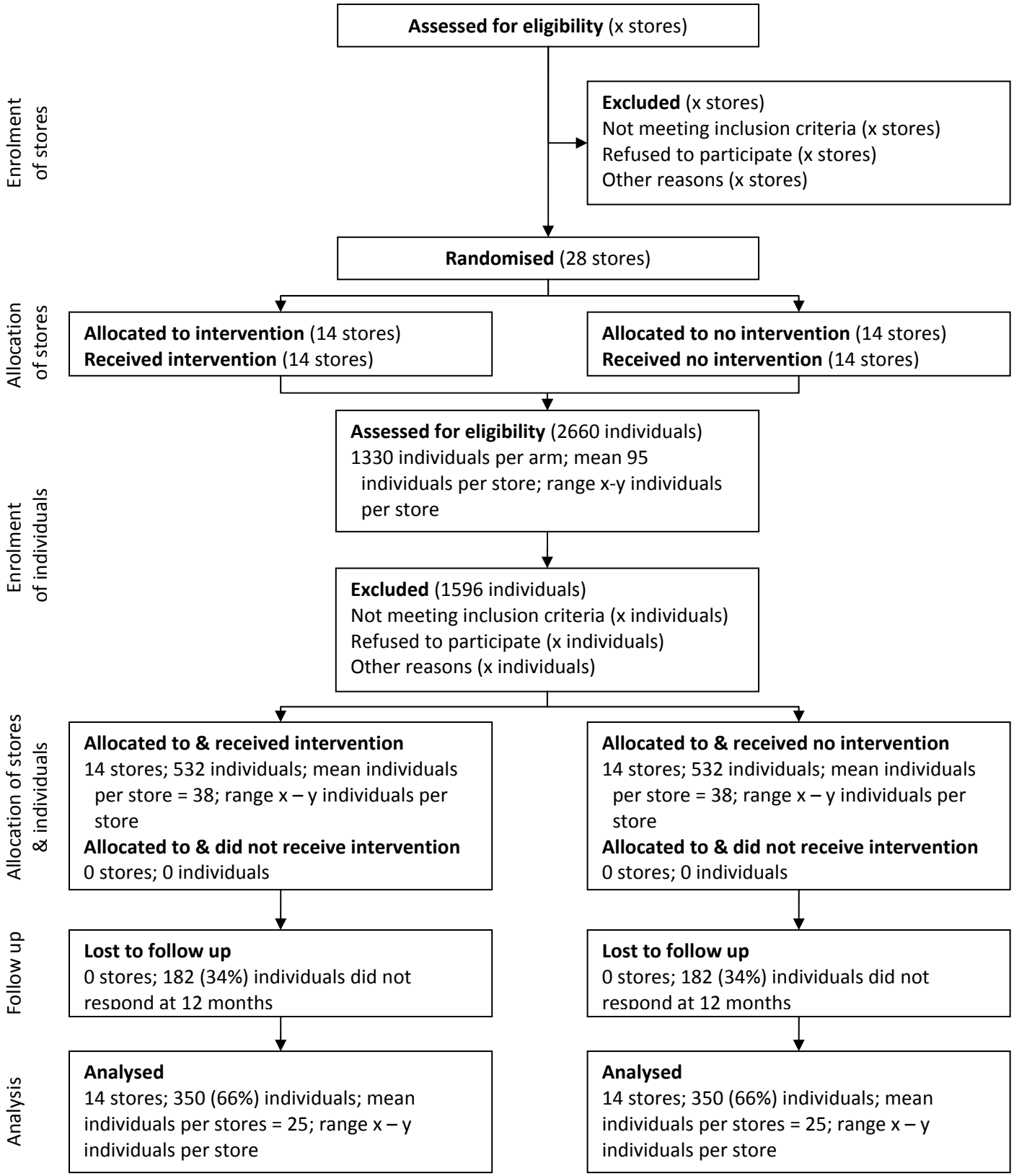
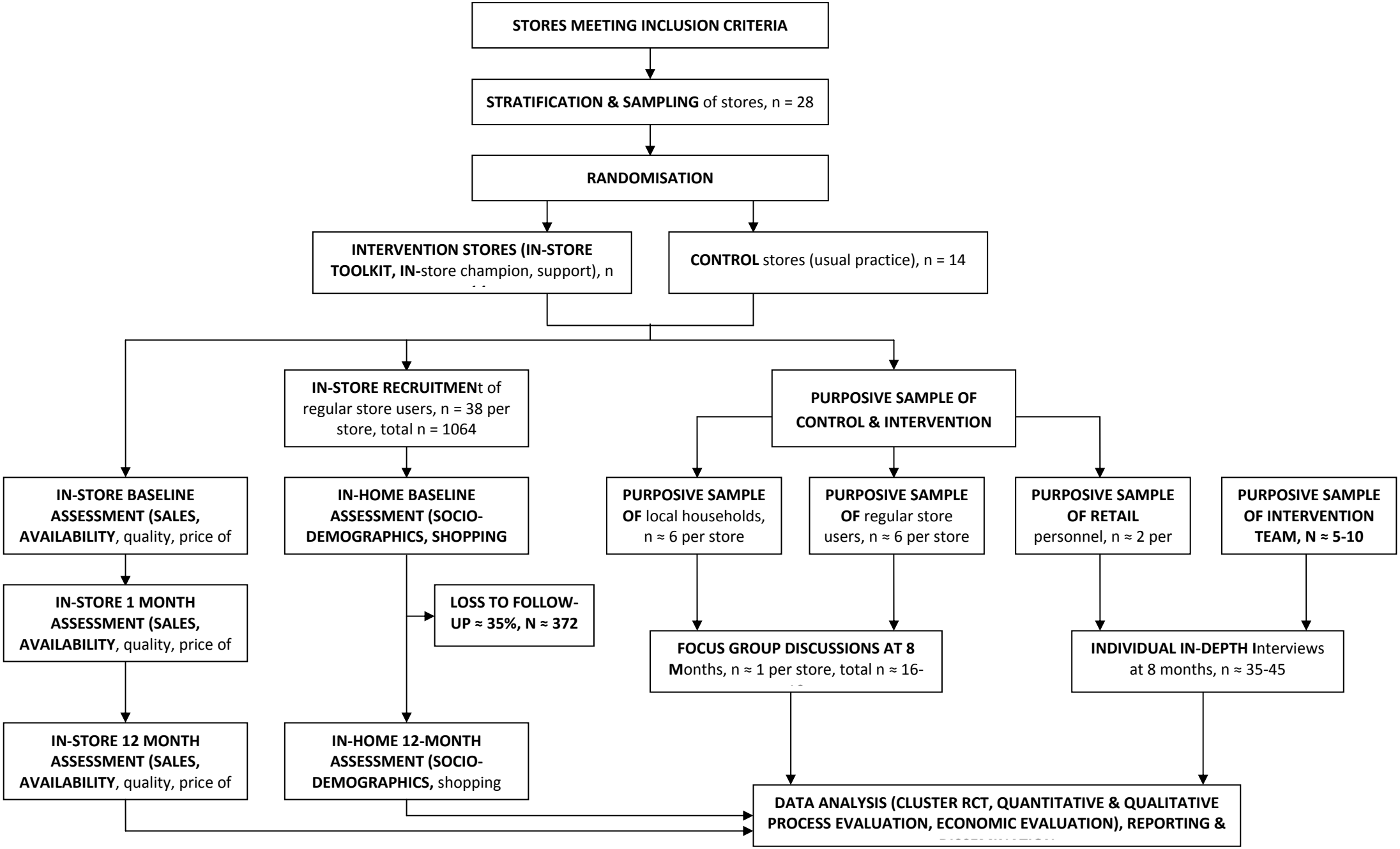
36. CONSORT FLOW DIAGRAM, CLUSTER RCT



