

# Dietary intake of fruit in relation to body weight management among adults

PhD thesis

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2012

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## Preface and acknowledgements

The present PhD thesis was carried out from 2007-2011 at the National Food Institute, Technical University of Denmark, Division of Nutrition as part of the ISAFRUIT project, funded by the European Commission under ‘Thematic Priority 5 – Food Quality and Safety’ of the 6<sup>th</sup> Framework Programme of RTD (contract no. FP6-FOODCT-2006-016279). The views and opinions expressed in this thesis may not in any circumstances be regarded as stating an official position of the European Commission.

My great appreciation goes especially to my supervisor, Professor Inge Tetens, one of the most enthusiastic and optimistic individuals I have had the pleasure of meeting. Your encouraging and constructive guidance at every step of the work and never-ending professional as well as personal support at difficult times have been an invaluable motivation for my continuation with this thesis.

Many people have contributed with eminent assistance throughout the exciting work with this thesis, particularly with regard to the implementation of the intervention studies in Copenhagen, Denmark and in Newcastle, UK, and with retrieval of data from the EFSA Comprehensive European Food Consumption Database. In this connection, I would like to thank Professor Chris J. Seal, Dr Kirsten Brandt, Dr Amelia A. Lake and Ms Charlotte E. Bryant for your tireless efforts that ensured a fruitful progression and finalisation of the study in Newcastle. I am also very grateful for the tremendous assistance and commitment from Scientific Officer at EFSA, Mr Davide Arcella, one of the key players that made it possible for me to carry out the cross-sectional study, included in this thesis. Also thanks to Mr Ole H. Hels, Mr Klaus K. Andersen and Mr Murat Kulahci for excellent statistical advice at various states of my work.

I also wish to thank my colleagues at the Division of Nutrition for always finding the time in their very busy schedules to offer me advice when I have needed it. Moreover, I wish to thank the lovely ladies at my office, PhD student Berit W. Rothausen, PhD Ulla H. Gondolf and project assistant Trine H. Nielsen for your support and advice and for creating a warm and welcoming work atmosphere at the office. Thank you for listening to my ups and downs.

Last but not least, my love and warmest thoughts go to my husband, Arne, and my family for your support and encouragement throughout the process and to my son, Storm, for being absolutely irresistible and an endless source of joy and smile.

## Abbreviations

RCT: Randomised Controlled Trial

E%: Percentage of total energy

BMI: Body Mass Index

EFSA: European Food Safety Authority

GIES: General Intake Estimated Systems

AOAC: Association of Analytical Communities

SES: Socio-economic status

FFQ: Food Frequency Questionnaire

NDNS: National Diet and Nutrition Survey

EI: Energy intake

BMR: Basal metabolic rate

SD: Standard deviation

CI: Confidence Interval

## List of papers

This PhD thesis is based on the following four papers (paper I-IV):

- Paper I: Alinia, S., Hels, O., & Tetens, I. (2009). The potential association between fruit intake and body weight--a review. *Obes. Rev.* 10, 639-647.
- Paper II: Alinia, S., Volatier, J. L., Szabó, M. S., D'Addezio, L., Arcella, D., & Tetens, I. A cross-sectional study of the association between fruit intake and body weight among the general adult population in Europe. Submitted 2012.
- Paper III: Alinia, S., Lassen, A. D., Krogholm, K. S., Christensen, T., Hels, O. H., & Tetens, I. (2011). A workplace feasibility study of the effect of a minimal fruit intervention on fruit intake. *Public Health Nutr.* 14, 1382-1387.
- Paper IV: Alinia, S., Bryant, C. E., Lake, A. A., Andersen, K. K., Brandt, K., Seal, C. J., & Tetens, I. The effectiveness of a free fruit, workplace intervention on body weight, dietary intake and blood pressure. Submitted 2012.

## Summary

The prevalence of overweight and obesity among adults worldwide is high with an increasing trend. Therefore, effective strategies in relation to body weight management, targeting to maintain normal body weight and prevent excessive weight gain, are warranted. Reducing the energy density of the diet may aid to achieve these goals. Energy density of the diet can be reduced by substituting energy-dense food items with less energy-dense food items such as fruit and vegetables. Fruit and vegetables are considered as relatively low energy-dense food groups due to their high content of water and dietary fibre. Most research, currently available, including intervention and observational studies, has investigated the combined role of fruit and vegetables in relation to body weight. However, a separation between these two food groups seems important as they differ in terms of nutrient composition and culinary use.

The overall aim of the present thesis was to examine the potential role of fruit intake in relation to body weight management among adults. The specific objectives were to investigate the association between fruit intake and body weight and aspects of other dietary intake and further to investigate the effectiveness of available and accessible fruit on body weight, fruit intake and certain other dietary intake among free-living individuals. These objectives were attempted achieved by conducting four studies (paper I-IV) upon which the present thesis is based.

The state of the art on the role of fruit intake in body weight management, including the association between fruit intake and body weight and the effect of fruit intake on body weight, among adults was assessed by carrying out a review (paper I) encompassing all human prospective observational, cross-sectional and intervention studies that could be identified and that met the eligibility criteria. The eligibility criteria included that the studies presented separate analyses for fruit and had body weight as a primary aim.

The association between fruit intake and body weight was further investigated in a cross-sectional study (paper II) among 9,758 normal- and overweight subjects, nationally representative of the general adult population in Denmark, France, Hungary, Italy and the UK, representing the East, West, North and South of Europe.

The effectiveness of increased fruit intake on body weight change was examined in an 18-week cluster-randomised, controlled intervention study (paper IV) in UK, including 409 slightly overweight adults allocated into an intervention group, who had access to two pieces of free

available fruit per person per day at the workplace and a control group who were not subject to any kind of intervention. As a precursor to the cluster-randomised controlled intervention study, a 5-month controlled feasibility intervention study (paper III) was conducted in order to investigate the possibility to increase fruit intake of the employees simply by increasing the availability and accessibility of fruit at the workplace. The study enrolled 124 mainly normal weight adults from eight Danish workplaces, divided into an intervention group with free access to at least one piece of fruit per person per day at the workplace and a control group who did not.

Only eight prospective observational and five cross-sectional studies and three RCTs could be identified that met the eligibility criteria and were hence included in the review. The majority of the cross-sectional and prospective observational studies showed a suggestive inverse association between fruit intake and body weight or long-term excess increase in body weight. In addition, the majority of the few RCTs showed that fruit intake reduced body weight. This was not supported by the cross-sectional study in paper II, which showed no significant association between fruit intake and body weight. However, there was a direct association between fruit intake and relatively nutrient-dense foods and beverages such as vegetables, fruit juice and processed fruit and an inverse association between fruit intake and relatively nutrient-dilute foods and beverages such as soft drinks and snack foods as well as energy density and E% from fat.

The feasibility study showed a significant increase of approximately 1½ portion of fruit per person per day at the end of the study in the intervention group which was significantly higher than the intake in the control group. Moreover, intake of dietary fibre increased significantly whereas intake of added sugar decreased significantly only within the intervention group not differing significantly than the intakes in the control group at the end of the study. Similarly, in the main intervention study, both groups increased their fruit intake significantly but the increase of approximately 0.7 portions of fruit per person per day at the end of the study was by 0.4 portions significantly higher in the intervention group than the control group. No significant between-group difference in body weight was seen at the end of the study, although those within the intervention group showed a tendency toward a borderline-significant reduction in BMI at the end of the study compared with baseline. Likewise, no significant between-group differences were seen in adiposity or blood pressure measurements at the end of the study but within the intervention group, a significant reduction in adiposity and diastolic blood pressure was seen at the end of the study compared with baseline. In terms of dietary changes, consumption of dietary fibre increased significantly in the intervention group at the end of the study, leading to a significant difference between the two

groups. Additional interesting findings included a significant decrease in the consumption of sweets and snacks and E% from fat within the intervention group and significant increase in the consumption of soft drinks within the control group. No significant between-group differences were seen in the three latter dietary changes.

The present PhD thesis suggests that fruit may play a role in prevention of overweight and obesity over time, as the prospective observational studies in the review indicated an inverse association between fruit intake and long-term excessive increase in body weight. Whether fruit, *per se*, causes the inverse association or it is a marker of a lifestyle and dietary pattern that promote body weight maintenance and prevent overweight and obesity is unclear, as inference making on a causal relationship is precluded, among other things due to the observational nature of the underlying studies. The cross-sectional study in paper II further supports the indication that fruit intake may be positively associated with a dietary pattern adopted by relatively health conscious individuals. Moreover, according to the present thesis, a simple intervention, comprising free available fruit at the workplace seems ineffective in terms of body weight change. However, such relatively simple interventions may be effective in increasing the consumption of fruit and may in addition enhance the overall quality of the diet.

## Resumé

Forekomsten af overvægt og fedme blandt de voksne på verdensplan er høj med en stigende tendens. Effektive strategier i forhold til kropsvægtregulering målrettet mod opretholdelse af en normal kropsvægt samt forebyggelse af en for stor vægtøgning er derfor påkrævede. Disse mål kan måske opnås ved at reducere kostens energidensitet. Kostens energidensitet kan reduceres ved at erstatte energitætte fødevarer med mindre energitætte fødevarer såsom frugt og grøntsager. Frugt og grøntsager anses for at være lav-energitætte fødevarer på grund af deres høje indhold af vand og kostfibre. Størsteparten af den foreliggende forskning, heriblandt interventions- samt observationelle studier, har undersøgt den kombinerede rolle af frugt og grøntsager sammen i forhold til kropsvægt. Det synes imidlertid vigtigt at skelne mellem disse to fødevarergrupper, idet de er forskellige i forhold til deres næringsstofsammensætning samt kulinariske anvendelse.

Det overordnede formål med denne afhandling var at undersøge den potentielle rolle af frugtindtag i forhold til kropsvægtregulering blandt de voksne. De specifikke formål var at undersøge sammenhængen mellem frugtindtag og kropsvægt samt visse aspekter af andet kostindtag og ydermere at undersøge effekten af gratis tilgængelig frugt på kropsvægt, frugtindtag samt andet kostindtag blandt fritlevende mennesker. Disse formål var forsøgt opfyldt ved at udføre fire studier (artikel I-IV), som nærværende afhandling bygger på.

Den aktuelle forskning om frugtindtagets rolle i forhold til kropsvægtregulering, herunder sammenhængen mellem frugtindtag og kropsvægt samt effekten af frugtindtag på kropsvægt blandt de voksne, blev vurderet i et review (artikel I) omfattende samtlige humane prospektive observationelle-, tværsnits- samt interventionsstudier, der kunne identificeres, og som opfyldte kvalifikationskriterierne. Kvalifikationskriterierne indbefattede, at studierne præsenterede separate analyser for frugt og havde kropsvægt som et primært formål.

Sammenhængen mellem frugtindtag og kropsvægt blev undersøgt yderligere i et tværsnitsstudie (artikel II) blandt 9.758 normal- og overvægtige personer, som var nationalt repræsentative for den generelle voksne befolkning i Danmark, Frankrig, Ungarn, Italien og Storbritannien, hvilke repræsenterede Øst-, Vest-, Nord- og Sydeuropa.

Effektiviteten af et øget frugtindtag på ændringer i kropsvægt blev undersøgt i et 18-uger gruppe-randomiseret, kontrolleret interventionsstudie (artikel IV) i Storbritannien, omfattende 409 moderat overvægtige voksne fordelt i en interventionsgruppe, der havde adgang til to stykker gratis

tilgængelig frugt per person per dag på arbejdspladsen samt en kontrolgruppe, der ikke blev udsat for nogen form for indgriben. Et 5-månders kontrolleret, feasibility interventionsstudie (artikel III) blev gennemført som en forløber for det gruppe-randomiserede, kontrollerede interventionsstudie med det formål at undersøge muligheden for at øge frugtindtaget blandt medarbejdere ved ganske enkelt at øge tilgængeligheden af gratis frugt på arbejdspladsen. 124 overvejende normalvægtige voksne fra otte danske arbejdspladser blev tilmeldt studiet og inddelt i en interventionsgruppe med gratis adgang til mindst et stykke frugt person per dag på arbejdspladsen samt en kontrolgruppe uden denne adgang.

Otte prospektive observationelle og fem tværsnitsstudier samt tre RCT'er opfyldte kvalitetskravene og blev inkluderet i reviewet. Majoriteten af tværsnitsstudierne samt de prospektive observationelle studier tydede på en omvendt sammenhæng mellem frugtindtag og kropsvægt eller en stigning i kropsvægt over en langvarig periode. Ydermere viste størstedelen af de få RCT'er, at frugtindtag reducerede kropsvægt. Dette blev ikke understøttet af tværsnitsstudiet i artikel II, som ikke viste en signifikant sammenhæng mellem frugtindtag og kropsvægt. Der var imidlertid en direkte sammenhæng mellem frugtindtag og forholdsvis næringsstof-tætte føde- og drikkevarer såsom grøntsager, frugtjuice og forarbejdet frugt og en omvendt sammenhæng mellem frugtindtag og forholdsvis mindre næringsstof-tætte føde- og drikkevarer såsom sodavand og snacks samt energidensitet og E% fra fedt.

Feasibilitetsstudiet viste en signifikant øgning i frugtindtaget i interventionsgruppen i slutningen af studiet på ca. 1½ portion per person per dag, hvilket var signifikant højere end indtaget i kontrolgruppen. Derudover steg indtaget af kostfibre signifikant, mens indtaget af tilsat sukker faldt signifikant i interventionsgruppen. Disse indtag var imidlertid ikke signifikant forskellige fra indtagene i kontrolgruppen i slutningen af studiet. I hovedinterventionsstudiet øgede begge grupper deres frugtindtag signifikant, men øgningen på 0,7 portioner per person per dag i slutningen af studiet var med 0,4 portioner signifikant højere i interventionsgruppen end i kontrolgruppen. Der kunne ikke ses en signifikant forskel i kropsvægt mellem grupperne i slutningen af studiet om end deltagerne i interventionsgruppen viste en tendens til en grænse-signifikant reduktion i BMI i slutningen af studiet sammenlignet med start. Ligeså sås der ingen signifikante forskelle mellem grupperne i kropsfedt- eller blodtryksmålingerne i slutningen af studiet, men i interventionsgruppen sås der en signifikant reduktion i kropsfedt samt diastolisk blodtryk i slutningen af studiet sammenlignet med start. I forhold til ændringer i kosten forekom der en signifikant stigning i indtaget af kostfibre i interventionsgruppen i slutningen af studiet, hvilket medførte en signifikant

forskel mellem de to grupper. Yderligere interessante resultater indbefattede et signifikant fald i indtaget af slik og snacks samt E% fra fedt i interventionsgruppen og en signifikant stigning i indtaget af sodavand i kontrolgruppen. Der sås ingen signifikante forskelle mellem grupperne i disse tre ændringer i kosten.

Nærværende Ph.d.-afhandling indikerer, at frugt over tid muligvis spiller en rolle i forebyggelsen af overvægt og fedme, idet de prospektive observationelle studier i reviewet antydede en omvendt sammenhæng mellem frugtindtag og stigning i kropsvægt over en langvarig periode. Hvorvidt frugt i sig selv forårsager den inverse sammenhæng eller er en markør for en livssil og et kostmønster, der promoverer en opretholdelse af kropsvægten og forebyggelse af overvægt og fedme, er uafklaret, idet der ikke kan drages én konklusion om en årsagsmæssig sammenhæng, bl.a. på grund af den observationelle karakter af de bagvedliggende studier. Indikationen af, at frugtindtag muligvis er positiv associeret med et kostmønster, der følges af forholdsvis sundhedsbevidste personer, understøttes yderligere af tværsnitsstudiet i artikel II. Endvidere synes en simpel intervention, der består af gratis tilgængelig frugt på arbejdspladsen, ifølge denne afhandling, ikke at være effektiv i forhold til ændringer i kropsvægten. Derimod viser resultaterne, at sådanne simple interventioner kan være effektive i at øge frugtindtaget samt forbedre den generelle kvalitet af kosten.

## 1. Introduction

Overweight and obesity pose a global public health problem that grows at an alarming rate and has reached epidemic levels with an estimate of 1.1 billion adults and 10% of children categorised as overweight or obese worldwide (Haslam & James, 2005). In Europe, overweight and obesity affects an estimate of 30-80% of the adult population and 20% of the children (WHO, 2007). Focusing on adults in the present thesis, if recent increasing trends in the prevalence of overweight and obesity continue, it is estimated that by 2030, 3.3 billion of the adult population worldwide could be overweight or obese (Kelly *et al.*, 2008). This poses further severe implications in terms of the general public health, as excess body weight can lead to comorbidities including cardiovascular diseases, type II diabetes, arthritis, several types of cancer and premature mortality (Haslam & James, 2005). According to WHO (WHO, 2009) overweight and obesity rank as number five among top 10 leading risk factors causing mortality. Therefore, effective dietary strategies are warranted with respect to body weight management including maintenance of normal body weight and prevention of excessive weight gain.

Decreasing the energy density of the diet could be a key factor in weight maintenance or reduction strategies. WHO report from 2003 (WHO, 2003) concludes that there is convincing evidence, primarily from prospective observational and other epidemiological studies, that high consumption of energy-dense foods results in increased body weight. Further, RCTs have suggested that reducing energy density of the diet promote increased satiety and satiation, which may facilitate decreased energy intake and thereby reduction in body weight (Drewnowski *et al.*, 2004, Duncan *et al.*, 1983, Ledikwe *et al.*, 2007, Rolls *et al.*, 2006, Yao & Roberts, 2001). One way of reducing the energy density of the meals and the overall diets of individuals is by substituting relatively energy-dense foods in the diet with less energy-dense foods. Fruit holds certain qualities, serving it as a viable alternative in this context and hence in relation to body weight management. The mechanisms behind the potential role of fruit in body weight management include the generally low energy density of fruit due to its high content of water and dietary fibre. The dietary fibre content in fruit may additionally, in itself, promote increased satiety and satiation (Burton-Freeman, 2000, Haber *et al.*, 1977, Heaton, 1973, Howarth *et al.*, 2001). Thus, increasing fruit intake may ultimately result in decreased energy intake which potentially may lead to decreased body weight or prevention of excessive weight gain over time.

