# Title

**Food for thought: pilot randomised controlled trial of Lay Health Trainers supporting dietary change to reduce cardiovascular disease in deprived communities**

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# Abstract

## Background

Cardiovascular disease (CVD) accounts for 30% of UK deaths. It is associated with modifiable lifestyle factors, including insufficient consumption of fruit and vegetables (F&V). Lay Health Trainers (LHTs) offer practical support to help people develop healthier behaviour and lifestyles. Our two-group pilot randomised controlled trial (RCT) investigated the effectiveness of LHTs at promoting a heart healthy lifestyle among adults with at least one risk factor for CVD, to inform a full scale RCT.

## Methods

Eligible adults (aged 21 to 78 years), recruited from five practices serving deprived populations, were randomised to health information leaflets plus LHTs’ support for three months (n = 76) versus health information leaflets alone (n = 38).

## Results

We recruited 114 participants, with 60% completing six month follow-up. Both groups increased their self-reported F&V consumption and we found no evidence for LHTs’ support having significant added impact. Most participants were relatively less deprived, as were the LHTs we were able to recruit and train.

## Conclusions

Our pilot demonstrated that a LHTs RCT whilst feasible, faces considerable challenges. However, to justify growing investment in LHTs, any behaviour changes and sustained impact on those at greatest need should be demonstrated in an independently evaluated, robust, fully powered RCT.

## Keywords

Lay Health trainer; cardiovascular disease; CVD; life style; primary health care; behaviour change

# Introduction

Cardiovascular disease (CVD) accounts for 30% of all deaths in the UK,[1](#_ENREF_1) with prevalence greatest among deprived communities.[2](#_ENREF_2) Risks of developing CVD are associated with key modifiable lifestyle factors.[3](#_ENREF_3) UK governments, as a core element of reducing health inequalities over the past two decades, consistently advocate heart-healthy lifestyles,[4](#_ENREF_4) through giving individuals and communities greater control over health[5](#_ENREF_5) specifically: help to reduce smoking;[6](#_ENREF_6) increase physical activity;[7](#_ENREF_7) and dietary fruit and vegetables (F&V) uptake.[8](#_ENREF_8) Consequently people in deprived communities are encouraged to develop heart-healthy lifestyle behaviours. However, substantialsocial, structural and economic barriers exist,[9-11](#_ENREF_9) including an individual’s understanding of their CVD risk.[4](#_ENREF_4),[12](#_ENREF_12),[13](#_ENREF_13)

## Literature Review

Randomised controlled trials (RCTs) show people can make favourable lifestyle changes, albeit small, reducing CVD risk.[14-20](#_ENREF_14) Also, peer-led practical advice and support is effective at encouraging individuals/families to translate knowledge into sustained heart-healthy lifestyle change, including those with restricted incomes/budgets.[8](#_ENREF_8),[21](#_ENREF_21) International evidence suggests this may be more efficient and effective than professional-led didactic approaches, where professionals may lack the requisite skill, time, socio-cultural experiences and empathy to work effectively with people facing complex barriers to health-related change.[21-23](#_ENREF_21)

Hence, interventions have shifted from professional-led clinical settings towards community based environments with a more personalised, informal approach using lay workers.[24](#_ENREF_24),[25](#_ENREF_25) The Public Health White Paper ‘*Choosing Health’* introduced health trainers advocating heart-healthy lifestyle promotion outside of a medical model, shifting public health approaches from “advice on high, to support next door”.[26](#_ENREF_26) Health Trainers were launched in April 2007, initially targeting areas of high deprivation but subsequently rolled out universally.[24](#_ENREF_24)

However, prior to this, lay health workers with many different titles already existed, having been introduced into many settings focusing on ‘hard to reach’ groups.[27](#_ENREF_27),[28](#_ENREF_28) They delivered interventions via home visits, telephone calls, community meetings, or healthcare centre appointments. Internationally, researchers have found some evidence of effectiveness including enhanced uptake of immunisations, improved outcomes for acute and TB respiratory infections, malaria, breastfeeding rates, and child morbidity and mortality.[29-31](#_ENREF_29) However, it is less straightforward to determine the extent to which health trainer interventions influence CVD risk reduction.[16](#_ENREF_16),[29](#_ENREF_29)