Note. All numbers shown here are estimates. Where numbers are represented by x or y, reasonable estimates cannot be made at this stage.

37. FLOW DIAGRAM SHOWING ALL STUDY COMPONENTS



38. TIMELINE

Activity 1	Staff recruitment			Ethics approval				Select & recruit cluster RCT individuals, 3 intervention & 3 control stores per month*					Baseline data checking & cleaning, cluster RCT							12 month follow up data collection from cluster RCT individuals, 3 intervention & 3 control stores per month*					12 month follow up data checking & cleaning, cluster RCT			Data analysis, cluster RCT			Data interpretation & reporting		
Activity 2	External contract finalisation					Select, recruit, randomise stores		Baseline data collection from cluster RCT individuals, 3 intervention & 3 control stores per month*					Pilot focus groups and individual in-depth interviews			Select & recruit qualitative process evaluation participants, 1 intervention & 1 control store per month					Transcription & analysis of focus group and individuals interview data			Data analysis , quantitative process evaluation					
Activity 3				Focus groups to confirm acceptability of methods; finalise measurement tools				In-store baseline data collection, 3 intervention & 3 control stores per month*								Focus group and individuals in-depth interviews, 1 intervention & 1 control store per month					Implement intervention, control stores, 3 stores per month*			Data analysis, economic evaluation					
Activity 4				Finalise sampling & analyses strategies					Implement intervention, intervention stores, 3 stores per month*										In-store 12 month follow up data collection, 3 intervention & 3 control stores per month*												
Activity 5										In-store 1 month follow up data collection, 2 intervention & 2 control stores per month*																				
Milestone			1		2		3, 4					5, 6	7	8							9		10		11			12			13
Month	-3	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
	May 10	June 10	July 10	August 10	September 10	October 10	November 10	December 10	January 11	February 11	March 11	April 11	May 11	June 11	July 11	August 11	September 11	October 11	November 11	December 11	January 12	February 12	March 12	April 12	May 12	June 12	July 12	August 12	September 12	October 12	November 12	December 12	January 13

*3 stores per month for first four months and 2 stores in the final month

All elements | Cluster RCT | Process evaluation | Economic evaluation | Intervention implementation | Milestones

39. MILESTONES

Milestone	Description	Completion date
1	All staff & contracts in place	End July 10
2	All approvals in place	End September 10
3	Consent from all study stores obtained	End November 10
4	All methods finalised	End November 10
5	Consent from all individuals (cluster RCT) obtained	End April 11
6	Baseline data collection from all individuals & stores (cluster RCT & quantitative process evaluation) complete	End April 11
7	Intervention implemented in all intervention stores	End May 11
8	One month follow up data collection from all stores (quantitative process evaluation) complete	End June 11
9	All focus groups and individual interviews complete	End January 12
10	12 month follow up data collection for all individuals & stores (cluster RCT & quantitative process evaluation) complete	End April 12
11	Intervention implemented in all control stores	End June 12
12	All analyses complete	End October 12
13	Reporting complete	End January 13

40. STUDY DOCUMENTATION APPENDICES

A number of documents are provided as appendices. These are grouped under the headings of the components of the study they relate to.

40.1. Cluster RCT & quantitative process evaluation documents (all provided at this stage)

A1 Letter to ACS regional managers about the study

A2 Consent form for regional managers to take part

A3 Letter to stores about the study

A4 Information sheet for stores describing the research process

A5 Consent form for store managers to take part

A6 a Letter to stores concerning allocation to intervention (now) group

b Letter to stores concerning allocation to control (later) group

A7 Information sheet for customers

A8 Consent form for customers

A9 Letter (6 months) to customers concerning retention

A10 Change of address and circumstances form for customers(base and six months)

A11 Letter to customers at 12 months concerning arrangements for follow up data collection

A12 Change of address form for customers at 12 months

A13 DRAFT feedback to participants

A14 Socio-demographic questions (for computer based questionnaire)

A15 Shopping habits questions (for computer based questionnaire)

A16 Shopping habits reminder card

A17 Food and drink diary instructions

A18 Food and drink diary

A19 Diary interviewer assessment schedule

A20 Diary Evaluation

A21 Diary reminder card

A22 Diary packaging card

A23 In-store implementation observation check list

A24 IHS Interviewer safety

A25 IHS Interviewer Safety Chart

A26 IHS Interviewer safety record sheet

A27 NatCen III Working safely Oct 2008

A28 NatCen V risk assessment Oct 2008

A29 NatCen Unsafe Areas Oct 2008

A30 IHS Code of confidentiality

40.2. Qualitative process evaluation documents (not provided at this stage as documents remain in development)

B1 In-store screening questionnaire used during recruitment of customers

B2 Information sheet for customers

B3 Letter to customers concerning confirmation of arrangements for focus groups

B4 Consent form recording informed consent of customers to take part

B5 Topic guide for individual interviews with customers

B6 Letter to retail sector personnel and intervention implementation professionals concerning confirmation of arrangements for one-to-one interviews

B7 Information sheet for retail sector personnel and intervention implementation professionals

B8 Consent form recording informed consent of retail sector personnel and intervention implementation professionals to take part

B9 Topic guide for individual interviews with retail sector personnel and intervention implementation professionals