The majority of current research has investigated the combined role of fruit and vegetables in relation to body weight (Buijsse *et al.*, 2009, Greene *et al.*, 2006, Hallund *et al.*, 2007, Rolls *et al.*, 2004, Tohill *et al.*, 2004). However, although fruit and vegetables possess some nutritional similarities such as low energy density and high dietary fibre content, they still are two different food groups with different nutrient profiles and may therefore exhibit differential impacts on body weight (Schroder, 2010). Thus, given the paucity of studies discriminating between fruit and vegetables, there is a need for an evaluation of the existing human studies that may provide evidence that fruit has an independent role in body weight management.

### 1.1. Evidence hierarchy of different study types

Different types of studies can be ranked in a hierarchical structure according to their ability to provide evidence for causal relationships (Figure 1.1).

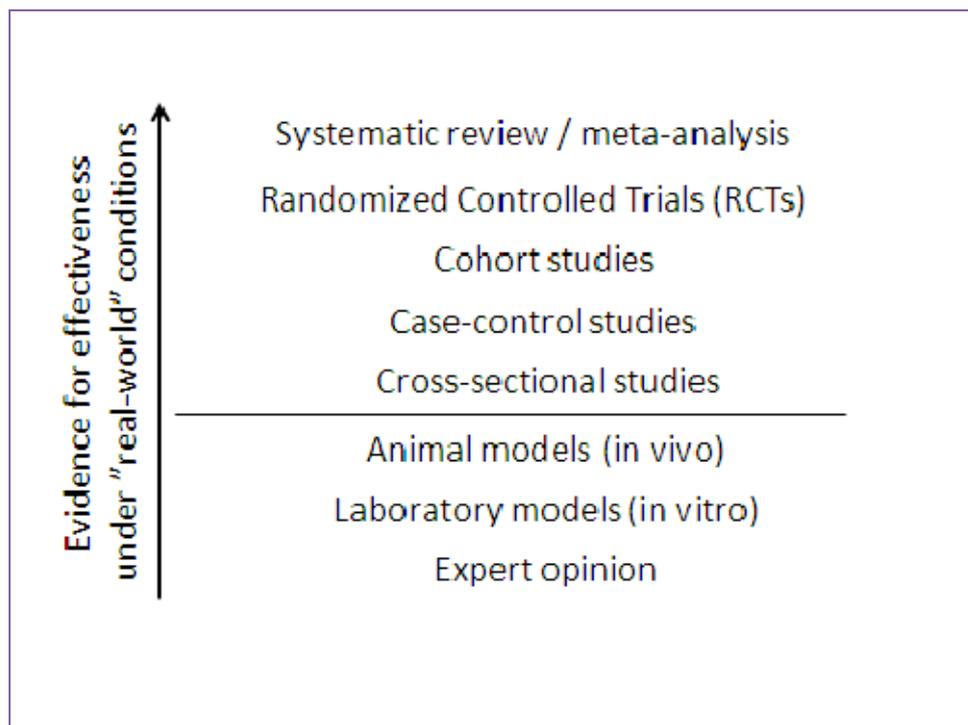


Figure 1.1. Evidence hierarchy of the different types of studies.

RCTs provide strong evidence for causal relationships mainly because confounding bias is limited in these types of studies. However, RCTs are not always applicable in nutritional science, especially

if an extensive period of time is required for the outcome of interest to develop. This is due to several factors including the inconvenience that would be put upon the subjects if they were asked to consume or avoid certain dietary items or groups for a long period, which, in addition can be unethical. Moreover, it is not possible firmly to determine whether an intervention effect was attributable to the dietary exposure of interest rather than to the absence of dietary items that were consequently substituted. Also, obviously it is not possible to conduct blinded trials when the exposures of interests are dietary items. Thus, observational studies are often the most implementable types of studies in nutritional science. Within observational studies, cohort studies rank highly mainly by virtue of the prospective nature of cohort studies that precludes the risk of recall bias and the fact that data on exposure are collected prior to the development of the outcome, preventing the risk of reverse causation. However, observational studies are only capable of finding associations and not causal relationships between exposure and outcome due to confounding bias and the risk of the exposure being a marker of a particular lifestyle causing the outcome rather than the outcome being caused by the exposure *per se*.

The evidence hierarchy was originally established in medical research and, as evident from the preceding, is prone to a number of obstacles when applied in nutritional science. Ideally, in nutritional science, an assembly of different types of studies are taken into account, when a potential causal relationship between exposure and outcome is assessed. In this process, the individual studies within each study type are evaluated according to a range of quality demands. When weighing typically conflicting study findings, the type and quality of each study is considered and the strength of the evidence is judged accordingly. The assembly of the studies should preferably include high-quality RCTs, to determine causal relationship, and cohort and other types of observational studies supporting the findings of one another in order for the body of evidence to be considered as convincing. Additionally, the causal relationship should be biologically plausible, substantiated by mechanistic/laboratory studies.



Based upon the foregoing, strong RCTs would be required in order to determine the effect of fruit intake on body weight management. Within RCTs, there is a distinction between two types of trials termed efficacy trials and effectiveness trials. In efficacy trials, the most suitable conditions are created in order to identify an effect of an intervention. In effectiveness trials, it is attempted to create conditions that are as similar as possible to the real world. One of the roles of science is to

provide evidence for decision-making at political (national and local) level. To transfer the scientific evidence into policy actions, effectiveness trials that mimic real-life settings are needed.

## 1.2. Conceptual framework for effectiveness trials

In effectiveness trials it is important to identify the most influential determinants in relation to the factors that are to be studied. In the EU funded multicentre Pro Children Project, Rasmussen *et al.* (Rasmussen *et al.*, 2006) developed a conceptual framework, considering both individual and environmental predictors for fruit and vegetable intake among school children (see appendix). The conceptual framework can with advantage be adopted in connection with effectiveness trials among other groups in different settings such as adults at workplaces (Figure 1.2).

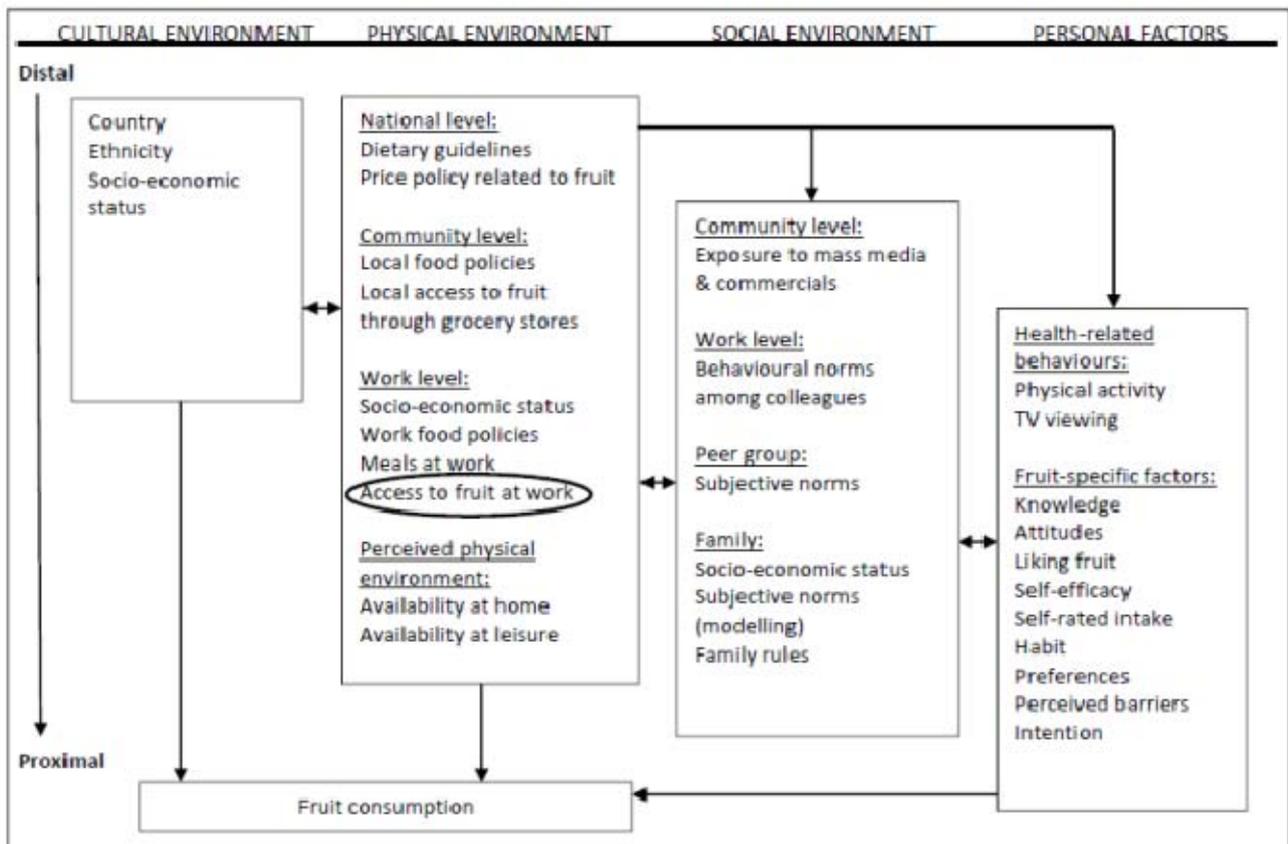


Figure 1.2. Conceptual framework applied to fruit consumption of adults.

As illustrated in Figure 1.2, fruit intake among adults can be influenced at different environments and at different levels within each environment. In this context, workplaces offer ideal settings,

because they provide readily access to a large number of individuals at the same time and the majority of the adult population spend a significant amount of their time at work (Bull *et al.*, 2008, Karnaki *et al.*, 2009, Nordic Council of Ministers, 2006, Quintiliani *et al.*, 2008, WHO/World Economic Forum, 2008). Workplace-interventions can be approached in a number of ways by adjusting one or a set of determinants shown in Figure 1.2. These include delivery of individual- or group counselling and education, attempting to influence some of the ‘fruit-specific factors’ within the ‘personal factors’ and/or increment of the availability and accessibility of healthy food options, attempting to influence the ‘physical environment’ at ‘work level’ in Figure 1.2. Hence, very extensive and comprehensive workplace interventions can be launched. However, considering the magnitude of the problem of overweight and obesity worldwide, it is important to explore if relatively simple actions at workplaces, that are not too demanding and time-consuming for the target group, can achieve successful results.

## 2. Aims and specific objectives

The overall aim of the present PhD thesis was to investigate the potential role of fruit intake in relation to body weight management among adults. The specific objectives were to investigate the association between fruit intake and body weight and aspects of other dietary intake, and further to investigate the effectiveness of freely available fruit on body weight, fruit intake and certain other dietary intake among free-living individuals.

The initial step was to elaborate the state of the art within fruit intake and body weight by conducting a review (paper I). Searching current literature, while carrying out the review, revealed that the major part of the cross-sectional studies in this field was conducted in the USA or single European countries. Thus a cross-sectional study exploring the association between fruit intake and body weight among a nationally representative sample of the adult population from selected countries across Europe was carried out (paper II). Furthermore, it was realized that the number of non-clinical intervention studies investigating the effectiveness of fruit intake alone on body weight among free-living individuals was scarce. Striving after a simple intervention, first, a workplace controlled feasibility intervention study was carried out in Denmark in order to identify the possibility of increasing the fruit intake of employees by making free fruit readily available at the workplace (paper III). Subsequently, a workplace cluster-randomised, controlled intervention study was conducted in the UK, determining the effectiveness of increased fruit intake on body weight change among the employees (paper IV). In papers III and IV, a simple approach was adopted by adjusting only one of the determinants in Figure 1.2, namely access to fruit at work.

### 2.1. Specific objectives

- To review current literature and examine the potential association between fruit intake and body weight (paper I)
- To examine the association between fruit intake and body weight, and intake of specific dietary items in different parts of Europe (paper II)
- To explore the feasibility of increasing fruit intake of the employees by increasing the availability and accessibility of fruit at their workplaces (paper III)
- To determine the effectiveness of increased fruit intake on body weight, blood pressure, adiposity and certain other dietary intake among employees at a workplace setting (paper IV)

### 3. Methods

The present PhD thesis contains four different papers, each with different designs and methodologies. In this section a summary of the designs and methods is presented. Further details can be obtained from the individual papers in the appendix. In addition, Table 3.1 summarises the details for each study.

Table 3.1. An overview of the papers featured in the present PhD thesis

	Paper I	Paper II	Paper III	Paper IV
Aim	Evaluation of the association between fruit intake and body weight	Examination of the association between fruit intake and BMI in a trans-European population	Examination of the feasibility of increasing fruit intake by increasing availability and accessibility of fruit	Examination of the effectiveness of increased fruit intake on body weight change
Study design	Review	Cross-sectional study	5-month, real-life, controlled intervention	18-week, real-life, cluster-randomised, parallel-designed, controlled intervention
Subjects	-	9,758 M and F from Denmark, France, Hungary, Italy and the UK	146 M and F from Denmark	409 M and F from the UK
Dietary assessment	-	3- or 7-day self-reported dietary record	2x24h dietary recall by interviewer	1-week based FFQ
Anthropometric measurement	-	Measured in France and the UK, self-reported in Denmark, Hungary and Italy	Measured	Measured
Place of implementation	Division of Nutrition, National Food Institute, Technical University of Denmark	Division of Nutrition, National Food Institute, Technical University of Denmark	8 Danish workplaces in the Copenhagen Area	A British regional local government office close to Newcastle upon Tyne

### **3.1. The review (Paper I)**

To carry out the review in paper I, a comprehensive search for published literature until November 2008 on fruit intake and body weight was conducted through Medline and manual search of bibliographies. For this purpose the following keywords were used: ‘fruit’, ‘obesity’, ‘overweight’, ‘body weight’, ‘body weight change’, ‘body mass index’ and ‘adult’.

The publications considered as eligible for the review consisted of intervention, prospective observational and cross-sectional studies published in English. Selection criteria included studies that focused on the separate and independent role of fruit intake in relation to body weight or body weight related measures, including waist circumference, body composition or sum of skinfolds. For intervention studies, only studies that measured the specific effect of fruit intake on body weight fulfilled the inclusion criteria. Likewise, prospective observational and cross-sectional studies were included, provided that they had carried out analyses on the specific association between fruit intake and body weight. The target group of all the studies was restricted to the adult population.

### **3.2. The cross-sectional study (Paper II)**

Data for paper II were retrieved from the EFSA Comprehensive European Food Consumption Database, which is data on food consumption for the total population and for consumers only, collected mainly for risk assessment purposes (EFSA, 2011). The database, containing nationally representative data from a total of 22 European countries, was initiated when EFSA, by the end of 2008, approached appropriate organisations in EU Member States to provide EFSA with data from the most recent national dietary survey in their country. In order to enhance the standard of comparison, only countries that used relatively harmonised dietary intake assessment methodologies were considered for the cross-sectional study in paper II. The eligible countries included those that had used three- or seven-day food records because this methodology provides relatively detailed consumption information. The data retrieved and used in paper II included mean food intake data per person per day for the total population from five countries: Denmark, Hungary, the UK, Italy and France, representing the North, East, West and South of Europe. A full description of the methodological procedures applied in the individual countries for recruitment and enrolment of participants and data collection has been provided in previous publications (EFSA, 2011).

The data on demographic, anthropometric, and dietary data were obtained from 9,758 adults (55.3% female), aged  $\geq 18$  years and  $18.5 \text{ kg/m}^2 < \text{BMI} < 30 \text{ kg/m}^2$ . For each country, Table 3.2 summarises the number of participants; number of days when dietary intake was recorded; and means of anthropometric measure assessments.

Table 3.2. Details about number of participants, food recording days and procedures for anthropometric measurements for each country

	N (9,758)	Number of food recording days	Anthropometric measures
Denmark	2,753	7	Self-reported
France	2,197	7	Measured
Hungary	1,057	3	Self-reported
Italy	2,514	3	Self-reported
UK	1,237	7	Measured

The dietary variables included in the study comprised purposely selected data to match the aim/objective of the study and included total energy, dietary fat and the food groups: fruit (fresh fruit), processed fruit, fruit juice, vegetables (including vegetable products, processed vegetables, and vegetable based meals), sweets, snack foods, and soft drinks (including regular and diet soft drinks). Energy density was calculated as total energy intake divided by the total amount of solid foods consumed.

### 3.3. The feasibility study (Paper III)

The feasibility study was a 5-month controlled free fruit intervention study. During the intervention, a fruit basket was provided and the participants had free and easy access to the basket each workday. Recruitment of the workplaces in paper III was carried out in cooperation with the Danish Cancer Society. The details of the recruitment are described in the paper. In short, workplaces in the Copenhagen area were eligible for the study. Eight workplaces signed up for the study and of these, the workplaces that were planning to offer free fruit to their employees were allocated as intervention workplaces. These included five workplaces. The remaining three workplaces, which had never had free fruit and were not considering introducing free fruit at the workplace at least for the following six months, were enrolled as control workplaces. All workplaces consisted mainly of white-collar workers with the exception of two, one in the intervention group and one in the control group, comprised mainly of blue-collar workers. A total of 146 participants, 82 in the intervention and 64 in the control group, were included at baseline. The study protocol was accepted by the Ethics Committee of Copenhagen and Frederiksberg municipality (J. No. KA-20060047).

Workplaces entered the study at distinct points in time, starting from June to September of the same year. Background information, including subject characteristics, anthropometric data and dietary assessments were made both at baseline and at the end of the intervention period, approximately five months later. At least one piece of fruit (mainly apples, pears, oranges and bananas) was available per participant per day for the intervention group but not the control group. The fruit intervention programme stood alone in that the participants in neither of the two groups received any further counselling or other means of intervention.

Dietary intake was assessed using a repeated 24-h recall questionnaire, which was a modified form of the dietary record questionnaire from the Danish National Dietary Survey 2000–2002 (Lyhne *et al.*, 2005). The repeated 24-h recall questionnaire was validated with an objective biomarker of fruit intake (Krogholm *et al.*, 2010). The repeated 24-h recall questionnaire was completed twice on two non-consecutive weekdays, covering the dietary intake of the previous weekday, carried out by trained interviewers in closed rooms, at baseline and again at endpoint. The software program GIES, version 0.995a (Danish Food Institute, Technical University of Denmark, Søborg, Denmark; released 26 June 2005) was used to calculate nutrient intake. Items included in the analysis were fruit, vegetables, total energy, fat, protein and total carbohydrates, as well as added sugar and dietary fibre separately. Added sugar was calculated as the sum of industrially manufactured refined sugars including sucrose, glucose, fructose and starch hydrolysates. The dietary fibre calculations were based on analytical values obtained by the AOAC method (Lyhne *et al.*, 2005).