## Current Study

Consequently, our research reflected this policy shift to using the support of Lay Health Trainers (LHTs), as the means to offer affordable, practical, socio-cultural relevant lifestyle advice within communities. Our paper describes a pilot RCT that compared LHT support plus health information leaflets, versus health information leaflets alone, among adults from deprived inner-city populations with at least one CVD risk factor. The purpose was to investigate the effectiveness of LHTs at promoting heart healthy lifestyles. We hypothesised that those who were offered a LHT intervention would be more likely to adopt heart healthy behaviours than a control group. Our pilot explored feasibility of a LHT intervention before embarking on a full RCT.[32](#_ENREF_32) To this end, our trial had three objectives: piloting of trial processes; a quantitative measurement of changes in heart healthy behaviours with an economic evaluation (results published)[33](#_ENREF_33); and a qualitative evaluation of LHTs training and intervention delivery, implementation and acceptability (results to be reported elsewhere).

# Methods

## Participant selection

Between February and August 2008, we planned to recruit from five North West England practice lists 100 eligible adults (18+ years) to the pilot trial with at least one CVD risk factor: hypertension; raised total cholesterol; diabetes; obesity; or currently smoking. Periodically groups of eligible adults were sent a single recruitment letter without follow-up. Volunteers were screened by telephone to confirm eligibility. Exclusion criteria included: established CVD; being on a diet that may conflict with ‘healthy heart’ dietary advice; groups with low control over diet e.g. the homeless, people in hostels, residential or nursing homes; life expectancy of less than two years; and those excluded by their GP on health grounds.

Participants were consented and recruited after discussing the trial in depth at a face-to face baseline meeting, either at home or at the university, until our target number was reached. The nature of the intervention precluded blinding of participant or researcher; consequently they were informed they would be randomised to LHT support plus health information leaflets versus health information leaflets alone after confirming eligibility with their GP. All participants received standard Primary Care Trust (PCT) ‘healthy heart’ advice leaflets sourced locally, which covered topics on diet, exercise, alcohol, and smoking. Once consented, a trial researcher randomised participants using computerised ran­dom numbers in independently prepared sequentially numbered opaque sealed envelopes. A 2:1 (Intervention:control) allocation ratio was used to maximise our ability to conduct a detailed assessment of intervention delivery. Control participants received no additional support but were encouraged to continue to see their practice team for diet or heart health support if required. Intervention participants were contacted by a LHT and invited to an assessment meeting.

## LHT Intervention

During the trial set-up phase in 2006, we trained a cohort of LHTs for this trial, recruited via community out-reach plus local newspaper adverts. Subsequently five women and one man were employed as part-time LHTs from among the trained cohort. Our ten-day training course was designed using social cognition models of health behaviour and best available evidence of efficacy consistent with local and national examples of intervention,[34-36](#_ENREF_34) which closely mirrored the subsequent national manual and accredited training programme published in June 2008.[37](#_ENREF_37) This focused on communication, client engagement and motivating long-term behaviour change by establishing short-term goals, and enabling the person to build self-efficacy. Following this training, we developed a LHT intervention specifically for this trial outlined in **Figure 1**. Specifically, our LHTs explored the ‘5-A-DAY’ F&V message.[38](#_ENREF_38) However, they also looked at other lifestyle behaviours, when participants expressed an interest and readiness to change. LHTs provided information and advice aimed at changing key beliefs such as perceptions of CVD risk, and advantages/disadvantages of behaviour change.