The background variables such as sex, age, education and occupation were obtained using a background questionnaire based on the validated questionnaire from the Danish National Dietary Survey 2000–2002 (Lyhne *et al.*, 2005). Body weight and height were measured three times, consecutively. The measurements were carried out without shoes in light indoor clothing using a Soehnle Verona Quattrotronic digital scale (model 63686; Soehnle, Backnang, Germany) to the nearest 0.1 kg and a Soehnle 5001 Ultrasonic Height Measure to the nearest cm, respectively.

### **3.4. The intervention study (paper IV)**

The intervention study in paper IV was a cluster-randomised, parallel-designed, controlled intervention study. The study was conducted according to the guidelines determined in the Declaration of Helsinki and all procedures involving human subjects/participants were approved by the Newcastle University Research Ethics Committee (CL08/09/15). The study took place at a

regional local government office close to Newcastle upon Tyne, UK, with over 1,000 employees as described in more details in Paper IV.

After recruitment, participants were randomised into either an intervention or a control group taking into consideration the physical structure and layout of the workplace. The randomisation resulted in 206 participants in the intervention group and 203 in the control group. Each participant was given a unique code and password that enabled them to securely log on to the study website ([www.fruitatwork.org](http://www.fruitatwork.org)) which enabled them to contact study researchers and complete on-line questionnaires.

The intervention took place over an 18-week period from February 2009 - June 2009 and consisted of two free pieces of fruit made available for the intervention group to collect at a designated point daily during the working week (Monday – Friday). The types of fruit were rotated on a weekly basis and comprised typically apples (range of varieties), oranges, pears, bananas and kiwi fruit. To support compliance, the control group received the same amount of fruit for 18 weeks after the intervention.

Demographic details, including age, gender, education level, income, occupation and smoking status, were collected at baseline. SES was derived from the demographic questionnaire, where respondents recorded their job title, as described in more details in the manuscript of Paper IV.

Participants' total dietary intake was assessed at baseline and end of intervention period, on-line, using a validated FFQ (Brownlee *et al.*, 2010), covering food consumed during the previous week. Participants completed the FFQs through the study website. Daily frequency of food group consumption was calculated from the FFQ data. Estimates of nutrient intake were calculated from frequencies using estimates of portion size and frequency of food consumed within each category based on NDNS data (Henderson *et al.*, 2002) and nutrient composition from standard food tables (Food Standards Agency, 2002).

Anthropometric measurements, referred to as 'health checks', including height, body weight, bio-impedance (using a portable Tanita body composition analyser (BC-420MA and TBF300MA)) and seated blood pressure measurements, were collected at baseline, midway through the intervention and at the end of the intervention by the researchers and trained assistants. The interim health checks had the purpose to motivate the participants to continue with the study.

### **3.5. Statistical analysis**

In all statistical tests a significance level of 5% was applied. All the analyses were made using the Statistical Analysis Systems statistical software package version 9.1 (SAS Institute, Cary, NC, USA).

#### **3.5.1. The cross-sectional study (Paper II)**

Diminution of the potential under-reporters was achieved by applying Goldberg's cut-off technique ( $EI/BMR < 1.1$ ) (Goldberg *et al.*, 1991). Multiple linear regression models were used to assess the relationship between: 1) BMI and daily intake of fruit, fruit and vegetables, processed fruit, and fruit juice; and between 2) fruit intake and daily intake of processed fruit, fruit juice, vegetables, sweets, snack foods, soft drinks, E% from fat, and energy density. Data on fruit intake were skewed and were therefore logarithmically transformed to achieve normal distribution. Both analyses were adjusted for age, gender and country. In addition to these cofactors, the model containing BMI as the response variable was also adjusted for energy intake.

#### **3.5.2. The feasibility study (Paper III)**

Prior to the study commencement, power analyses were conducted in order to estimate the number of participants needed for the study. The power analyses showed that with a mean expected difference of 100 (SD  $\pm$  220) g/d in fruit intake between intervention and control group, with a power of 80% and a significance level of 5%, at least seventy-five participants were necessary in each group. Paired t tests were performed in the intervention and control group separately to evaluate changes in intake from baseline to endpoint. Two-sample t tests were performed to evaluate differences in changes from baseline to endpoint between the intervention and control group. Homogeneity of variance and normal distribution were confirmed by plots, histograms and Shapiro–Wilk's tests.

#### **3.5.3. The intervention study (paper IV)**

Respondent numbers required for assessment of changes in body weight were estimated from the power analyses conducted before the initiation of the study. Based on a two sample t-test it was estimated that in order to detect a significant ( $P < 0.05$ ) mean change of 1.25 kg in body weight from baseline to end of intervention period with a power of 0.80 and SD of 5 kg, 252 participants

would be needed in the intervention- and control group, respectively. This number was the target for recruitment. Baseline characteristics for the intervention and control group were compared univariately. T-tests were used to compare continuous variables and within contingency table analysis for comparing categorical variables. Unadjusted changes in food and nutrient intake from baseline to end of intervention period, including fruit intake, and anthropometric measures, were estimated for each group and tested, using paired t-tests. Adjusted differences between the intervention and control group were obtained using multiple linear regression models. These analyses were adjusted for age, gender, education, SES, smoking status and baseline values. The analyses were carried out after the principle of intention to treat, applying last value carried forward in order to increase the probability of the changes observed to be true, because intention to treat analyses yield the most conservative estimates.

## 4. Results

This section summarises the findings from the four papers included in the present PhD thesis. In addition, a few unpublished results are presented. For closer details, the reader is referred to the individual papers in the appendix.

### 4.1. The review (Paper I)

For the preparation of the review, a search in Medline resulted in identification of 33 generally relevant articles. After a scanning and classification process and manual searches of bibliographies, a total of 16 articles remained, that met all of the selection criteria. These included three intervention studies, eight prospective observational studies and five cross-sectional studies, all published from 1996 to 2008. A summary of all the included studies is shown in Tables 4.1, 4.2 and 4.3. These Tables are, with the exception of a few modifications, similar to Table 1 in paper I. The modifications include separate Tables for the individual study types, slightly altered head rows, addition of one column in Tables 4.1 and 4.3 and two columns in Table 4.2, presenting dietary assessment methods in all three Tables and amount of fruit consumed in Table 4.3. Furthermore, Tables 4.2 and 4.3 are updated with a recent study by Schroder (Schroder, 2010), which contains both longitudinal and cross-sectional analyses. The study is described more closely later in this section.

Almost half of the 16 studies were carried out in the USA and the majority of the subjects were overweight ( $BMI \geq 25$ ) or obese ( $BMI \geq 30$ ). In 11 of the 16 studies, fruit intake was inversely associated with body weight (Davis *et al.*, 2006, de Oliveira *et al.*, 2008, Drapeau *et al.*, 2004, Fujioka *et al.*, 2006, He *et al.*, 2004, Lin & Morrison, 2002, Linde *et al.*, 2006, Moreira & Padrao, 2006, Nooyens *et al.*, 2005, Trudeau *et al.*, 1998, Vioque *et al.*, 2008), among two of which the inverse association concerned women only (Moreira & Padrao, 2006, Trudeau *et al.*, 1998). The remaining five studies showed no significant association between fruit intake and body weight (Rodriguez *et al.*, 2005, Sanchez-Villegas *et al.*, 2006, Schulz *et al.*, 2002, Serdula *et al.*, 2004, te Velde *et al.*, 2007). None of the included studies found a positive association between fruit intake and body weight.

In all of the RCTs, anthropometric measurements were carried out by study staff. This was also the case in the majority of the prospective observational studies, except for three studies (He *et al.*, 2004, Sanchez-Villegas *et al.*, 2006, Schulz *et al.*, 2002). In contrast, all but one (Davis *et al.*, 2006)

of the cross-sectional studies used participants' self-reported anthropometric measurements. The most commonly used methodology for dietary assessment in both the prospective observational and the cross-sectional studies was the use of FFQs. The study duration stretched from eight to twelve weeks in the intervention studies and from two to eight years in the prospective observational studies.

When writing the present PhD thesis, further search for relevant studies published after 2008 was carried out. This search resulted in identification of one combined prospective observational and cross-sectional study by Schroder from the USA (Schroder, 2010) that would have been eligible to be included in paper I. The researchers in the study conducted cross-sectional and longitudinal analyses of anthropometric and dietary data originally assessed for a weight-loss intervention among overweight and obese subjects, predominantly consisting of women. Thus, this study would have been added both as a prospective observational and a cross-sectional study in paper I. Details about this study have therefore been added to Table 4.2, presenting the longitudinal results and in Table 4.3, presenting the cross-sectional results. The new study adds to the pool of studies that suggest that fruit intake has a body weight reducing/ maintaining role as both the longitudinal and cross-sectional analyses in the study resulted in an inverse association between fruit intake and body weight.

Table 4.1. Overview of the intervention studies investigating the role of fruit intake in body weight status

Author, year	Country Population n* (sex) Age, weight status	BMI (kg/m <sup>2</sup> )	Intervention	Anthropometrics	Dietary assessment	Study duration	Results
de Oliveira <i>et al.</i> , 2008	Brazil n = 34 (♀) 44.1 (5.4) years <sup>†</sup> , OB	31.9 (4.2)	Randomised to add apples or pears (300 g/d) or oat cookies (60 g/d) to a hypocaloric diet	Measured	3-d food record	10 wk	<b>Apple gr:</b> ↓BW (β coef -0.92 kg), S, (P<0.0001) ↓BMI (β coef -0.39), S, (P<0.0001) <b>Pear gr:</b> ↓BW (β coef -0.84 kg), S, (P=0.0004) ↓BMI (β coef -0.34), S, (P=0.0006) <b>Oat gr:</b> ↑BW (β coef +0.21 kg), NS, (P=0.35) ↑BMI (β coef +0.005), NS, (P=0.40)
Fujioka <i>et al.</i> , 2006	USA n = 77 (♀ ♂) 18-65 years, OB	35.6 (4.7)	4-armed (fresh grapefruit (1½ piece/d), grapefruit juice, grapefruit extract or placebo added to the usual diet) randomised double-blinded placebo-controlled	Measured	Not assessed	12 wk	<b>Fresh grapefruit gr:</b> ↓BW (-1.6 kg) vs. placebo gr: S, (P=0.048) <b>Juice gr:</b> ↓BW (-1.5 kg) vs. placebo gr: NS <b>Extract gr:</b> ↓BW (-1.1 kg) vs. placebo gr: NS
Rodríguez <i>et al.</i> , 2005	Spain n = 15 (♀) 32.6 (5.8) years, OB	34.9 (2.3)	Randomised to receive a low-fruit or a high-fruit diet. Amount of fruit not reported	Measured	Preintervention: 3-d food record; day 14, 35, 56: 24-h food records	8 wk	Difference between groups: BW and BMI: NS WC: S (P=0.048) <b>High-fruit gr:</b> ↓BW (t <sub>0</sub> : 91.6 (6.0) kg, t <sub>8</sub> : 85.5 (6.1) kg), S, (P<0.05) ↓BMI (t <sub>0</sub> : 34.2 (2.6), t <sub>8</sub> : 32.0 (2.9)), S, (P<0.05) ↓WC (t <sub>0</sub> : 95.1 (5.2) cm, t <sub>8</sub> : 89.6 (5.2) cm), S, (P<0.05) <b>Low-fruit gr:</b> ↓BW (t <sub>0</sub> : 91.1 (13.0) kg, t <sub>8</sub> : 84.7 (11.6) kg), S, (P<0.05) ↓BMI (t <sub>0</sub> : 35.6 (3.3), t <sub>8</sub> : 33.1 (3.0)), S, (P<0.05) ↓WC (t <sub>0</sub> : 96.3 (8.9) cm, t <sub>8</sub> : 93.9 (6.0) cm), NS

\*Number of subjects analysed.

<sup>†</sup>Mean (SD) (all such values).

gr: group; BW: bodyweight; BMI: body mass index; WC: waist circumference; WG: weight gain; β coef: β coefficient; S: significant; NS: non-significant; OB: obese; d: day; wk: week; ↓: decrease; ↑: increase.

Table 4.2. Overview of the prospective observational studies investigating the role of fruit intake in body weight status

Author, year	Country Population n* (sex) Age, weight status	BMI (kg/m <sup>2</sup> )	Anthropometrics	Dietary assessment	Fruit intake	Follow-up	Results
Vioque <i>et al.</i> , 2008	Spain n = 206 (56.8% ♀, 43.2% ♂) 41.5 (17.9) <sup>†</sup> years, OW	25.8 (4.8)	Measured	FFQ	g/d: Q1: <149 Q2: 149-248 Q3: 249-386 Q4: >386	10 years	↓Risk of ≥3.41 kg mean WG, NS, ( $P_{\text{trend}}=0.059$ ): Q4 vs. Q1 (OR=0.43 [CI: 0.13, 1.40]), NS Q3 vs. Q1 (OR=0.27 [CI: 0.09, 0.76]), S Q2 vs. Q1 (OR=0.53 [0.20, 1.41]), NS
te Velde <i>et al.</i> , 2007	Holland n = 168 (92 ♀, 76 ♂) 36.6 (0.6) years, NW	24.1 (2.9)	Measured	4-wk dietary history by interviewer	g/d (SD): baseline ♂:137.8 (77.3), ♀: 178.4 (92.4) follow-up ♂: 66.6 (56.7), ♀: 59.8 (64.2)	24 years	↓BMI, NS Q3 (reg coef -0.364 [CI: -0.864, 0.135]) Q2 (reg coef -0.336 [CI: -0.869, 0.196]) Q1 (reg coef -0.404 [CI: -0.996, 0.189])
Sanchez-Villegas <i>et al.</i> , 2006	Spain n = 6,319 (♀ ♂) 37.0 (11.6) years, NW	23.4 (3.4)	Self-reported	FFQ	g/d: Tertile 1: <189.2 Tertile 2: 189.2-355.0 Tertile 3: >355.0	2 years	↓Risk of WG, NS, ( $P_{\text{trend}}=0.46$ ) T1 (mean WG = 0.77 [CI: 0.61, 0.93]) T2 (mean WG = 0.76 [CI: 0.53, 0.99]) T3 (mean WG = 0.68 [CI: 0.44, 0.93])
Linde <i>et al.</i> , 2006	USA n = 988 (697 ♀, 291 ♂) 50.7 (0.4) years, OB	34.2 (0.2)	Measured	Block Screening Questionnaire	Mean freq/mo (SD): Baseline: ♂: 14.2 (9.8), ♀: 16.6 (10.5) follow-up: ♂: 17.7 (9.9), ♀: 20.1 (10.1)	2 years	↓BMI ♂ ( $\beta = -0.07$ (SE = 0.02)), S, ( $P<0.01$ ) ↓BMI ♀ ( $\beta = -0.04$ (SE = 0.01)), S, ( $P<0.01$ )
Nooyens <i>et al.</i> , 2005	Holland n = 288 (♂) 54.9 (2.5) years, OW	26.4 <sup>‡</sup>	Measured	FFQ	Not reported	5 years	↓Fruit (-0.02 times/wk):↑BW (1 kg/year), S ( $P<0.01$ ) ↓Fruit (-0.03 times/wk):↑WC (1 cm/year), S ( $P<0.01$ )
Drapeau <i>et al.</i> , 2004	Canada n = 248 (136 ♀, 112 ♂) 39.6 (14.2) years, OW	25.3 (4.7)	Measured	3-d food record	Not reported	6 years	↑Fruit: WG (mean±SEM: 1.5±0.5 kg) ↓Fruit: WG (mean±SEM: 6.5±2.5 kg) Difference between groups: S, ( $P<0.001$ )
He <i>et al.</i> , 2004	USA n = 74,063 (♂) 50.7 (7) years, NW	24.9 (5)	Self-reported	FFQ	serv/d: baseline: 1.9 Follow-up: Q1: -1.27; Q5: +1.86	12 years	↓Risk of OB, S Q5 vs Q1 (OR=0.75 [CI: 0.69, 0.81]), ( $P_{\text{trend}}<0.0001$ )

Table 4.2. *Continued*

Author, year	Country Population n* (sex) Age, weight status	BMI (kg/m <sup>2</sup> )	Anthropometrics	Dietary assessment	Fruit intake	Follow-up	Results
Schulz <i>et al.</i> , 2002	Germany n = 17,369 (11005 ♀, 6364 ♂) 50.1 (8.8) years, OW	26.3 (4.3)	0 years: measured 2.2 years: self- reported	FFQ	Not reported	2.2 years	↑Fruit (100 g/d) and risk of WG, NS: large WG (OR=0.94 [CI: 0.83, 1.05]) small WG (OR=1.04 [CI: 0.96, 1.13]) small loss (OR=1.05 [CI: 0.97, 1.13]) large loss (OR=1.03 [CI: 0.93, 1.14])
Schroder, 2010	USA n = 55 42.3 (10.8) years, OB	34.8 (5.5)	Measured	8-d food record	serv/d (SD): 1.30 (1.01), no change during follow-up	6 mo	↑fruit => ↓BMI ( $\beta = -0.27$ ), S ( $P=0.10$ ) <sup>§</sup>

\*Number of subjects analysed.

†Mean (SD) (all such values).

‡Mean (all such values).

§Due to a considerably smaller sample size than what was estimated from the power analyses prior to the study and hence limited power, the critical  $\alpha$  level was set to 0.10.

BW: bodyweight; BMI: body mass index; WC: waist circumference; WG: weight gain; OR: odds ratio; CI: confidence interval (95%); reg coef: regression coefficient; S: significant; NS: non-significant; SE: standard error; SEM: standard error of the mean; OB: obese; OW: overweight; NM: normal weight; serv: serving; d: day; ↓: decrease; ↑: increase.

Table 4.3. Overview of the cross-sectional studies investigating the role of fruit intake in body weight status

Author, year	Country Population n* (sex) Age	Anthropometrics	Dietary assessment	Results
Moreira <i>et al.</i> , 2006	Portugal n = 39,640 (20977 ♀) 50.3 (18.9) <sup>†</sup> years (18663 ♂) 47.7 (18.5) years	Self-reported	Asked if eaten fruit during the previous day by interviewer	♀ ↓OB (OR=0.77 [CI: 0.64,0.92]), S (P=0.004) ♂ ↓OB (OR=0.94 [CI: 0.79, 1.12]), NS (P=0.44) Amount of fruit intake not reported
Davis <i>et al.</i> , 2006	USA n = 104 (68 ♀, 36 ♂) 39.8 (12.3) years	Measured	FFQ	Fruit intake: OW/OB: 0.9 (0.9) serv/d NW: 1.6 (1.0) serv/d Difference: S (P<0.01)
Lin <i>et al.</i> , 2002	USA n = 9,117 (4408 ♀, 4709 ♂) ≥ 19 years	Self-reported	2x24-h recall by interviewer	Fruit intake: ♀ OB: 1.3 serv/d NW: 1.5 serv/d difference: S (P<0.05) ♂ OB: 1.2 serv/d NW: 1.6 serv/d difference: S (P<0.01)
Trudeau <i>et al.</i> , 1998	USA n = 1,450 (863 ♀, 587 ♂) 44 <sup>‡</sup> years	Self-reported	FFQ	Fruit intake: ♀ BMI<23.1: 1.4 serv/d BMI≥32.2: 0.97 serv/d difference: S (P<0.001) ♂ BMI<23.1: 1.09 serv/d BMI≥32.2: 1.09 serv/d difference: NS
Serdula <i>et al.</i> , 1996	USA n = 21,892 (12,599 ♀, 9293 ♂) ≥ 18 years	Self-reported	FFQ by telephone interviewer	Fruit intake (mean [±CI]): ♀ NW: 0.79 [±0.14] serv/d OB: 0.76 [±0.17] serv/d difference: NS ♂ NW: 1.02 [±0.16] serv/d OB: 1.09 [±0.22] serv/d difference: NS

Table 4.3. *Continued*

Author, year	Country Population n* (sex) Age	Anthropometrics	Dietary assessment	Results
Schroder, 2010	USA n = 77 (66 ♀, 11 ♂) 42.3 (10.8) years	Measured	8-d food record	↑fruit => ↓BMI ( $\beta = -0.40$ ), S ( $P=0.001$ ). Mean fruit intake, serv/d (SD): 1.30 (1.01)

\*Number of subjects analysed.

†Mean (SD) (all such values).

\*Mean (all such values).

BMI: body mass index; OR: odds ratio; CI: confidence interval (95%); S: significant; NS: non-significant; OB: obese; OW: overweight; NM: normal weight; serv: serving; d: day; ↓: decrease; ↑: increase.

## 4.2. The cross-sectional study (Paper II)

The study population in paper II with data from Denmark, Hungary, France, Italy, and UK was reduced from the original 9,758 to 8,143 after application of Goldberg's cut-off technique, equivalent to a reduction of approximately 16.6%. The basic characteristics of the participants, including gender, age, BMI, and mean daily fruit intake, are illustrated in Table 2 of paper II. Briefly, both genders were almost equally represented (50.1% women), mean age (SD) was 45.8 (15.9) years, mean BMI (SD) was in the upper end of the normal-weight classification (24.1 (2.8) kg/m<sup>2</sup>) and median fruit intake was 136.5 g/d.

Pairwise comparison analyses, adjusted for age and gender, showed that, compared to the other countries, participants from the UK had the highest mean BMI and the lowest mean fruit intake, whereas those from Italy had the lowest mean BMI (though not significantly lower than those from France) and the highest mean fruit intake. These results are presented in Table 4.4, which is not included in paper II.

Table 4.4. Mean \*, SE and P-values for the differences in BMI (kg/m<sup>2</sup>) and fruit intake (g/d) between countries

		UK		Italy		Hungary		France	
		BMI	Fruit	BMI	Fruit	BMI	Fruit	BMI	Fruit
Denmark	Mean diff.	-0.92	24.4	0.18	-36.1	-0.67	1.5	0.12	10.2
	SE	0.10	0.02	0.07	0.02	0.10	0.02	0.08	0.02
	P-value	<.0001	<.0001	0.0164	<.0001	<.0001	NS	NS	<.0001
France	Mean diff.	-1.08	11.0	0.06	-43.9	-0.77	-8.8		
	SE	0.11	0.02	0.08	0.02	0.11	0.02		
	P-value	<.0001	<.0001	NS	<.0001	<.0001	0.0008		
Hungary	Mean diff.	-0.33	28.0	0.86	-40.1				
	SE	0.12	0.02	0.10	0.02				
	P-value	0.0079	<.0001	<.0001	<.0001				
Italy	Mean diff.	-1.14	65.5						
	SE	0.10	0.02						
	P-value	<.0001	<.0001						

\*Adjusted for age and gender; SE: standard error; diff: difference.

The association between BMI and consumption of fruit, fruit and vegetables, processed fruit, and fruit juice are described in paper II and presented in Table 3 of the paper. Overall, no significant associations between intake of these selected food groups and BMI were found. However, gender-specific analyses showed a slightly significant inverse association between fruit juice intake and BMI among women (Regression coefficient: -0.001; 95% CI: -0.002, -0.000). Further, separate

analyses for those with self-reported and measured anthropometric data did not show any significant association in either group.

Associations between fruit intake and intake of fruit juice, processed fruit, vegetables, soft drinks, sweets, snack foods, E% from fat and energy density were examined as described in paper II and presented in Table 4 of the paper. Fruit intake had a significant and direct association with intake of fruit juice, processed fruit, and vegetables while it had significant and inverse association with intake of soft drinks and snack foods. Furthermore, fruit intake had a significant inverse association with E% from fat and energy density. No significant association between intake of fruit and sweets was found. Gender-specific analyses showed that the inverse association between consumption of fruit and snack foods was significant among men (Regression coefficient: -0.26; 95% CI: -0.47, -0.02) and not among women.

#### **4.3. The feasibility study (Paper III)**

The controlled feasibility study proceeded for approximately five months. At endpoint, the total number of participants was reduced from 146 to 124 (~15.1% reduction), comprising 68 in the intervention and 56 in the control group.

Baseline characteristics, including sex, age, educational level, occupation, smoking status and BMI, are presented in Table 1 of paper III. Both groups consisted predominantly of white-collar workers. Mean daily intake values with their standard errors for the intervention and control groups at baseline and endpoint for fruit (exclusive of juice), vegetables (exclusive of potatoes), energy and macronutrients (including added sugar and dietary fibre) are presented in Table 2 of paper III. Baseline values for mean daily fruit intake were slightly higher among the participants in the intervention and control group compared to the results from the Danish National Dietary Survey (260 and 234 g vs. 199 g) (Hallund *et al.*, 2007). There were no significant differences between the two groups in intake values of the above listed dietary factors. After the intervention, mean daily fruit and dietary fibre consumption increased significantly by 112 g and 3.0 g, respectively, whereas mean daily consumption of added sugar decreased significantly by 10.7 g in the intervention group. In the control group, no significant changes in any of the intake variables were observed from baseline to endpoint. Endpoint values for mean daily fruit intake were significantly different between the two groups (372 g in the intervention group vs. 244 g in the control group).

Overall, this study showed that by making free fruit available at workplaces, it was possible to increase the mean fruit consumption in the intervention group.

#### 4.4. The intervention study (paper IV)

In the cluster-randomised controlled intervention study in paper IV, 351 of the 409 participants, initially enrolled for the study, completed all aspects of the study (~14.2% dropout). Of these, 186 were in the intervention group and 165 in the control group.

Details about the baseline characteristics are described in paper IV and presented in Table 1 of the paper. Overall, the intervention and control group matched for age, gender and education level, whereas SES and smoking status differed significantly between the two groups. Relative to the control group, the participants in the intervention group belonged to higher SES groups and were more frequently smokers.

Anthropometric and blood pressure measurements were similar for the intervention and control groups at baseline (table 2 in paper IV). Participants from both groups were on average slightly overweight with a mean BMI of 26.6 and 25.9 kg/m<sup>2</sup> in the intervention and control group, respectively. At the end of the intervention period, no significant differences between the two groups in any of the anthropometric or blood pressure measures were observed. Within the intervention group fat mass and diastolic blood pressure decreased significantly from 29.1% to 28.6% and from 79.0 mmHg to 76.9 mmHg, respectively, from baseline to the end of the intervention. Additionally, the intervention group tended to have a lower BMI compared with baseline, though only significant at borderline-level. Diastolic blood pressure also fell significantly in the control group, but the fall was non-significantly less than in the intervention group (from 77.7 mmHg to 76.4 mmHg).

Consumption of energy and macronutrients, including dietary fibre, for each group at baseline and at the end of the intervention period are presented in table 3 of paper IV. Baseline values for these dietary factors were not significantly different between the two groups. Similarly, at the end of the intervention period, none of the values were significantly different except for dietary fibre intake. Mean daily intake of dietary fibre increased significantly only in the intervention group from 17.7 to 19.1 g, resulting in a significantly higher consumption of dietary fibre in the intervention group compared to the control group at the end of the intervention period (+1.9 g/d). Within the intervention group, daily E% from fat decreased significantly from 38.2 E% at baseline to 37.4 E%

at the end of the intervention period, whereas daily E% from carbohydrate increased significantly from 46.7 E% to 47.7 E%. In the control group, daily E% from protein increased significantly from 14.0 E% at baseline to 14.4 E% at the end of the intervention period.

Table 4 in paper IV shows the mean daily intakes for fresh fruit, sweets and snacks, and soft drinks at baseline and at the end of the intervention period for the intervention and the control group. Mean baseline intake values for fresh fruit of 1.6-1.7 portions per day (equivalent to approximately 128-136 g/d) in these two groups are higher compared to the median intake of 69.1 g/d among the representative sample of the adult population in UK apparent from Table 2 in the cross-sectional study in paper II. Fresh fruit consumption increased significantly from baseline to the end of the intervention period in both groups, but the increase was significantly greater in the intervention group compared to the control group. Mean daily consumption of sweets and snacks fell significantly within the intervention group at the end of the intervention period compared with baseline. In contrast, mean daily consumption of soft drinks increased significantly within the control group at the end of the intervention period compared with baseline. The changes in intake values for sweets and snacks, and soft drinks from baseline to the end of the intervention period were not significantly different between the two groups.

## 5. Discussion

In the following, a discussion of the individual papers is presented. Subsequently, an overall discussion and conclusion of the present thesis is carried out.

### 5.1 The review (paper I)

The evaluation of the existing published literature on human observational and intervention studies carried out in connection with the review (paper I) in this thesis and the one study by Schroder (Schroder, 2010), identified subsequently, showed inconclusive findings but led to a modest indication that fruit intake may play a potential role in body weight management in the adult population by preventing long-term excessive weight gain. Overall, the sum of studies, of all included types, that showed an association between fruit intake and body weight or an effect of fruit intake on body weight exceeded the sum of those that did not.

Whether fruit intake has an effect on body weight in adults can only be deduced from RCTs. However, only three RCTs (de Oliveira *et al.*, 2008, Fujioka *et al.*, 2006, Rodriguez *et al.*, 2005) could be identified that had examined the separate effect of fruit intake on body weight. Of these, two (de Oliveira *et al.*, 2008, Fujioka *et al.*, 2006) found that relatively more fresh fruit in the diet of the intervention groups resulted in a significant reduction in body weight compared to the control groups. One found no significant difference between the high-fruit intervention group and the low-fruit control group (Rodriguez *et al.*, 2005). However, both groups in the latter study were delivered hypocaloric diets. Moreover, important determinants of the diets consumed by the subjects, including content of energy, fruit and other dietary factors potentially important in this context such as fat, vegetables, and energy density, were not available in all of the studies. Common for the RCTs included in paper I was that they were all of a short duration (8-12 weeks), subjects were overweight or obese, assumingly motivated to lose weight and the conditions under which the trials were conducted were restricted and controlled. Thus, these three studies do not provide a solid foundation for inferring that increased fruit intake reduces body weight or aids maintaining a normal body weight in the long term under real-life conditions.

Observational studies do not provide basis for making inferences on causal relationships between exposures, here being fruit intake, and outcomes, here being body weight. However, observational studies are often applied in nutritional science because they offer the opportunity to investigate the association between exposure and outcome under real-life conditions among a relatively large study

population. Furthermore, prospective observational studies offer the possibility for a long-term follow-up of a cohort. When carrying out paper I, it was recognised that there is a paucity in the number of observational studies that have as their primary aim to investigate the separate association between fruit intake and body weight. Nevertheless, the majority of the observational studies included in paper I suggested that there is an inverse association between fruit intake and body weight. Among the prospective observational studies that found an association between fruit intake and body weight, most did so by showing that a relatively high fruit intake was associated with less long-term weight gain, which is common with increasing age (Drapeau *et al.*, 2004, He *et al.*, 2004, Linde *et al.*, 2006, Nooyens *et al.*, 2005, Vioque *et al.*, 2008). In most cases the cohort predominantly consisted of overweight or obese subjects.

There are some limitations when attempting to compare results from observational studies of both prospective and cross-sectional type. One limitation is that the physical form of fruit is not reported in all of the studies. Hence, it is not clear if the 'fruit' category only includes fresh fruit or also fruit juice, puréed, dried or canned fruit, or fruit that is prepared and added sugar or fat etc. These are important determinants as the energy density and content of water and dietary fibre can vary between the different physical forms. It has been reported (Flood-Obbagy & Rolls, 2009, Haber *et al.*, 1977) that the physical form of fruit can affect satiety and thereby energy intake and ultimately possibly body weight. Moreover, different types of dietary assessment methodologies are applied. Although the majority of the studies use FFQs, not all do so and, in addition, some use sub-varieties of FFQs specifically developed for the individual study. Further, some studies use self-reported anthropometric data while others use measured anthropometric data. Additionally, most of the observational studies in paper I, especially the cross-sectional studies, are from USA. This restricts the possibility to extrapolate the results to populations from other parts of the world with other food cultures.

Overall, although the majority of the studies in paper I indicates that fruit intake is inversely associated with body weight or reduces body weight, a firm conclusion of the role of fruit in relation to body weight management, including body weight reduction or prevention of overweight and obesity is precluded. This is due to several factors such as the heterogeneity in methodological procedures, missing information on important determinants in some of the studies, the physical profile of the study sample consisting predominantly of overweight or obese individuals and most of the studies being carried out in USA. Furthermore, the paucity in the number of RCTs impairs the possibility to infer, with certainty, that there is a causal relationship between fruit intake and

body weight. The restricted conditions the RCTs are carried out under and lack of effectiveness trials among free-living individuals further limit the possibility to extrapolate their findings to the general population under real-life conditions.

## 5.2. The cross-sectional study (paper II)

The cross-sectional study in paper II was conducted in continuation of the findings in paper I, identifying an absence of cross-sectional studies in a European context. In contrast to most of the cross-sectional studies in paper I, the cross-sectional study in paper II did not find a significant inverse association between fruit intake and body weight, expressed as BMI, among nationally representative samples of the general populations in a selected number of countries representing the North, East, South and West Europe. This conflict in findings can be a reflection of several important factors. The study sample in paper II consisted of normal- and overweight individuals with a relatively high median daily fruit intake (136.5 g, compared to the mean daily intake of ~70 - 128 g among those in paper I) from different countries across Europe, while those in paper I were mainly from USA and included both underweight and obese individuals. Furthermore, in paper II, 3- or 7-day food records were applied for dietary assessment against FFQs which were the most frequent tools used in paper I. Compared with FFQs, food records are considered to provide a more detailed and accurate picture of the individuals' food intake, among other things because they offer better estimates of portion sizes and thereby reduce error associated with quantification. Moreover, there is no consistency between the studies in the way the anthropometric data were assessed, as both self-reported and measured data were used. Self-reported anthropometric measures can be prone to bias if the participants, consciously or unconsciously, report more ideal measures rather than the actual ones (Palta *et al.*, 1982). In addition, the classification of the fruit category varies between the studies and is not described clearly in all studies, entailing that in some studies only fresh fruit is classified as the fruit category while others also might classify fruit products, including fruit juice or processed fruit, as the fruit category. Fruit related products might be more energy dense compared to fresh fruit and therefore the frame of comparison between the results would evidently be impaired.

Cross-sectional studies capture a snapshot of a possible association between exposure and outcome, not including the time dimension in the analyses. Therefore, based on paper II, it cannot be precluded that, rather than being associated with low BMI *per se*, fruit intake may be associated with long-term changes in BMI, such that individuals with relatively high fruit intake are less

disposed to excessive weight gain over time than those with relatively low fruit intake. This would be in accordance with the indicative findings from prospective observational studies in paper I (Drapeau *et al.*, 2004, He *et al.*, 2004, Linde *et al.*, 2006, Nooyens *et al.*, 2005, Vioque *et al.*, 2008), which, by virtue of their longitudinal design, offer the opportunity to follow a cohort over a period of time and thereby detect potential long-term changes in body weight.

Previous research, including both observational and intervention studies, has predominantly investigated the combined association between fruit and vegetable intake and body weight (Buijsse *et al.*, 2009, Ledoux *et al.*, 2011, Rolls *et al.*, 2004, Tohill *et al.*, 2004, Zazpe *et al.*, 2011). Most of these find that fruit and vegetable intake is inversely associated with body weight, although it is not clear whether the determinative factors for the inverse association are the consumption of fruit and vegetables or an overall implementation of a healthy lifestyle by the participants. However, in the cross-sectional study in paper II, focus was on the separate association between BMI and fresh fruit, not including vegetables or other fruit products such as fruit juice or processed fruit.

Notwithstanding that in paper II, fruit intake, neither separately nor combined with vegetable intake, showed an inverse association with BMI, the separation of fruit from vegetables seems important, as the nutritional composition and culinary use of fruit is different from vegetables. Similarly, it is essential to distinguish between fresh fruit and fruit products, especially when the outcome to be investigated is body weight, because the relatively low energy density and high dietary fibre content in fruit are important factors in this respect and are likely altered when fruit is processed.