## Outcome Measures

We collected participant demographic data plus respondent characteristics at baseline and 6 month follow-up. We asked participants to complete questionnaires (self-reported or by researcher interview) to assess heart healthy behaviours:

* Primary Outcome: Daily dietary intake (specifically F&V portions/day) via a modified 125 item Food Frequency Questionnaire (FFQ) and 3-day Food Diary (FD).[39](#_ENREF_39)
* Secondary outcomes: Health Status using EQ-5D; Physical activity using International Physical Activity Questionnaire Long (IPAQ); Alcohol usage via WHO Alcohol Use Disorders Identification Test (Full AUDIT); Smoking; Health Service use; and Total cholesterol via venous blood test carried out by GP.[40-42](#_ENREF_40)

If the participant was unable or did not attend their follow-up appointment, or were not contactable, we sent the questionnaires and food diary, for self-completion and return. In addition, data were collected from the LHTs to examine the fidelity of the intervention and conduct an economic evaluation.[33](#_ENREF_33)

### Statistical analysis

Data were entered using Microsoft Access (2007) and analysed using SPSS (version 17.0). Descriptive statistics including means, standard deviations, and frequency distributions were used to summarise the data. Index of Multiple Deprivation (IMD) 2007 score was based on post codes to understand variations in deprivations and inequity within the target areas.[43](#_ENREF_43) Concurrent validity of the FFQ was assessed by comparing dietary intakes from FFQ-baseline with that of the FD-baseline using Pearson’s correlation coefficients.[44](#_ENREF_44) Although the trial was not powered to detect significant differences in outcomes, analysis adjusting for baseline using analysis of covariance (ANCOVA) to test for any interactions between time and group on outcome measures was done to provide preliminary data for intervention effects and variability. All analyses were done according to random allocation based on intention-to-treat principles with no substitution of missing data by the research team.[45](#_ENREF_45)

# Results

## Participants

Of 2275 trial invitations sent, 162 (7.1%) people responded (**Figure 2**), of whom 145 fulfilled the inclusion criteria and 114 agreed to take part in baseline data collection. Most were white, relatively well educated, employed or retired, and home owners, and thus not the most deprived population. We found no significant baseline differences between the two groups (**Table 1**). The majority self-reported two or more CVD risk factors, with over half describing themselves as being overweight and/or having a raised cholesterol level. Six months after baseline assessment, 68 (60.0%) were successfully followed up. Follow-up did not vary by randomisation group (P=0.21), although respondents were significantly older (mean age 57.2 v 47.0, P<0.001) and non-respondents were more likely to be in paid work (68.8% v 45.6%, P=0.013).

## LHT Intervention

We randomised 76 participants to our LHT intervention. Whilst our LHTs reliably recorded 74 face-to-face meetings with 40 (55.6%) participants (mean = 1.25, range 0–7), telephone contacts were not consistently documented to be reliably included in the analysis. Three participants declined our intervention after LHT contact. However, of the 36 participants that did not undertake face-to-face visits, LHTs reported many difficulties in either contacting or meeting many of them.

## Outcome measures

Our primary and secondary outcomes are summarised in **Table 2**. Our FFQ v FD validity results are comparable to other research (Pearson’s 0.55), confirming its utility in this type of trial.[44](#_ENREF_44) At baseline, participants (aged 21 to 78 years), consumed on average 2.6 F&V portions/day (SD=1.6) for intervention group and controls consumed 2.7 F&V portions/day (SD=1.5), which was below the UK and European average.[46](#_ENREF_46),[47](#_ENREF_47) Participants completing the study had higher baseline F&V consumption than those lost to follow-up (2.8 vs. 2.5 portions/day respectively). At baseline, we found only 13.2% of all participants were meeting a ‘5-A-DAY’ recommendation. Both groups had notably increased their consumption of F&V at follow-up (mean portions/day: intervention 5.9, SD=2.8; control 5.4, SD=3.1). There was no statistically significant additional benefit from seeing a LHT (P=0.95). For our secondary outcome measures no significant changes were observed in mean EQ-5D, total cholesterol, or total physical activity scores in our participants. However, a fall (p=0.07) was observed in mean AUDIT alcohol scores in the LHT intervention group.