Overall, no significant association between consumption of fruit juice or processed fruit and BMI was found in paper II. However, gender-specific analyses showed a slight, but significant, inverse association between consumption of fruit juice and BMI among women. Current research on fruit juice intake and body weight among adults is scarce and findings are ambiguous. Hence, the inverse association among women in paper II is in agreement with a previous cross-sectional study (Akhtar-Danesh & Dehghan, 2010) but conflicts findings from a number of prospective observational studies, which have suggested that increased fruit juice intake is associated with long-term increase in body weight (Bes-Rastrollo *et al.*, 2006, Schulze *et al.*, 2004). One reason for the ambiguous findings may be the inconsistency between the studies on whether or not to classify sugar-sweetened fruit beverages as fruit juice. In paper II, separate analyses for fruit juices with and without added sugar were not carried out, as data on this were not available. The lack of association between consumption of processed fruit and BMI in paper II could not be related to prior findings, because no previous studies on this subject could be identified. Taking into account the relatively

low intake of fruit juice and processed fruit (median g/d: 7.3 and 4.3, respectively) among the sample in paper II, results from the study need to be interpreted with caution. Further research is therefore warranted and based upon the foregoing, future studies need to be clear and consistent in their classification of fruit juice and processed fruit.

The results on the association between fruit intake and intake of fruit juice, processed fruit, vegetables, soft drinks, snack foods, E% from fat and energy density in paper II, showed an interesting pattern. Intake of relatively nutrient-dilute food groups and factors generally considered as ‘unhealthy’, here being soft drinks, snack foods, E% from fat and energy density, was inversely associated with fruit intake, whereas intake of relatively nutrient-dense food groups generally considered as ‘healthy’, here being fruit juice, processed fruit and vegetables, was directly associated with fruit intake. These findings suggest that fruit intake may be part of a generally healthy dietary pattern characterised among other things by a relatively low energy density. Previous studies (McNaughton *et al.*, 2007, Newby *et al.*, 2006, Newby *et al.*, 2003, Quatromoni *et al.*, 2002, Schulz *et al.*, 2005, Schulze *et al.*, 2006), showing that dietary patterns perceived as healthy comprise a relatively high amount of fruit while being low in energy density, support the findings in paper II. Interestingly, it has also been shown that individuals aiming to reduce or maintain body weight adopt these types of dietary patterns as a component in their overall effort to pursue a healthy lifestyle (Andreyeva *et al.*, 2010, Wilson *et al.*, 2010). Thus, in paper II, fruit may be an indicator of a lifestyle, potentially promoting a healthy body weight rather than independently be associated with BMI.

Strengths of paper II included the relatively large study size and the representativeness of the study sample reflecting the general adult population in selected countries from Europe. Moreover, the application of 3- or 7-day dietary records provided a better estimate of the actual intake, compared to FFQs. Further, separate analyses of fruit and vegetables and additional separation of the different physical forms of fruit enhanced the possibility to estimate the independent association between consumption of fresh fruit and BMI.

The cross-sectional design of paper II also includes some limitations. Collection of dietary and anthropometric data at the same point in time posed the study to the risk of reverse causation. Moreover, although adjustments for possible confounders were carried out, risk of residual confounding cannot be eliminated. Unavailable information on and, hence, lack of adjustment for physical activity level and SES adds to the risk of confounding bias. There is also a risk of social

desirability bias when dietary data are self-reported (Johansson *et al.*, 2001), as was the case in paper II. The relatively small reported consumption of foods perceived as ‘unhealthy’, including soft drinks, sweets and snack foods are indicative of such bias. Likewise, BMI was computed from self-reported anthropometric data in some of the participating countries and is therefore at risk of being under-estimated (Palta *et al.*, 1982). However, no association between fruit intake and BMI was found when the countries with self-reported data and countries with measured data were analysed separately.

Summing up, the cross-sectional study in paper II did not show any association between fruit intake and BMI among a sample of the general adult population in selected countries across Europe. Interestingly, however, there was an inverse association between fruit intake and intake of relatively nutrient-dilute food groups and factors commonly perceived as ‘unhealthy’, while there was a direct association between fruit intake and intake of relatively nutrient-dense food groups commonly perceived as ‘healthy’.

### **5.3. The feasibility study (paper III)**

The controlled feasibility intervention study in paper III that was carried out as a precursor to the larger-scale cluster-randomised controlled intervention study in paper IV showed that it was possible to increase the fruit intake of the participants in the intervention group significantly. This was achieved by a minimal intervention, addressing only one of the elements in the physical environment (see Figure 1.2), namely by increasing the availability and accessibility of fruit at the intervention workplaces.

Other intervention studies with more extensive approaches, both at workplace settings and elsewhere, have succeeded, although modestly, to enhance the quality of the diets of participants, among other things, by slightly increasing their fruit intake (Beresford *et al.*, 2001, Buller *et al.*, 1999, Elliot *et al.*, 2007, Engbers *et al.*, 2006, Lassen *et al.*, 2004, Lassen *et al.*, 2011, Quintiliani *et al.*, 2010, Sorensen *et al.*, 1999, Sternfeld *et al.*, 2009). Attempts to identify most effective approaches to enhance the quality of the diets of individuals are in continuous focus. Hence, a recent 6-month, randomised, controlled intervention study by Bandoni *et al.* (Bandoni *et al.*, 2011) which took place at a sample of workplaces in Brazil, including 1,214 participants (~33% female), showed a modest but significant increase in fruit and vegetable intake of approximately 11 g at the end of the intervention in the intervention group, by introducing changes in the workplace

environment. A separate value for the change in fruit intake, excluding vegetables, was not reported. The changes in the workplace involved counselling and instruction of the cafeteria staff to increase fruit and vegetable proportion of the menus and motivational and educational reading materials for the employees to encourage increased fruit and vegetable consumption. In general, most intervention studies in this field have sought to achieve behavioural changes by offering counselling and education to the participants. The novel approach adopted by the study in paper III pursued to increase the fruit intake of the participants through a minimal intervention by simply providing freely available fruit to the participants.

Additional changes in consumption of dietary fibre and added sugar, which were significantly increased and decreased, respectively, were also achieved in the intervention group in paper III. However, no changes in total energy intake were observed in either group, which could suggest that fruit intake had substituted intake of other dietary items. This substitution may have involved dietary items containing added sugar, thereby explaining the reduction in the intake of added sugar. Previous RCTs, including both efficacy and effectiveness trials, have shown that dietary interventions involving increased fruit intake can affect total energy intake (de Oliveira *et al.*, 2008, Ledikwe *et al.*, 2006, Rodriguez *et al.*, 2005, Svendsen *et al.*, 2007, Thomson *et al.*, 2005). Common for these studies was that the enrolled participants were either overweight or obese, likely with an incentive to reduce total energy intake and lose weight. Participants in paper III were mainly normal weight with a relatively high baseline fruit intake, which could indicate a relatively healthy dietary habit prior to the study. This could possibly be one of the explanations to the absence of intervention effect on dietary changes, including total energy intake. Furthermore, especially given the minimal nature of the study, an extended timeframe might have influenced the effectiveness of the study on dietary changes.

The intervention effectiveness on fruit intake in paper III comprised some limitations and requires therefore caution when extrapolating the findings to the general population. The allocation of the workplaces to the intervention or control arm of the study was self-selected and not randomised, on the basis of whether or not the workplaces planned to offer their employees company benefits in terms of free fruit. Therefore, participants from intervention workplaces may have been more health conscious and, hence, more inclined to increase their fruit intake than others at large. Because the intervention workplaces purchased the fruit themselves, the number of workplaces available for the intervention group was limited, possibly entailing risk of selection bias. Furthermore, the enrolled workplaces had a relatively homogenous profile, as they all were located in the Copenhagen area

and most consisted of white-collar employees. Workplaces from other areas and with different employee profile might have yielded different results.

In brief, the feasibility study in paper III showed that a minimal intervention only focusing on increasing the availability and accessibility of fruit at the workplace can be effective in increasing the fruit intake of the employees. Further intervention effects in terms of increased intake of dietary fibre and decreased intake of added sugar were also achieved, while total energy intake remained unchanged, indicating a substitution effect by fruit.

#### **5.4. The intervention study (paper IV)**

It became evident from the review in paper I that there was a paucity in RCTs in general and among these, effectiveness intervention trials under real-life conditions in particular, investigating the independent effect of fruit intake on body weight. The large-scale, workplace, cluster-randomised, controlled, intervention study among free-living individuals in paper IV was conducted based on these findings. Results from the study showed no significant difference in anthropometric and blood pressure measurements between the intervention and control groups after the end of the intervention. Within the intervention group, however, several significant changes from baseline to the end of the intervention occurred. These included significant reductions in adiposity and diastolic blood pressure and a borderline-significant reduction in BMI. Compared to the intervention group, a smaller, but significant, decrease in diastolic blood pressure was also seen in the control group.

These changes in the anthropometric and blood pressure measurements may be ascribed to certain changes found in the dietary intake of the participants. At the end of the intervention, significant differences between the two groups were seen in intakes of fruit and dietary fibre. Both groups had significantly increased their fruit intake compared to baseline, but the increase of about 0.7 portions per day was significantly higher in the intervention group. The intervention group, but not the control group, had also significantly increased its consumption of dietary fibre at the end of the intervention, which partly may be attributed to the increased fruit intake in this group. Additional significant changes in dietary and macronutrient intake within each group occurred, although these were not significantly different between the two groups at the end of the intervention. In the intervention group, the contribution of E% from fat decreased significantly, whereas for carbohydrate, E% increased significantly from baseline to the end of the intervention, which is coherent with the increase in fruit and dietary fibre intake. The intervention group also reduced

intake of sweets and snacks significantly from baseline to the end of the intervention, which could explain some of the decrease in E% from fat. In the control group, consumption of soft drinks and E% from protein increased significantly from baseline to the end of the intervention. These changes in other aspects of the diet than only fruit indicate that a relatively simple fruit intervention and structural modifications at the workplace may reach beyond the amount of fruit consumed at work and influence overall dietary habits outside the workplace as well.

Baseline mean fruit intake of the participants in paper IV was higher compared to the median intake of the population sample from UK in paper II, which could indicate that the participants in paper IV are more health conscious and have healthier dietary habits than the average population in UK. The intervention effectiveness on dietary changes, including energy intake, and potential consequent changes in anthropometric and blood pressure measures might possibly have been more pronounced among participants with less healthy dietary habits. The modesty of the intervention effectiveness could further be due to the relatively short duration of the study as well as limited power, because the number of recruited participants did not reach the intended number, calculated prior to the initiation of the study, potentially increasing the risk of type II error.

The reduction in diastolic blood pressure, especially in the intervention group with the most marked increase in fruit intake and additional increase in dietary fibre intake, is consistent with the well-acknowledged blood pressure lowering effect of fruit from previous research, including human intervention studies and animal models (Appel *et al.*, 1997, Mancina *et al.*, 2007). This effect might be mediated through certain minerals, dietary fibre and flavonoids, which are readily available in fruit (Perez-Vizcaino *et al.*, 2009, Reshef *et al.*, 2005, Rouse *et al.*, 1983). Moreover, the decrease in diastolic blood pressure in the intervention group may also be attributable to the slight reduction in BMI and adiposity in this group. The decrease in diastolic blood pressure in the control group was more modest and may have been a result of the participants' adaptation to the measurement procedures (Verdecchia *et al.*, 1995, Verdecchia *et al.*, 1997).

The findings related to certain aspects of dietary intake suggest that some substitution has taken place in paper IV. Despite the increase in fruit intake, especially in the intervention group, total energy intake remained unchanged, indicating, similar to the finding in paper III, that fruit was not added to the usual diet but may have rather substituted other dietary items. Moreover, total energy intake was also not affected by the fall in intake of sweets and snacks in the intervention group, while E% from carbohydrate increased in spite of this fall. Given the relatively high carbohydrate

content in sweets and snacks, a fall in intake of these food groups would be more consistent with a decrease, and not increase, in E% from carbohydrate. These factors further support the potential substitution effect of fruit. It was also indicated that the free supply of fruit at the workplace substituted some of the fruit already consumed by the intervention group prior to the initiation of the intervention, because fruit intake was only increased by 0.7 portions per day in this group, even though they had free access to two portions of fruit each day and almost no fruit was left at the collection points at the end of each working day.

Development of effective strategies aiming to reduce the body weight of a target group is under great attention and has been addressed by several intervention studies (de Oliveira *et al.*, 2008, Ello-Martin *et al.*, 2007, Elmer *et al.*, 2006, Fujioka *et al.*, 2006, Greene *et al.*, 2006, Rodriguez *et al.*, 2005, Rolls *et al.*, 2005, Shintani *et al.*, 2001, Svendsen *et al.*, 2007, Toubro & Astrup, 1997), including a number of workplace intervention studies (Anderson *et al.*, 2009, Benedict & Arterburn, 2008, Goetzel *et al.*, 2010, Siegel *et al.*, 2010). Workplaces are considered as appropriate settings, by national and international bodies, for implementation of health-promoting lifestyle and dietary actions (Bull *et al.*, 2008, Karnaki *et al.*, 2009, Nordic Council of Ministers, 2006, Quintiliani *et al.*, 2008, WHO/World Economic Forum, 2008), because they offer a unique opportunity to address a large proportion of the adult population each day. Most intervention studies, within and outside workplace settings, have undertaken a holistic approach attempting to modify several aspects of the diet and lifestyle of the involving individuals through extensive educational and counselling programs, while only a few have focused on the efficacy of fruit intake alone on body weight changes, carried out under strict and controlled conditions (de Oliveira *et al.*, 2008, Fujioka *et al.*, 2006, Rodriguez *et al.*, 2005). Given the globally increasing challenge of overweight and obesity, effective but at the same time easy to implement strategies reaching a large number of individuals under real-life conditions are much needed. Hence, the novelty and the underlying thought with the intervention study in paper IV was to examine the effectiveness of a relatively simple dietary intervention, namely provision of freely available fruit, on changes in body weight among free-living individuals at a workplace, employing a relatively large workforce. The dietary intervention was simple in that it implemented only minimal structural modifications in the workplace and required as little as possible from the enrolled participants and other involving staff. However, the modesty of the intervention effectiveness on body weight may indicate that more than just one food group need to be in focus in order to see more substantial changes in the outcome. Previous research has shown that weight loss interventions that only aim to increase fruit and vegetable intake of the

participants are less effective than those that emphasise the body weight reducing goal of the intervention and include reduction in dietary fat and total energy intake as an additional intervention aim (Rolls *et al.*, 2004). Moreover, a longer time frame and a larger sample size may also have influenced the outcome, especially taking into consideration that the number of participants was smaller than the targeted number estimated by the power analysis prior to the intervention, increasing the risk of type II error.

To sum up, the intervention effectiveness of the study in paper IV on body weight was modest and appeared as changes in adiposity, diastolic blood pressure and only slightly in BMI, mainly within the intervention group. Dietary changes as a result of the intervention were more pronounced, especially changes in fruit and dietary fibre intake in the intervention group. Furthermore, some substitution effect of fruit was also suggested, as the energy intake remained unchanged despite the increase in fruit intake. Regardless of the intervention effectiveness being modest, these types of relatively simple interventions among free-living individuals are needed in order to improve the diet quality and body weight status of the general population. Future interventions may achieve more substantial changes in bodyweight if they are of longer duration, include a larger number of participants, and focus on more determinants than just a single food group.

## 6. Overall discussion and conclusion

The sum of findings from all four studies included in the present PhD thesis suggests that fruit intake may play a potential role in body weight management in terms of prevention of overweight and obesity in adults by decelerating long-term excessive weight gain progressing with age. However, free available fruit at the workplace seems not to be effective in reducing body weight among free-living adults in the short term. Although, those provided with free available fruit at the workplace increased their consumption of fruit and dietary fibre significantly compared to the control group.

Whether the tendency for an inverse association between fruit intake and body weight is caused by fruit intake *per se* or is also due to other known and unknown factors remains unclear because of the types and number of the studies. The review (paper I) showed that the studies that have investigated the separate association between fruit intake and body weight and changes in body weight are relatively few and mainly of prospective observational and cross-sectional nature. Due to their observational design, prospective observational and cross-sectional studies are prone to confounding bias and therefore preclude inference making for a causal relationship between fruit intake and body weight. Thus, based on these studies, it cannot be eliminated that fruit intake is a marker of a healthy and body weight maintaining dietary pattern and lifestyle rather than in itself causing body weight maintenance. Interestingly, and in continuation with this potential role of fruit being a marker of a healthy dietary pattern, the cross-sectional study in paper II showed that fruit intake was inversely associated with intake of relatively nutrient-dilute food groups and factors commonly perceived as ‘unhealthy’ while being directly associated with relatively nutrient-dense food groups perceived as ‘healthy’.

The cross-sectional study in paper II showed no association between fruit intake and body weight, which was conflicting with the majority of previous cross-sectional studies, mainly conducted in USA. A number of inconsistencies, including body weight status of the study population, tools used for dietary assessment, methodological approaches for anthropometric data collection, and classification of the ‘fruit’ category may have been some of the potential causes of the conflicting results. Furthermore, the cross-sectional design urges caution when drawing up a conclusion. Hence, a potential association between fruit intake and body weight cannot be eliminated and further research, both epidemiological and experimental type, are needed for verification of the findings in paper II. Given the current inconclusive pool of study results, future cross-sectional

studies need to incorporate similar procedures in the design and initiation phase of the studies, including a standardised dietary assessment method, ensuring findings suitable for comparison.

Presence of a causal relationship between fruit intake and body weight has been indicated in a few RCTs under strict conditions among overweight and obese individuals. However, the paucity of the RCTs, their strict designs, the enrolled study sample consisting only of overweight and obese subjects, and missing information on potentially important determinants for changes in body weight calls into question the presence of an actual causal relationship and if so, the sustainability of it under real-life conditions. This was attempted elaborated in the intervention study in paper IV, investigating if a simple increase in the availability and accessibility of fruit at the workplace could eventually affect the body weight of the participating employees. The results showed only modest intervention effectiveness on changes in body weight, which could indicate absence of a causal relationship between fruit intake and body weight. However, the presence of an effect, even though modest, could also indicate that there is a causal relationship, which would have been expressed more clearly if certain conditions were modified. I.e. the purpose of keeping the intervention at a relatively simple level in order to impose minimal demands to those involved may have to be reconsidered. Moreover, the size of the study sample, being smaller than assessed by the pre-intervention power analysis, exposing the results for type II error, and the relatively short duration of the study may also have been influential determinants.

The rationale behind the potential role of fruit in body weight management originates from the mechanisms characteristic of fruit, particularly the low-energy density and high dietary fibre content of fruit. However, keeping in mind that fruit, as a food group, comprises a wide and diverse range of dietary items with distinct nutritional and biochemical compositions, differentiation and more in-depth exploration of the food group, fruit, in relation to body weight, may be required. This could expand the current knowledge of potential compounds in different types of fruit possibly influential in relation to body weight and provide the opportunity to identify new potential compounds beyond those currently known.