## Sample size calculation for full RCT

The FFQ daily F&V intake we observed was approximately normally distributed. Assuming the difference we found between the intervention and control group means of 0.5 F&V portions/day,[48](#_ENREF_48),[49](#_ENREF_49) is true, a sample of 394 (552 to account for 40% dropouts) per group will be required to reject the null hypothesis (population means of the intervention and control groups are equal) with probability 0.8 (80% power) at this lowest clinically significant relative dietary improvement.

# Discussion

## Main findings of this study

LHTs represent a complex intervention, with several interacting intervention components and other characteristics, including the number and variability of outcomes.[32](#_ENREF_32) The Medical Research Council framework for evaluating complex interventions stresses the importance of understanding problems of recruitment, retention, compliance, and intervention delivery, via thorough piloting before embarking on a RCT,[32](#_ENREF_32) a key aim of our pilot trial. We have identified several technical challenges that any future RCT design of a LHT complex intervention has to overcome. We observed low recruitment rates, high loss to follow-up, and significantly increased self-reported F&V consumption for both groups. Despite targeting populations in high deprivation neighbourhoods, our participants were mostly the relatively affluent, more educated residents, and self-selected by their motivation to learn additional ways of continuing to improve their health. As our LHT intervention was low intensity, the trial data collection processes could also be seen as an intervention. Paradoxically, the process of volunteering, discussing the trial, and completing behaviour focused questionnaires may cover much of the basic LHT intervention components and highlighted potential behaviour changes to participants.

## What is already known on this topic

UK evaluations of health trainer services report that most clients focus on diet related behaviour changes,[50](#_ENREF_50) with 47% classed as fully, and 23% partly successful in completing their Personal Health Plans.[51](#_ENREF_51) Clients perceive health trainer support as achieving behaviour change in a variety of community settings.[52](#_ENREF_52) Existing literature reports significant reductions in BMI, 31.0 to 29.7,[53](#_ENREF_53) and increases in mean F&V consumption,[54](#_ENREF_54) recent data showing increases from 2.9 F&V portions/day to 4.6 F&V portions/day.[50](#_ENREF_50) In addition, a health trainer’s role signposting individuals to specific services, such as smoking cessation, has achieved some small success.[55](#_ENREF_55) However, this evidence is from ‘before and after uncontrolled’ evaluations, with outcomes based mainly on informal self-report measures.[54](#_ENREF_54) Our economic analysis estimates a health trainer intervention is potentially cost-effective for people at risk of CVD, though there was a large level of uncertainty associated with that finding.[33](#_ENREF_33)

## What this study adds

A variety of lessons have been learnt from this research. Despite the low initial response rate to mail-shot invitation (7.1%), and high loss after 6-month follow-up (40%), ours is the first pilot trial to provide evidence for the feasibility of a LHT RCT in a primary care setting. We suspect difficulties in attracting those at greatest risk may be common, and reflect the likely response to offers of health trainer support within primary care as this was also an experience shared by a local practice-based health trainer service (Gabbay M. GP. Personal communication. 1st August 2008).

A crucial component to a LHT role is community recruitment,[56](#_ENREF_56) nevertheless, we had difficulties in recruiting locally. Our six LHTs were not local and three were health professionals looking for new opportunities in public health. So the notion of recruiting lay people as effective ‘culture brokers’,[57](#_ENREF_57) that remains central to the conceptual premise of a lay helping model, may be difficult to achieve. A similar issue of a cross-section of lay and knowledgeable people as health trainer recruits, is reflected in the evolving national health trainer initiative.[52](#_ENREF_52)

National activity reports show that health trainers target a broad range of disadvantaged communities.[58](#_ENREF_58),[59](#_ENREF_59) Accordingly a health trainer service has the potential to decrease health inequalities.[51](#_ENREF_51),[54](#_ENREF_54) Our data support this in that it is possible to identify individuals with CVD risk factors through GP records to reach people with needs living in areas of deprivation. However, our participants had a higher than expected level of home ownership, were mainly employed or retired, relatively well educated, motivated, and already making lifestyle changes. Consequently, resources may be reaching those least needing it within those communities, paradoxically increasing health inequalities. Whilst this may be a research specific effect, high missed appointment rates with local health trainers suggest this is a wider concern.