In conclusion, fruit intake may play a potential role in body weight management by preventing progression of overweight and obesity in the long term. However, simple interventions involving only increased accessibility and availability of fruit at workplace settings seem not to be substantially effective for weight loss purposes, while seemingly effective in terms of increased

fruit intake by the participants and possible additional improvement of the quality of their general diet.

## 7. Perspectives

The present PhD thesis shows that fruit intake may play a role in relation to body weight management. However, the pool of evidence necessary in order to determine whether fruit intake affects or is associated with body weight is inadequate.

Following the findings from the review (paper I), it is evident that more studies, especially effectiveness intervention trials under real-life conditions, investigating the separate effect of fruit intake on body weight, are needed. As a response to this finding, the cluster-randomised controlled intervention study in paper IV was carried out. However, dietary interventions are very complex in that it is not possible to add or remove a dietary item to or from the diet while keeping all other factors in the diet constant. I.e. addition or removal of dietary items would affect the energy intake or cause a substitution effect as indicated in paper III and IV. Thus it is difficult to determine whether it was the dietary item, the variation or lack of variation in energy intake, or the substitution that caused or prevented a potential effect.

Based upon the intervention study in paper IV, future effectiveness intervention trials need to have a larger study size and be of longer duration. Furthermore, it may be necessary with a less simple intervention involving additional factors than only fruit. This could include additional focus on vegetables, dietary fat and communication to the participants about the body weight reducing aim of the study. However, given the growing challenge of overweight and obesity worldwide and the boundaries related to implementation of effective strategies for body weight management, the interventions need to be of minimal demands to those involved. Moreover, multifactorial interventions, focusing on other additional factors than only fruit, diminish the possibility to infer with certainty whether it was fruit *per se* or the other factors that caused the potential changes in body weight, notwithstanding the possibility of adjustment for the other factors in the statistical analyses.

When investigating the possible role of fruit in relation to body weight management, it is important to distinguish between body weight maintenance and reduction. Hence, taking the results from paper IV and the prospective observational studies in paper I into account, moderate increase in fruit intake may not reduce the body weight substantially, but may contribute to body weight management in terms of prevention of overweight and obesity over several years. Prospective observational studies may be a more suitable approach for exploration of the potential association between fruit intake and body weight maintenance, as a relatively long observation period is

required before a stability of the body weight can be determined. However, due to the risk of residual confounding, prospective observational studies do not allow identification of causal relationships.

One of the purposes of nutritional science is to provide evidence for official dietary recommendations. However, as apparent from the present thesis, dietary intervention studies, which are supposed to deliver these evidences, are complex to carry out. Thus, dietary recommendations need to be established based on several high quality intervention and prospective observational studies, ideally reviewed systematically in a meta-analysis. A common request for both intervention and prospective observational studies in the future, investigating the potential role of fruit in relation to body weight management, is that they need to report clearly all the important determinants and further, they need to be consistent in their study sample profile, methodological approaches, classification of the 'fruit' category etc. in order to improve the basis for comparison of the results.

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## **Appendices**

**Paper I**

**Paper II**

**Paper III**

**Paper IV**

**Illustration, Conceptual framework**

## Paper I

**The potential association between fruit intake and body weight – a review**

## Obesity Prevention

# The potential association between fruit intake and body weight – a review

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### Summary

Both national and international bodies recommend an increased intake of fruits and vegetables in order to decrease the risk of overweight and obesity. However, there is a rationale to investigate the separate role of fruits. The aim of this paper was to systematically review and analyse published human intervention, prospective observational and cross-sectional studies on fruit intake and body weight in adults. We identified three intervention, eight prospective observational and five cross-sectional studies that explored this relationship. Two of the intervention studies showed that fruit intake reduced body weight, five of the prospective observational studies showed that fruit consumption reduced the risk of developing overweight and obesity, and four of the cross-sectional studies found an inverse association between fruit intake and body weight. Important methodological differences and limitations in the studies make it difficult to compare results. However, the majority of the evidence points towards a possible inverse association between fruit intake and overweight. Future intervention and prospective observational studies examining the direct and independent role of fruit in body-weight management in free-living individuals are needed. Moreover, important determinants such as energy density, energy content, fruit and vegetable consumption, physical form of fruit and preparation methods need to be included in future studies.

**Keywords:** Dietary habits, obesity, weight maintenance, weight reduction.

**obesity reviews** (2009) **10**, 639–647

### Introduction

Overweight and obesity are some of the most challenging and steadily rising public health problems worldwide. Strategies to effectively reduce and maintain a healthy body weight are urgently required. A number of national and international bodies recommend an increased intake of fruits and vegetables in order to decrease the risk of developing lifestyle-related diseases including overweight and obesity (1,2).

The risk-reducing effect of fruits and vegetables on overweight and obesity may in part be exerted through their possible reduction upon the total energy intake. This may be explained by various factors. Fruits and vege-

tables are low in energy density, high in water content and they contain a considerable amount of dietary fibres, soluble dietary fibres in particular (3). Low-energy-dense foods are characterized as foods that contain relatively low amount of energy per unit food weight. According to some short-term studies, food intake is seemingly regulated by the weight of the food ingested rather than by the energy content (4). When consuming low-energy-dense foods, satiation may occur relatively early and the feeling of satiety may persist for a relatively long period (3). Hence, substitution of high-energy-dense foods with low-energy-dense foods, such as fruits and vegetables, could potentially decrease the total energy intake.

Soluble dietary fibres, abundant in fruits and vegetables, reportedly also decrease total energy intake and can consequently cause body-weight reduction (5). This may partly be due to a dilution of the energy density of the diet and partly a delay in gastric emptying of the ingested food. Thereby, the feeling of satiation and satiety increases, causing a reduction in the total energy intake (6). In addition, soluble dietary fibres form a gel-like environment in the small intestine, resulting partly in decreased activity of the enzymes involved in the digestion of fat, protein and carbohydrates (7) and partly in the capture and subsequent loss of these energy-yielding macronutrients, resulting in overall lowered energy absorption (3,8). The gel-like environment in the small intestine and the subsequent slow digestion of the nutrients may also presumably prolong the contact of the nutrients with receptors in the small intestine, potentially causing the release of putative satiety peptides (9). Another aspect of dietary fibres in relation to satiety is that they decrease the glycaemic index of the food. The glycaemic index compares the incremental area under the blood glucose response curve of, usually, a 50-g carbohydrate portion of a test food relative to 50 g of a standard food, following ingestion by the subject. Foods with low glycaemic index generate small and sustained elevation in postprandial blood glucose concentrations, which may be associated with long-term satiety (10).

A number of observational and intervention studies have investigated the possible association between fruit and vegetable intake and body weight. Most of these studies find an inverse association (11–13). In the present paper, however, emphasis is given to the role of fruits alone and the risk of developing overweight and obesity. The rationales for this are several: (i) fruits are typically consumed at other occasions than vegetables as they can be obtained in various physical forms, such as fresh, dried, canned, pureed, making them convenient as between-meal snacks, potentially substituting more energy-dense snacks; (ii) the culinary use of fruits differs from that of vegetables. For example, because of the various physical forms and commonly sweet taste, they are suitable as desserts. Also, here they may act as the relatively healthier alternative to the traditionally more energy-dense deserts and (iii) fruits are frequently consumed raw, whereas vegetables are often prepared by addition of fatty substances, which diminishes the low energy-dense characteristics of vegetables. Although, to our knowledge, the plausible differential physiological mechanisms of fruits and vegetables have not been explored, fruits possess a distinct physical profile, which may be manifested differently in relation to body weight status. Fructose, the main sugar in fruits, has a relatively low glycaemic index (14), producing a slow increase in postprandial blood glucose followed by a possible increase in satiety. The slow absorption may also increase satiety as a result of extended contact time with

the gastrointestinal receptors that produce satiety signals. Another factor that may connect fructose to satiety involves incomplete absorption of fructose with subsequent hyperosmolar environment in the colon (15). This results in attraction of fluids into the gut lumen, causing a feeling of indisposition and lost interest in further food consumption. Based upon these and other as yet unknown probable factors, we find it appropriate to distinguish between fruits and vegetables in relation to overweight and obesity. The aim of this paper is, thus, to systematically review and analyse human intervention, prospective observational and cross-sectional studies on fruit intake and body-weight status among an adult population.

## Methodology

### Search strategy

Studies were identified through Medline and manual searches of bibliographies until November 2008. Keywords used included: 'fruit', 'obesity', 'overweight', 'body weight', 'body weight change', 'body mass index' and 'adult'.

### Selection criteria

Intervention, prospective observational and cross-sectional studies published in English, examining the association between fruit intake and body weight or indicators of body weight, such as waist circumference, body composition or sum of skin folds, among an adult population were included. Intervention studies included were narrowed to studies aiming to specifically increase the subjects' fruit intake and analyse the effect on body weight, keeping other variables such as vegetable or fat intake, also potentially affecting body weight, out of the intervention. Prospective observational and cross-sectional studies had to have a separate and direct analysis of the association between fruit intake and body weight.

## Results

Initially, a total of 33 articles were identified through Medline. After scanning, classification process and manual searches of bibliographies, a total of three intervention studies, eight prospective observational studies and five cross-sectional studies published from 1996 to 2008 that met all the selection criteria were included in the present paper. A summary of all the included studies is shown in Table 1. Almost half of the studies were carried out in the USA, but there were also studies from Spain, Brazil, the Netherlands, Sweden, Germany, Canada and Portugal. The majority of the subjects were overweight (body mass index [BMI]  $\geq 25$ ) or obese (BMI  $\geq 30$ ), but apparently healthy except in two of the intervention studies where subjects

**Table 1** Epidemiological studies on fruit intake and body weight

Author, year	Country population n* (sex) age, weight status	BMI (kg m <sup>-2</sup> )	Intervention	Anthropometrics	Follow-up	Results
Intervention studies n = 3						
de Oliveira <i>et al.</i> (16), 2008	Brazil n = 34 (♀) 44.1 (5.4) years <sup>1</sup> , OB	31.9 (4.2)	Randomized to add apples or pears (300 g d <sup>-1</sup> ) or oat cookies (60 g d <sup>-1</sup> ) to a hypocaloric diet	Measured	10 wk	Apple gr: ↓BW (β coef -0.92 kg), S (P < 0.0001) ↓BMI (β coef -0.39), S (P < 0.0001) Pear gr: ↓BW (β coef -0.84 kg), S (P = 0.0004) ↓BMI (β coef -0.34), S (P = 0.0006) Oat gr: ↑BW (β coef +0.21 kg), NS (P = 0.35) ↑BMI (β coef +0.005), NS (P = 0.40) Fresh grapefruit gr: ↓BW (-1.6 kg) vs. placebo gr: S (P = 0.048) Juice gr: ↓BW (-1.5 kg) vs. placebo gr: NS Extract gr: ↓BW (-1.1 kg) vs. placebo gr: NS Difference between groups: BW and BMI: NS WC: S (P = 0.048) High-fruit gr: ↓BW (t <sub>0</sub> : 91.6 [6.0] kg, t <sub>8</sub> : 85.5 [6.1] kg), S (P < 0.05) ↓BMI (t <sub>0</sub> : 34.2 [2.6], t <sub>8</sub> : 32.0 [2.9]), S (P < 0.05) ↓WC (t <sub>0</sub> : 95.1 [5.2] cm, t <sub>8</sub> : 89.6 [5.2] cm), S (P < 0.05) Low-fruit gr: ↓BW (t <sub>0</sub> : 91.1 [13.0] kg, t <sub>8</sub> : 84.7 [11.6] kg), S (P < 0.05) ↓BMI (t <sub>0</sub> : 35.6 [3.3], t <sub>8</sub> : 33.1 [3.0]), S (P < 0.05) ↓WC (t <sub>0</sub> : 96.3 [8.9] cm, t <sub>8</sub> : 93.9 [6.0] cm), NS
Fujioka <i>et al.</i> (17), 2006	USA n = 77 (♀ ♂) 18-65 years, OB	35.6 (4.7)	Four-armed (fresh grapefruit, grapefruit juice, grapefruit extract or placebo added to the usual diet) randomized double-blinded placebo-controlled	Measured	12 wk	
Rodriguez <i>et al.</i> (27), 2005	Spain n = 15 (♀) 32.6 (5.8) years, OB	34.9 (2.3)	Randomized to receive a low-fruit or a high-fruit diet	Measured	8 wk	
Prospective observational studies n = 8						
Vioque <i>et al.</i> (26), 2008	Spain n = 206 (56.8% ♀, 43.2% ♂) 41.5 (17.9) years, OW	25.8 (4.8)	po	Measured	10 years	↓Risk of ≥3.41 kg mean WG, NS (P <sub>trend</sub> = 0.059); Q4 vs. Q1 (OR = 0.43 [CI: 0.13, 1.40]), NS Q3 vs. Q1 (OR = 0.27 [CI: 0.09, 0.76]), S Q2 vs. Q1 (OR = 0.53 [CI: 0.20, 1.41]), NS

Table 1 Continued

Author, year	Country population n* (sex) age, weight status	BMI (kg m <sup>-2</sup> )	Intervention	Anthropometrics	Follow-up	Results
te Velde et al. (31), 2007	Holland n = 168 (92 ♀, 76 ♂) 36.6 (0.6) years, NW	24.1 (2.9)	po	Measured	24 years	↓BMI, NS Q3 (reg coef -0.364 [CI: -0.864, 0.135]) Q2 (reg coef -0.336 [CI: -0.869, 0.196]) Q1 (reg coef -0.404 [CI: -0.996, 0.189])
Sanchez-Villegas et al. (28), 2006	Spain n = 63 19 (♀ ♂) 37.0 (11.6) years, NW	23.4 (3.4)	po	Self-reported	2 years	↓Risk of WG, NS (P <sub>trend</sub> = 0.46) T1 (mean WG = 0.77 [CI: 0.61, 0.93]) T2 (mean WG = 0.76 [CI: 0.53, 0.99]) T3 (mean WG = 0.68 [CI: 0.44, 0.93])
Linde et al. (22), 2006	USA n = 988 (697 ♀, 291 ♂) 50.7 (0.4) years, OB	34.2 (0.2)	po	Measured	2 years	↓BMI ♂ (β = -0.07 [SE = 0.02]), S (P < 0.01) ↓BMI ♀ (β = -0.04 [SE = 0.01]), S (P < 0.01)
Nooyens et al. (24), 2005	Holland n = 288 (♂) 54.9 (2.5) years, OW	26.4 <sup>‡</sup>	po	Measured	5 years	↓Fruit (-0.02 times wk <sup>-1</sup> ): ↑BW (1 kg year <sup>-1</sup> ), S (P < 0.01) ↓Fruit (-0.03 times wk <sup>-1</sup> ): ↑WC (1 cm year <sup>-1</sup> ), S (P < 0.01)
Drapeau et al. (19), 2004	Canada n = 248 (136 ♀, 112 ♂) 39.6 (14.2) years, OW	25.3 (4.7)	po	Measured	6 years	↑Fruit: WG (mean ± SEM: 1.5 ± 0.5 kg) ↓Fruit: WG (mean ± SEM: 6.5 ± 2.5 kg) Difference between groups: S (P < 0.001)
He et al. (20), 2004	USA n = 74063 (♂) 50.7 (7) years, NW	24.9 (5)	po	Self-reported	12 years	↓Risk of OB, S Q5 vs. Q1 (OR = 0.75 [CI: 0.69, 0.81]), (P <sub>trend</sub> < 0.0001)
Schulz et al. (29), 2002	Germany n = 17369 (11005 ♀, 6364 ♂) 50.1 (8.8) years, OW	26.3 (4.3)	po	0 year: measured 2.2 years: self-reported	2.2 years	↑Fruit (100 g d <sup>-1</sup> ) and risk of WG, NS: large WG (OR = 0.94 [CI: 0.83, 1.05]) small WG (OR = 1.04 [CI: 0.96, 1.13]) small loss (OR = 1.05 [CI: 0.97, 1.13]) large loss (OR = 1.03 [CI: 0.93, 1.14])
Cross-sectional studies n = 5						
Moreira and Padrao (23), 2006	Portugal n = 39640 (20977 ♀) 50.3 (18.9) years (18663 ♂) 47.7 (18.5) years	cs	cs	Self-reported	cs	♀ ↓JOB (OR = 0.77 [CI: 0.64, 0.92]), S (P = 0.004) ♂ ↓JOB (OR = 0.94 [CI: 0.79, 1.12]), NS (P = 0.44)

Table 1 Continued

Author, year	Country population n* (sex) age, weight status	BMI (kg m <sup>-2</sup> )	Intervention	Anthropometrics	Follow-up	Results
Davis <i>et al.</i> (18), 2006	USA n = 104 (68 ♀, 36 ♂) 39.8 (12.3) years	cs	cs	Measured	cs	Fruit intake: OW/OB: 0.9 (0.9) serv d <sup>-1</sup> NW: 1.6 (1.0) serv d <sup>-1</sup> Difference: S (P < 0.01)
Lin and Morrison (21), 2002	USA n = 9117 (408 ♀, 4709 ♂) ≥19 years	cs	cs	Self-reported	cs	Fruit intake: ♀ OB: 1.3 serv d <sup>-1</sup> NW: 1.5 serv d <sup>-1</sup> difference: S (P < 0.05) ♂ OB: 1.2 serv d <sup>-1</sup> NW: 1.6 serv d <sup>-1</sup> difference: S (P < 0.01)
Trudeau <i>et al.</i> (25), 1998	USA n = 1450 (863 ♀, 587 ♂) 44 years	cs	cs	Self-reported	cs	Fruit intake: ♀ BMI < 23.1: 1.4 serv d <sup>-1</sup> BMI ≥ 32.2: 0.97 serv d <sup>-1</sup> difference: S (P < 0.001) ♂ BMI < 23.1: 1.09 serv d <sup>-1</sup> BMI ≥ 32.2: 1.09 serv d <sup>-1</sup> difference: NS
Serdula <i>et al.</i> (30), 1996	USA n = 21892 (12599 ♀, 9293 ♂) ≥18 years	cs	cs	Self-reported	cs	Fruit intake (mean [±CI]): ♀ NW: 0.79 [±0.14] serv d <sup>-1</sup> OB: 0.76 [±0.17] serv d <sup>-1</sup> difference: NS ♂ NW: 1.02 [±0.16] serv d <sup>-1</sup> OB: 1.09 [±0.22] serv d <sup>-1</sup> difference: NS

\*Number of subjects analysed.

†Mean (standard deviation) (all such values).

‡Mean (all such values).

↓, decrease; ↑, increase; β coef, β coefficient; BMI, body mass index; BW, body weight; CI, confidence interval (95%); cs, cross-sectional study; d, day; gr, group; NS, non-significant; NW, normal weight; OB, obese; OR, odds ratio; OW, overweight; po, prospective observational study; reg coef, regression coefficient; S, significant; SE, standard error; SEM, standard error of the mean; serv, serving; WC, waist circumference; WG, weight gain; wk, week.

were hypercholesterolaemic (16) or had metabolic syndrome (17). Because of substantial differences between the included studies concerning study types or factors such as measuring or reporting changes in intake, they were estimated as ineligible for meta-analysis.

### Association between fruit intake and body weight

In 11 of the 16 studies, increased fruit intake facilitated a significant reduction in body weight, decreased the risk of overweight or obesity, was associated with less increase in body weight or was inversely associated with body weight (16–26). In two of the 11 studies, the inverse association applied only to women (23,25). The remaining five studies found no significant association between fruit intake and body weight (27–31). None of the included studies found a positive association between fruit intake and body weight.

### Intervention studies

All the intervention studies were randomized, controlled, clinical trials comparing the efficacy of a diet high in fruit, with a control diet on body weight among overweight or obese individuals. Subjects were asked to either follow their usual diet (17), an energy-restricted diet (16), or they were delivered a hypocaloric diet (27). The intervention groups were either supplied with a specific amount of fruit, whereas the control groups were not (16,17), or the intervention group received a hypocaloric high-fruit diet, in contrast to the control group, who received a hypocaloric low-fruit diet (27).

Two out of three studies found that increased fruit intake (an addition of approximately one and a half to three pieces of fruit per day) significantly decreased mean body weight with about 0.84–1.6 kg (16,17). However, one of the studies failed to report the total energy content or energy density of the diets (17). One intervention study did not find a significant difference in body-weight reduction between a high-fruit diet and a low-fruit diet group, although only the high-fruit diet group significantly reduced their waist circumferences (27). The energy density or the amount of fruit in the diets was missing in the latter study. Nor was it reported whether the vegetable content in the diets was held constant.

### Prospective observational studies

More than half (five out of eight) of the prospective observational studies found that fruit intake decreased the relative risk of developing overweight or obesity (19,20,22,24,26). In all but one of these studies, the cohort mainly consisted of overweight or obese subjects at baseline. In the remaining study, the mean BMI of the subjects was bordering the overweight category

(BMI = 24.9) (20). The inverse association between fruit intake and body weight was expressed in three different ways in the included studies: (i) in three of the studies, although the whole cohort had a main increase in body weight during follow-up, those with increased fruit intake gained significantly less body weight compared with those with decreased or unchanged fruit intake (19,20,26); (ii) in one of the studies, increased fruit intake was significantly associated with decreased body weight (22); and (iii) in the last study, decreased fruit intake was significantly associated with increased body weight (24). In two of the three studies not showing an association between fruit intake and body weight, body weight was self-reported (28,29).

### Cross-sectional studies

Four of the five cross-sectional studies found an inverse association between fruit intake and body weight (18,21,23,25), although in two of the studies, the inverse association was observed only among women (23,25). Reported fruit intake was indicated either as mean servings per day (18,21,25,30) or as odds ratio in relation to obesity (23).

### Anthropometrics, intervention/follow-up period and sample size

In all of the intervention studies, anthropometric measurements were carried out by study staff. This was also the case in the majority of the prospective observational studies, except for three studies (20,28,29). In contrast, all but one (18) of the cross-sectional studies used participants' self-reported anthropometric measurements. The follow-up period stretched from 8 to 12 weeks in the intervention studies and from 2 to 8 years in the prospective observational studies.

### Discussion

Results from the three different types of included studies that have investigated the association between fruit intake and body weight in an adult population are concurrent in that the majority suggests that fruit intake is inversely associated with body weight. However, there is a paucity of adequate research available that solely examines the effect of fruit intake on body weight parameters. Large behavioural, randomized, controlled intervention studies and prospective studies focusing on the direct and independent effect of fruit intake on body weight among free-living individuals would contribute significantly to the clarification of this subject. The intervention studies included in the present paper, although indicating that fruit intake has a reducing effect on body weight, contain a considerable number of limitations. For example, it is impossible to

predict whether relatively strict interventions, such as those included here, are feasible to implement in the everyday life among free-living individuals as well as impossible to predict whether the effect will sustain in the long term. Relatively long-term behavioural intervention studies among free-living individuals examining the effect of fruit intake on body weight have been performed (32–34). However, they failed to examine the independent effect of fruit intake, as they did not only advise the subjects to increase their fruit intake, but rather encouraged them to pursue a generally healthy lifestyle, including increased vegetable intake, decreased fat and sugar intake, and increased physical activity level. Moreover, the body weight-reducing effect attained in the majority of the included intervention studies can be due to a reduction in the total energy intake rather than fruit intake *per se*. Hence, in one of the intervention studies (27), both groups, whether consuming a high-fruit or a low-fruit diet, had similar total energy intake from a hypocaloric diet and reduced similar amounts of body weight. However, important factors, such as the quantity of fruit consumed by each group, the energy density of the diets or whether vegetable intake was held constant, was not reported and may have differed between the two groups. In this context, it can be argued that a high-fruit diet may be easier to adhere to in the long term compared with a low-fruit diet because of its low energy dense characteristics that may, as aforementioned, increase satiety, thus, potentially resulting in decreased total energy intake. In agreement with this, in one of the intervention studies (16), subjects in the intervention group, who received 300 g of fruits per day and were instructed to follow an energy-restricted diet, had a significant reduction in the energy density of their diet compared with the control group. The control group received the same dietary instructions as the intervention group but, instead of the fruit supplement, this group received 60 g of oat cookies per day, although it contained the same amount of energy as the fruit supplements. Consequently, only the intervention group managed to significantly reduce their total energy intake and obtain a significant body weight reduction. The same may have occurred in the study examining the effect of grapefruit on body weight (17), where the grapefruit group had a significant body weight reduction compared with the placebo group. However, important variables, such as the total energy intake of the participants or the energy density of their diet, was not reported, impeding the possibility to ascertain whether it was grapefruit consumption *per se* or substitution of more energy-dense foods that caused the body weight decrease. In the latter study, the effect of fresh grapefruit, grapefruit juice and grapefruit capsules (containing a whole grapefruit including the peel) on body weight was tested. Compared with the placebo group, a significant reduction in body weight was only achieved in the fresh grapefruit group. In addition

to a potential substitution effect and the relatively low energy content and density of fresh grapefruit, it can be argued that this effect may have been mediated through the dietary fibre content of fresh grapefruit. However, of note is that there was no observed effect of grapefruit capsules on body weight.

Common for the included intervention studies was that the subjects were all overweight or obese, possibly with a desire to reduce body weight. Whether body-weight maintenance can be achieved by increasing the fruit intake among normal-weight subjects can therefore not be excluded. Further long-term studies are needed in order to be able to establish that compliance to a high-fruit diet is high and that the potential unchanged body weight is sustainable. Prospective, observational studies may be a more appropriate approach to investigate the role of fruit intake on body-weight maintenance because of the relatively long duration characteristic for these types of studies. Prospective, observational studies present in this review indicate that fruit intake may be associated with body-weight maintenance among normal-weight or slightly overweight adults. Some of the included prospective, observational studies show that increased body weight over time is slightly smaller among those with relatively high fruit intake compared with those with relatively low fruit intake. The degree of less body-weight increase in the long term in these studies, though small, is nevertheless important from a public health point of view. It is, however, difficult to substantiate the amount of fruit intake required to prevent body-weight increase, based on the included prospective, observational studies as most of these lack this information or only inform on the change in fruit intake rather than report the actual fruit intake. Most of the included studies, both prospective observational and cross-sectional studies, also fail to report other variables that could affect a relationship between fruit consumption and body weight. These include the physical form of the fruit, if and how the fruit is prepared and what is classified as the fruit category (fruit juice, canned or dried fruit, etc.). Furthermore, the majority of the included prospective observational and cross-sectional studies do not have the relationship between fruit intake and body weight as their main objective. Additionally, cross-sectional studies are, in general, prone to reverse causation. Based on these studies, it is difficult to confirm whether fruit consumption is causal for the observed body-weight reduction/maintenance or whether it is a marker for a generally healthy lifestyle.

Clearly, the sum of studies showing an inverse association between fruit intake and body weight exceeds the sum of those not showing an association. However, we must express caution as the under-representation of studies not finding any association may be due to publication bias.

In summary, the studies in the present paper do not adequately satisfy a conclusive aim of assessing the role of

fruit intake on body weight. However, a predominance of the included studies, regardless of study type, shows an inverse association between these two variables. Thus, promotion of increased fruit consumption in the general population may form part of the strategies to handle the increasing global challenge of overweight and obesity. This review emphasizes the need for future intervention and prospective observational studies, investigating a direct and independent effect of fruit intake on body weight among free-living individuals. It also stresses the need to include important determinants, such as energy density, energy content, fruit and vegetable consumption, physical form of fruit and preparation methods in future studies to advance the research in this field.

### Conflict of Interest Statement

No conflict of interest was declared.

### Acknowledgements

This study is a part of the ISAFRUIT project, funded by the European Commission under the Thematic Priority 5 – Food Quality and Safety of the 6th Framework Programme of RTD (Contract no. FP6-FOOD–CT-2006-016279). The views and opinions expressed in this publication are purely those of the writers and may not in any circumstances be regarded as stating an official position of the European Commission.

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## **Paper II**

**A cross-sectional study of the association between fruit intake and body weight among the general adult population in Europe**

## **A cross-sectional study of the association between fruit intake and body weight among the general adult population in Europe**

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Running title: Association between fruit intake and body weight

Key words: BMI; overweight; obesity; fruit intake

## Abstract

**Background:** the prevalence of overweight/obesity worldwide is high and increasing. Therefore, more knowledge on the association between body weight and potentially influential factors on body weight is warranted.

**Objective:** the primary aim was to investigate the association between fruit intake and BMI among adults in selected European countries. The secondary aim was to investigate the association between fruit intake and intake of selected food groups, fat energy% and energy density.

**Design:** a cross-sectional study among 9,758 (55.3% females) nationally representative adults, aged  $\geq 18$  years, from Denmark, France, Hungary, Italy and the UK. Dietary intake was assessed using 3- or 7-days dietary records. Anthropometric measures were self-reported in Denmark, Hungary and Italy, and measured in France and UK. Eligibility criteria included  $18.5 < \text{BMI} < 30 \text{ kg/m}^2$ .

Goldberg's cut-off technique was applied to diminish the number of under-reporters.

**Results:** removal of potential under-reporters resulted in 8,143 remaining participants. Participants were in the upper end of the normal weight category (BMI: (mean $\pm$ SD)  $24.1 \pm 2.8 \text{ kg/m}^2$ ) with median fruit intake of 136.5g/d (25 and 75% percentile: 50.0 and 237.0g/d). The adjusted association between BMI and per 100g increase in fruit intake was non-significant (0.02 (95% CI: -0.02, 0.06)). The adjusted association between intake of fruit and selected dietary factors were as follows: energy density: -116.73 (95% CI: -112.38, -121.16), fat E%: -3.82 (95% CI: -3.91, -3.70), soft drinks: -0.03 (95% CI: -0.04, -0.03), sweets: -0.01 (95% CI: -0.04, 0.03), snack foods: -0.23 (95% CI: -0.40, -0.04), fruit juice: 0.05 (95% CI: 0.04, 0.07), processed fruit: 0.24 (95% CI: 0.18, 0.31) and vegetables: 0.13 (95% CI: 0.11, 0.14). Except for sweets, all of the above associations were significant.

**Conclusions:** no association between BMI and fruit intake was found. However, fruit intake was directly associated with intake of relatively nutrient-dense foods, while inversely associated with intake of relatively nutrient-dilute foods, energy density and fat E%.

## **Introduction**

The role of overweight and obesity in the development of numerous chronic diseases including cardiovascular diseases, type II diabetes, hypertension and different types of cancers among adults is well recognized (1). This situation is deteriorated by the high and escalating prevalence of overweight and obesity worldwide and in Europe (1, 2), calling for immediate attention. Therefore, public health strategies addressing the problem of overweight and obesity are warranted.

Incorporating a higher proportion of low energy-dense foods such as fruit and vegetables in the diet of individuals could be one of the initiatives in such strategies (2). This is supported by the WHO board of experts, who judges the evidences that fruit and vegetable intake decreases the risk of developing obesity and that high energy-dense foods promote weight gain as convincing (1). The potential role of fruit and vegetables in body weight reduction or maintenance may be exerted through different mechanisms. In the present study, the focus is on fruit, as it seems important to distinguish between fruit and vegetables, because, despite similarities, these two food groups also possess differences in their nutrient content and composition, and culinary use.

Fruit has a relatively low energy density mainly due to its high content of water and dietary fibre. Low energy-dense foods may be associated with increased satiation and satiety, which ultimately may decrease the risk of overweight and obesity (3-7). Moreover, the sugar, fructose, in fruit may have an anti-obesity effect. This is in part because of the relatively low glycaemic index of fructose and its incomplete absorption in the gastrointestinal tract, potentially influencing the total energy intake (8, 9). Further, fruit is a rich source of flavonoids, a group of nonnutritive phytochemicals that may play a role in reducing body weight through their effect on energy expenditure and other mechanisms, including glucose uptake and fatty acid catabolism (10).

Previously, most observational and intervention studies among adults, suggesting a link between fruit intake and a preventive or decreased risk of overweight and obesity have done so by examining the combined role of fruit with vegetables or as a component in certain dietary patterns (11-17). However, it is not possible to draw a direct link between one single food group and overweight and obesity based upon studies that focus on dietary patterns or a combination of different food groups. The few observational and intervention studies, that have focused on the separate and independent association between fruit intake and body weight, yield inconsistent results, though indicating an inverse association (18-21). The samples in these studies mainly consist of overweight or obese individuals at study entrance, thus, possibly highly motivated to reduce body weight.

Among the observational studies, only a few cross-sectional studies have investigated the separate association between fruit intake and body weight. These are first and foremost carried out in the United States while only a small number is carried out in single European countries (22-27). Furthermore, important determinants, such as the physical form of fruit and specification of the ‘fruit’ category, are not always reported in the existing studies. Therefore, cross-sectional studies, investigating the association between fruit intake and body weight in a European context, and which differentiate between fresh fruit and fruit products, such as fruit juice and processed fruit, are needed. The present cross-sectional study uses nationally representative dietary survey data from selected European countries, representing the North, East, South and West of Europe. The primary objective of this study is to examine the association between body weight, expressed as BMI, and fruit intake among a general and nationally representative adult population in selected European countries. The secondary objective is to examine the association between fruit intake and intake of selected dietary components.

## **Methods**

In the present cross-sectional study, nationally representative data from Denmark, Hungary, Italy, France and the UK were included to represent countries from different parts of Europe. These data were retrieved from the European Food Safety Authority (EFSA), who has collected data from 22 European countries in a comprehensive databank for risk assessment (28). The methodology used for recruitment and enrolment of participants and data collection in each country is described in full elsewhere (29).

### *Study sample and data*

For each country, Table 1 summarises the number of participants; number of days when dietary intake was recorded; and means of anthropometric measure assessments. Demographic, anthropometric, and dietary data from 9,758 adults (55.3% female), aged  $\geq 18$  years and  $18.5 \text{ kg/m}^2 < \text{BMI} < 30 \text{ kg/m}^2$ , were selected for the present study. A criterion for inclusion was that dietary intake assessment methods used in the different countries were comparable with one another. Hence, the countries selected for this study assessed dietary intake by using three- or seven-day food records (Table 1).

### *Dietary variables*

The dietary variables included in this study consisted of total energy, dietary fat and the food groups: fruit (fresh fruit), processed fruit, fruit juice, vegetables (including vegetable products, processed vegetables, and vegetable based meals), sweets, snack foods, and soft drinks (including regular and diet soft drinks). Energy density was estimated as total energy intake divided by total amount of solid foods consumed.

### *Statistical analysis*

Goldberg's cut-off technique ( $EI/BMR < 1.1$ ) was applied in order to exclude or minimize the number of potential under-reporters (30).

Multiple linear regression models was used to assess the relationship between: 1) BMI and daily intake of fruit, fruit and vegetables, processed fruit, and fruit juice; and between 2) fruit intake and daily intake of processed fruit, fruit juice, vegetables, sweets, snack foods, soft drinks, percentage energy intake from dietary fat, and energy density. Data on fruit intake were skewed and were therefore logarithmically transformed to achieve normal distribution. Both analyses were adjusted for age, gender and country. In addition to these cofactors, the model containing BMI as the response variable was also adjusted for energy intake. In all statistical tests a significance level of 5 % was applied. The Statistical Analysis Systems statistical software package version 9.1 (SAS Institute, Cary, NC, USA) was used for all statistical analyses.

## **Results**

Application of Goldberg's cut-off technique reduced the study population from 9,758 to 8,143. The basic characteristics of the participants, including gender, age, BMI, and mean daily fruit intake, are illustrated in Table 2. The lowest percentage of women is found in the UK (46.5%) while the highest percentage is found in Hungary (57.0%). Moreover, participants from the UK have the lowest mean age (42.5 years) against those from Italy with the highest mean age (48.3 years). The mean BMI of all the participants ( $24.1 \text{ kg/m}^2$ ) is in the upper end of the normal weight category with participants from the UK having the highest mean BMI of  $24.9 \text{ kg/m}^2$ . In addition, participants from the UK have the lowest consumption of fruit (median: 69.1 g/d). Pairwise comparison analyses, adjusted for age and gender show that, compared to the other countries, participants from the UK have the highest mean BMI and lowest mean fruit intake while those from Italy have the

lowest mean BMI (though not significantly lower than those from France) and highest mean fruit intake (data not shown).