In part, our LHTs were peers of those recruited to the trial but based on recorded face-to-face contacts, delivered a low frequency intervention (mean visits=1.25). Our results show that all participants had increased self-reported F&V consumption at follow-up, reflecting similar gains seen in national activity reports. Furthermore, it is not known if these gains were sustained beyond last contact or have a clinical impact on CVD outcomes. Nevertheless, a potentially clinically important improvement of 0.5 F&V portions/day was observed between intervention and control groups,[48](#_ENREF_48),[49](#_ENREF_49) making it possible to calculate a sample size for a full RCT. Therefore to be confident about the sustainability of any initial lifestyle-related gains, further follow-up after 12-18 months would be required. However, relatively disappointing follow-up return rates suggest that collecting longer-term follow-up data from a representative sample of participants will be challenging.

Future trials should also collect data on motivation and behavioural intentions using psychological measures. Effective targeting may require active motivation for change as part of a LHT referral, an additional challenge within time-limited clinical consultations adding to the overall intervention cost. Participant recruitment should be stratified for ‘deprivation index’ and other measures of educational attainment. Employment and other key confounders should be collected to ensure sampling is more representative. Also, if LHTs are to work within deprived communities with worse health and greater co-morbidity rates they will need extended training to manage the additional complexity. Furthermore, to account for the difficulty of separating and controlling for the influences of trial measurements as an intervention, we should compare control group versus a low (awareness raising and dietary monitoring alone) versus a higher intensity intervention with motivation and goal setting interventions undertaken by the health trainer. Finally, synchronised health and local authority policies are needed to tackle the barriers to improving health behaviours.[60](#_ENREF_60)

## Limitations of this study

There are known limitations for self-reported methods to assess dietary intake.[44](#_ENREF_44) FFQ’s are often chosen for research as they are quicker and easier for participants to fill out compared to FD (gold standard) and are easier to analyse. However, both tools can be used to highlight current diet and to enhance motivation. We gave both to our participants at baseline and six month follow-up, and they may have modified their eating habits accordingly. Our findings could in part be explained by participants being aware of the intent of the trial to target diet (5-A-DAY), which was not possible to blind, with the intervention,[61](#_ENREF_61) or ‘social desirability bias’,[62](#_ENREF_62) exacerbated by a tendency for FFQ’s to over-estimate F&V consumption.[63](#_ENREF_63),[64](#_ENREF_64) Finally, it may reflect sampling bias, because in many cases our LHTs considered their potential impact was limited since our participants were already eating a ‘healthy’ diet, were ex-smokers, undertaking moderate to high level of physical activity and drinking sensibly; suggesting an awareness of healthy lifestyle modifications, the means to achieve them, and motivation to make them. These are key areas targeted by the LHT model; consequently our LHTs had to find lesser targets for the participant to achieve, which may or may not have meaningful impact for heart-healthy lifestyles.

# Conclusions

The UK health trainer initiative offers something quite distinctive from professional advice, helping individuals to access support and services within local communities. UK funding has been rising, from £10.5 million in 2007-08 to £25 million during 2008-09,[59](#_ENREF_59) with the North West alone receiving £9 million funding during 2009-10.[55](#_ENREF_55) Given its relatively low costs, local flexibility and resonance with strategic trends towards social prescribing, we foresee that a lay health trainer model could provide locally responsive support for health and wellbeing and disease prevention initiatives, with the potential to tackle health inequalities. Future studies could recruit through UK health trainer service, whose workforce is expanding year on year with increasing numbers of clients,[58](#_ENREF_58),[59](#_ENREF_59),[65](#_ENREF_65) which potentially offers solutions to recruitment and retention issues. However, evidence of any treatment effect and its sustained impact on the most deprived should be demonstrated in an independently evaluated, robust fully powered RCT, before justifying growing investment in this solution for tackling health inequalities through reducing lifestyle risks. Attention to the conceptual and theoretical frameworks underpinning the intervention will also be crucial.

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# Conflict of interest

The authors have no competing interest to declare.

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# Figures & Tables Captions

Figure 1: LHT Intervention

**162** initiated contact and assessed for eligibility

**2275** potential participants contacted via mail shot

Excluded (n=17)

Not meeting inclusion criteria (n=3)

Refused to participate (n=9)

Unable to participate at that time (n=5)

**145** invited for baseline data collection

**114** randomised (2:1 Ratio)

Excluded (n=31)

Not meeting inclusion criteria (n=3)

Did not attend (n=28)

**76** were assigned to Intervention Group

**38** were assigned to Control Group

**44** Completed ‘Visit Two’

**2** Withdrew

**30** Lost to follow up

**24** Completed ‘Visit Two’

**2** Withdrew

**12** Lost to follow up

**76** were included in Intention-to-treat analysis

**Recruitment**

**Randomisation**

**Follow-up**

**Analysis**

**38** were included in Intention-to-treat analysis

**Enrolment**

Figure 2: Participant recruitment, allocation and retention by trial group (Consort flow diagram)

Table 1: Characteristics of participants at baseline

|  |  |  |
| --- | --- | --- |
| **Characteristics** | **Intervention Group** | **Control Group** |
|  | **(n = 76)\*** | **(n = 38)\*** |
| **Age, years, mean (SD, range)** | 53.7 | 52.6 |
|  | (12.5, 21 to 78) | (14.2, 28 to 78) |
| **Demographic details, n (%)** | | |
| **Gender** | | |
| **Female** | 45 (59.3) | 23 (60.5) |
| **Ethnicity** | | |
| **White** | 74 (97.4) | 37 (97.4) |
| **Black** | 1 (1.3) | 0 (0) |
| **Mixed ethnicity** | 1 (1.3) | 1 (2.6) |
| **Accommodation** | | |
| **Home Owner** | 57 (75.0) | 30 (78.9) |
| **Rented** | 17 (22.4) | 7 (18.5) |
| **Other arrangements** | 2 (2.6) | 1 (2.6) |
| **Highest Qualification** | | |
| **Degree** | 16 (21.1) | 10 (26.3) |
| **Trade or professional** | 17 (22.4) | 14 (36.8) |
| **NVQ** | 16 (21.1) | 2 (5.3) |
| **A or AS Level** | 3 (3.9) | 2 (5.3) |
| **O level/CSE/GCSE** | 7 (9.2) | 4 (10.5) |
| **No qualifications** | 17 (22.4) | 6 (15.8) |
| **Employment** | | |
| **In paid work (full/part-time)** | 39 (51.3) | 23 (60.5) |
| **Retired** | 20 (26.3) | 12 (31.6) |
| **Long-term disability/ill health** | 11 (14.5) | 2 (5.3) |
| **Unemployed** | 5 (6.6) | 0 (0) |
| **Home carer** | 0 (0) | 1 (2.6) |
| **Other** | 1 (1.3) | 0 (0) |
| **IMD 2007 Average Score (SD, range)** | 39.89 | 38.73 |
|  | (16.32, 13.21 to 82.26) | (16.32, 13.79 to 66.59) |
| **Medical History (self-reported), n (%)** | | |
| **Hypertension (>140/90 mmHg)** | 31 (40.8) | 14 (36.8) |
| **Raised Cholesterol (≥5.2 mmol/l)** | 38 (50.0) | 20 (52.6) |
| **Diabetes** | 10 (13.2) | 5 (13.2) |
| **Overweight (BMI>30)** | 48 (63.2) | 24 (63.2) |
| **Ever Smoked** | 49 (64.5) | 24 (63.2) |
| **Current Smoker** | 17 (22.0) | 8 (21.0) |
| **Level of Physical Activity (IPAQ-Long category score), n (%)** | | |
| **Low** | 13 (17.1) | 6 (15.8) |
| **Moderate** | 29 (38.2) | 19 (50.0) |
| **High** | 34 (44.7) | 13 (34.2) |

*\*P-values for comparison between the two groups: all >0.05. Missing data were excluded.*

Table 2: Primary and Secondary Outcome measure: Effects by randomisation groupα

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **LHT Intervention Group (n = 76)** | | | | | **Control Group (n=38)** | | | | | **ANCOVA** | | | |
|  | **mean** | **SD** | **min** | **max** | **n** | **mean** | **SD** | **min** | **max** | **n** | **95% CI** | **Sig(p)** | | |
| **FFQ Fruit and Vegetable (F&V) consumption** | | | | | | | | | | | | | | |
| Baseline |  |  |  |  |  |  |  |  |  |  |  | | |  |
| Grams/day | 209.9 | 126.3 | 20.2 | 560.8 |  | 212.6 | 118 | 40.9 | 559.39 |  |  | | |  |
| Portions/day | 2.6 | 1.6 | 0.3 | 7 | 72 | 2.7 | 1.5 | 0.5 | 6.9 | 36 |  | | |  |
| Follow-up***β*** |  |  |  |  |  |  |  |  |  |  |  | | |  |
| Grams/day | 476.4 | 224.6 | 61.2 | 1074 |  | 434.1 | 244.8 | 134.2 | 1012.6 |  |  | | |  |
| Portions/day | 5.9 | 2.8 | 0.8 | 13.4 | 43 | 5.4 | 3.1 | 1.7 | 12.7 | 20 | -1.62 to 1.53 | | | 0.95 |
| **EQ-5D score** | | | | | | | | | | | | | | |
| Baseline | 0.81 | 0.23 | -0.02 | 1 | 76 | 0.83 | 0.23 | 0.03 | 1 | 38 |  | |  | |
| Follow-up | 0.79 | 0.25 | -0.18 | 1 | 44 | 0.84 | 0.22 | 0.06 | 1 | 24 | -0.09 to 0.09 | | 1.00 | |
| **WHO AUDIT Total score** | | | | | | | | | | | | | | |
| Baseline | 6.2 | 6.3 | 0 | 32 | 76 | 5.1 | 4.3 | 0 | 18 | 37 |  | |  | |
| Follow-up | 3.9 | 4.8 | 28 | 11.2 | 42 | 5 | 4.6 | 0 | 18 | 22 | -0.07 to 1.58 | | 0.07 | |
| **Total Cholesterol (mmol/l)** | | | | | | | | | | | | | | |
| Baseline | 5.1 | 0.8 | 3.1 | 7 | 35 | 4.9 | 1 | 3.4 | 6.8 | 21 |  | |  | |
| Follow-up | 5.2 | 0.9 | 3.2 | 6.4 | 13 | 5 | 0.9 | 3.9 | 6.7 | 12 | -0.67 to 0.66 | | 0.99 | |
| **Total Physical Activity (Standard Metabolic Equivalent (MET) hours/day)** | | | | | | | | | | | | | | |
| Baseline | 6.4 | 4.9 | 0 | 19.2 | 74 | 5.5 | 4.2 | 0 | 17.6 | 33 |  | |  | |
| Follow-up | 5.4 | 4.7 | 0 | 17.4 | 40 | 6.2 | 5.3 | 0 | 17.9 | 20 | -0.51 to 4.81 | | 0.11 | |
| **α** *Intention to treat analysis and Limits of agreement ±2 SD of mean*  ***β*** *Three outliers in* F&V *data were removed, equating to >13 portions/day (>2 SD of the mean)* | | | | | | | | | | |  | |  | |