The adjusted relationships between BMI and consumption of fruit, fruit and vegetables, processed fruit, and fruit juice are statistically non-significant (Table 3). Additional adjustment for energy intake did not modify the results and are therefore not presented. Furthermore, separate analyses for females and males did not alter the results substantially (data not shown). However, an inverse association was seen between consumption of fruit juice and BMI among women (Regression coefficient: -0.001; 95% CI: -0.002, -0.000). Participants with self-reported and measured height and weight were also analysed separately but no statistically significant associations were found between BMI and the dietary factors outlined in Table 3 (data not shown).

Adjusted analysis of the association between fruit intake and intake of other selected dietary items show statistically significant and direct associations between fruit intake and intake of fruit juice, processed fruit, and vegetables, while statistically significant and inverse associations are found between fruit intake and intake of soft drinks and snack foods (Table 4). Furthermore, fruit intake has a statistically significant inverse association with the percentage of energy intake from dietary fat and energy density. Gender-specific analyses do not attenuate the outcome considerably (data not shown). However, the analyses show that the inverse association between consumption of fruit and snack foods is only statistically significant among men (Regression coefficient: -0.26; 95% CI: -0.47, -0.02).

## **Discussion**

The present cross-sectional study did not find a significant association between fruit intake and BMI among the included study sample representing the general adult population in selected countries in Europe. Nor did it find any association between consumption of fruit and vegetables, processed fruit or fruit juice and BMI in this population.

These findings are not in agreement with the majority of the previous cross-sectional studies examining the association between fruit intake and body weight (31-35), although findings similar to the present study results have also been shown (36). Several issues may explain this discrepancy. In the present study, dietary intake was assessed by using three- or seven-day food records, while the majority of the previous cross-sectional studies have applied other assessment methods, including food frequency- or food frequency-type questionnaires. This inconsistency in the dietary intake assessment methodologies may yield different information, potentially making comparison

of the results subject to error. Other issues that require attention when comparing results from different studies include between-study inconsistency in the dietary items classified as the fruit category (i.e. inclusion of fresh fruit only vs. additional inclusion of fruit products such as fruit juice, processed fruit etc.) and the physical profile of the study population, which in the present study consisted of normal- and overweight individuals, in order to represent the general adult population, while previous studies included underweight and obese individuals as well.

Also prospective observational studies have examined the independent and separate association between fruit intake alone and the risk of overweight and obesity (37-47). These are relatively few and the findings are ambiguous. However, the majority has suggested that fruit intake may aid to facilitate long-term body weight maintenance or prevent excess increase in body weight (38, 48-54). One of the potential reasons for this disagreement with findings from the present cross-sectional study includes the heterogeneous designs of the studies. Given the longitudinal design of prospective observational studies, it is possible to follow the cohort over time and investigate the potential association between fruit intake and changes in body weight. Thus, in prospective observational studies, it seems that fruit intake reduces the risk of long-term increases in bodyweight, which is common with increasing age, rather than being associated with relatively low body weight *per se*. Moreover, the cohorts investigated in most of the studies were overweight or obese at baseline and may therefore have been liable to reduce body weight. Aforementioned inconsistent dietary assessment methods and dietary items classified as the fruit category are also potential causes for the discrepancy in this case.

Only a limited number of randomized, controlled trials (RCTs) have investigated the cause-effect relationship between fruit intake alone and body weight and among these none were conducted in real-life settings (55-57). Therefore, the basis for inference making is not sufficiently strong. Some (55, 58), but not all (59) RCTs have found that interventions with increased fruit intake led to decreased body weight. In most RCTs, participants were overweight or obese when entering the study, thus, likely highly motivated to reduce body weight. Moreover, in some of the studies the participants were supplied with or requested to follow an energy-restricted diet (60, 61), consequently impairing the possibility to determine the independent and separate effect of fruit intake on body weight.

In contrast to the findings from the present study, most previous cross-sectional, prospective observational and intervention studies suggest that there is an inverse association between fruit and

vegetable intake in combination and body weight (62-64). However, whether this association was due to fruit and vegetable consumption, independently, or to implementation of a generally healthy lifestyle by the participants has not clearly been accounted for in current studies. In the present study we desegregated fruit from vegetables and even fruit consumed as fresh fruit or as processed fruit or fruit juice. Even though the desegregation of fruit from vegetables did not generate different results for fruit alone and fruit and vegetables together, it still seems important to separate between these two food groups as they have distinct biochemical compositions and culinary uses.

Consumption of fruit juice and processed fruit was not positively associated with BMI in the present study population. Although, interestingly, a moderate inverse relationship between fruit juice intake and BMI was found among women. In prospective observational studies, increased consumption of fruit juice has been associated with increased body weight over time (65, 66) while a cross-sectional study found a slight but statistically significant inverse association between fruit juice intake and BMI (67). However, studies on the role of fruit juice and body weight among adults are not abundant and yield inconclusive results. Furthermore, the decision of whether or not to categorise sugar-sweetened fruit beverages as fruit juice has not been consistent between studies. This is an important factor, because addition of sugar can alter the energy content of the beverage and hence be of significance in relation to body weight. In the present study, it was not possible to differentiate between fruit juices with and without added sugar, as this information was not available. No studies investigating the association between processed fruit and body weight have been identified. Processed fruit has a relatively high energy density and could thus rationally, contradictory of the present results, be positively associated with BMI. However, given the cross-sectional design of the present study and the relatively low average consumption of fruit juice and processed fruit in the present population, a potential association between these two dietary groups and body weight cannot be precluded. The current divergent findings emphasise the importance of a clear and consistent separation of the food categories and allocation of the individual dietary items into each food category.

Additional results in the present study suggested that fruit intake was directly associated with consumption of fruit juice, processed fruit and vegetables, while inversely associated with consumption of soft drinks, snack foods, percentage energy intake from dietary fat and energy density. These findings are interesting, as they suggest that fruit may be an indicator of a relatively healthy and relatively low energy-dense dietary pattern. This is in accordance with earlier research findings, which have shown that dietary patterns considered as healthy include a relatively high

amount of fruit while low in energy density (68-71). Further, these dietary patterns were adopted by individuals who attempted to modify their general lifestyle in a healthy direction in order to reduce or maintain body weight. Thus, in the present study fruit may be a component in a generally health promoting dietary pattern potentially leading to a healthy body weight rather than independently being associated with a relatively low body weight status.

Strengths of the present study include the study population being large and representative of the general adult population in selected countries in Europe. Moreover, compared to most of the previous cross-sectional studies that have used food frequency questionnaires, the use of dietary records in the present study for assessment of dietary intake provides a higher level of detail of foods consumed. In addition, differentiation between fruit and vegetables and further differentiation between the various physical forms of fruit provides the opportunity for estimating the separate association between BMI and fresh fruit.

The cross-sectional design of the present study poses the study to some limitations including the risk of reverse causation, as dietary and anthropometric data were collected at the same time point. Moreover, the observational nature of the study could not provide evidence for or against a causal relationship between fruit intake and body weight, because, despite adjustments for identified relevant cofactors, the possibility of residual confounding could not be precluded. Missing data on physical activity level and socio-economic status of the participants and hence the lack of adjustments for these factors further increases the risk of confounding bias. In addition, self-reported dietary data in the present study might have been disposed to social desirability biases, indicated by the small median intake values for soft drinks, sweets and snack foods. One common issue is that relatively heavy participants may be more liable to under- or over-report intake of foods regarded as unhealthy or healthy, respectively (72). Such misreporting would diminish a potential inverse association between fruit intake and BMI. Similarly, BMI might have been underestimated among the participants with self-reported anthropometric measures (73), although separate analysis of the association between BMI and fruit intake among participants measured by staff and self-reported measurements showed no significant associations in either group.

In conclusion, the present cross-sectional study did not find an association between fruit intake and body weight among the included general adult trans-European study population. Fruit intake was, however, directly associated with dietary items regarded as 'healthy' and inversely associated with dietary items/factors regarded as 'unhealthy'.

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**Table 1** Details about number of participants, food recording days, and procedures for anthropometric measurements for each country

	N (9,758)	Number of food recording days	Anthropometric measures
Denmark	2,753	7	Self-reported
France	2,197	7	Measured
Hungary	1,057	3	Self-reported
Italy	2,514	3	Self-reported
UK	1,237	7	Measured

**Table 2** Basic characteristics, mean BMI, and median, 25% and 75% percentile daily fruit intake of all the participants together and each country separately

	N	Gender (% female)	Age (year)		BMI (kg/m <sup>2</sup> )		Fruit (g/d)		
			Mean	SD	Mean	SD	Median	25%	75%
Denmark	2,400	48.7	43.5	14.9	24.0	2.7	121.4	42.9	219.6
France	1,640	49.2	46.3	15.5	23.9	2.8	108.6	38.6	199.4
Hungary	994	57.0	47.8	17.5	24.7	2.9	137.0	50.0	250.0
Italy	2,185	50.5	48.3	17.3	24.0	2.7	200.0	116.7	297.7
UK	924	46.5	42.5	12.2	24.9	2.7	69.1	14.3	160.0
All	8,143	50.1	45.8	15.9	24.1	2.8	136.5	50.0	237.0

SD: standard deviation

**Table 3** The regression coefficient, 95% CI and *p*-value for the relationship between BMI and consumption of fruit, fruit and vegetables, and fruit related dietary items\* (N=8,143)

Dietary factors	Reg coeff	95% CI	<i>p</i> -value
Fruit (100g)	0.02	-0.02, 0.06	NS
Fruit+vegetables (100g)	0.03	-0.01, 0.05	NS
Processed fruit (100g)	-0.19	-0.42, 0.05	NS
Fruit juice (100g)	-0.05	-0.11, 0.01	NS

\*Adjusted for age, gender and country; Reg coeff: regression coefficient; CI: confidence interval

**Table 4** Median, 25% and 75% percentile daily intake of selected dietary factors and their relationship, estimated as regression coefficient, 95% CI and *p*-value, with fruit intake\* (N=8,143)

Dietary factors	Median	25%	75%	Reg coeff	95% CI	<i>p</i> -value
Fruit juice (g)	7.3	0.0	91.4	0.05	0.04, 0.07	< 0.0001
Processed fruit (g)	4.3	0.0	17.1	0.24	0.18, 0.31	< 0.0001
Vegetables (g)	174.4	119.0	241.0	0.13	0.11, 0.14	< 0.0001
Soft drinks (g)	0.0	0.0	100.0	-0.03	-0.04, -0.03	< 0.0001
Sweets (g)	11.9	0.0	33.3	-0.01	-0.04, 0.03	NS
Snack foods (g)	0.0	0.0	0.0	-0.23	-0.40, -0.04	0.0173
Energy from fat (%)	35.1	31.3	38.7	-3.82	-3.91, -3.70	< 0.0001
Energy density (kJ/g)	8.8	7.6	10.2	-116.73	-112.38, -121.16	< 0.0001

\* Adjusted for age, gender and country; Reg coeff: regression coefficient; CI: confidence interval

## Paper III

**A workplace feasibility study of the effect of a minimal fruit intervention on fruit intake**

# A workplace feasibility study of the effect of a minimal fruit intervention on fruit intake

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Submitted 21 September 2009; Accepted 5 August 2010; First published online 8 December 2010

## Abstract

*Objective:* The main purpose of the study was to investigate the feasibility of using workplaces to increase the fruit consumption of participants by increasing fruit availability and accessibility by a minimal fruit programme. Furthermore, it was investigated whether a potential increase in fruit intake would affect vegetable, total energy and nutrient intake.

*Design:* A 5-month, controlled, workplace study where workplaces were divided into an intervention group (IG) and a control group (CG). At least one piece of free fruit was available per person per day in the IG. Total fruit and dietary intake was assessed, using two 24 h dietary recalls at baseline and at endpoint.

*Setting:* Eight Danish workplaces were enrolled in the study. Five workplaces were in the IG and three were in the CG.

*Subjects:* One hundred and twenty-four (IG, *n* 68; CG, *n* 56) healthy, mainly normal-weight participants were recruited.

*Results:* Mean daily fruit intake increased significantly from baseline to endpoint only in the IG by 112 (SE 35) g. In the IG, mean daily intake of added sugar decreased significantly by 10.7 (SE 4.4) g, whereas mean daily intake of dietary fibre increased significantly by 3.0 (SE 1.1) g. Vegetable, total energy and macronutrient intake remained unchanged through the intervention period for both groups.

*Conclusions:* The present study showed that it is feasible to increase the average fruit intake at workplaces by simply increasing fruit availability and accessibility. Increased fruit intake possibly substituted intake of foods containing added sugar. In this study population the increased fruit intake did not affect total energy intake.

**Keywords**  
Fruit intake  
Dietary intervention  
Dietary change

According to WHO, poor nutrition accounts for 4.6% of the total disability-adjusted life-years (DALY) lost in the EU<sup>(1)</sup>, where one DALY represents the loss of one year of healthy life. An additional 3.7% of DALY are lost due to overweight and obesity. International experts conclude that the global obesity epidemic poses one of the largest threats to public health and that low fruit and vegetable consumption is among the top ten risk factors for mortality worldwide<sup>(2)</sup>. Moreover, WHO states that there is convincing evidence that consumption of a diet high in fruit and vegetables reduces the risk of obesity<sup>(2)</sup>. This is supported by a recent review suggesting that high fruit intake may be associated with low body weight<sup>(3)</sup>.

Several national food-based dietary guidelines recommend an increased consumption of fruit and vegetables<sup>(4,5)</sup>. In addition, a Nordic Plan of Action on better health and quality of life through diet and physical activity, adopted by the Nordic Council of Ministers, emphasizes the importance

of reversing the alarming tendency of an increasing number of overweight and obese individuals in the Nordic region by different schemes such as enhancing the consumption of fruit and vegetables and reducing the consumption of added sugar<sup>(6)</sup>.

In Denmark, only 16% of the adult population consumes the amount of fruit and vegetables that meets the official Danish recommendations of 600 g/d<sup>(7,8)</sup>. At the same time, it is estimated that 55% of the adult Danish population is overweight (BMI  $\geq$  25 kg/m<sup>2</sup>) and 15% is obese (BMI  $\geq$  30 kg/m<sup>2</sup>)<sup>(8)</sup>. Thus, effective community-based strategies that aim to promote healthy eating habits and increase the average fruit and vegetable consumption of the general population are much needed. Adopting workplaces for this purpose seems a suitable approach and is in accordance with recommendations from different international and regional bodies such as WHO, the Nordic Plan of Action, and Guidelines for the Prevention

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of Obesity at the Workplace (GPOW) Project<sup>(6,9,10)</sup>. The rationale behind this is that workplaces constitute appropriate settings for health promotion programmes as a substantial amount of the adult population attends a workplace each day and a relatively large number of individuals can be addressed simultaneously. Furthermore, one must assume that employers are interested in investing in their human resources and offering them healthy alternatives.

Several workplace-based programmes attempting to implement healthy dietary behaviour among employees have been conducted<sup>(11–17)</sup>. The majority of these studies aimed to change the overall dietary intake patterns of the participants through relatively extensive interventions including education and counselling. In the present workplace study, we attempted, through minimal intervention, to increase fruit consumption of the participants by addressing only two important determinants for increased fruit intake: availability and accessibility of fruit<sup>(18)</sup>. This decision was based upon the assumption that fruit can be introduced at a workplace relatively easily and without any radical demands such as extensive involvement of the canteen or other staff. Further, fruit can be consumed as a snack without any form of preparation and it does not require much modification of the physical environment of the workplace.

In addition to elevating the employees' fruit intake, implementation of free available fruit at the workplace may contribute to an alteration in their snacking habits. Fruit can be consumed as a between-meal snack and as such may substitute snacks that are relatively high in fat and added sugar, thereby decreasing total energy intake. Furthermore, consumption of fruit may affect satiety due to its low energy density and high water and dietary fibre content<sup>(19,20)</sup>. Hence, intake of the subsequent meal and therefore the total energy intake may potentially be reduced.

The main purpose of the present study was to investigate the feasibility of using workplaces as settings to increase fruit consumption of the participants through minimal intervention by increasing fruit availability and accessibility, using a minimal fruit programme. A 'minimal fruit programme' is without any additional instructions, counselling or other health promotion activities and holds the advantages that it is relatively low in cost and easy to implement. Furthermore, it was investigated whether a possible increase in fruit intake would affect vegetable and nutrient intake and whether such an effect would influence the total energy intake.

## Materials and methods

### *Workplaces and participants*

Recruitment of the workplaces was carried out in cooperation with the Danish Cancer Society, who contacted the companies that supply fruit and asked them to place a briefing letter on their website, encouraging workplaces to enrol in the present study. Workplaces that were planning

to offer free fruit to their employees and therefore contacted the company-fruit dealers could then, if interested, sign up for the study. The briefing letters were also distributed to 1000 workplaces, randomly selected from a company database provided by an information service company, and printed in a magazine published by a company sports union, which covered more than 150 000 members. Furthermore, staff at the Danish Cancer Society were consulted about workplaces that were considering to introduce free fruit.

Eight workplaces in the Copenhagen area signed up for the study. The workplaces were allocated as intervention workplaces if they were planning to offer free fruit to their employees. Hence, five workplaces were enrolled as intervention workplaces. The remaining three workplaces, which had never had free fruit or were not considering having free fruit at the workplace at least for the following 6 months, were enrolled as control workplaces. The workplaces consisted mainly of white-collar workers with the exception of two, one in the intervention group and one in the control group, consisting mainly of blue-collar workers. Recruitment at the workplaces of individuals who were interested in participating in the study occurred through a contact person who was nominated at each workplace. A total of 146 participants, eighty-two in the intervention and sixty-four in the control group, were included at baseline. Pregnant and lactating women, and individuals who did not expect to be at the particular workplace at the study endpoint, were excluded from the study. The study protocol was accepted by the Ethics Committee of Copenhagen and Frederiksberg municipality (J. No. KA-20060047).

### *Intervention*

Workplaces entered the study at distinct points in time, starting from June to September. Assessments were made both at baseline and at endpoint approximately 5 months later. The intervention was a fruit programme, consisting of a fruit basket that was set out in a room to which participants had free and easy access, such as the reception or the staff kitchen. At least one piece of fruit was available per participant per day. Fruits available were mainly apples, pears, oranges and bananas. The fruit programme stood alone in that the participants did not receive any further counselling, etc.

### *Dietary assessment*

Dietary intake was assessed using a 24 h recall questionnaire, which was a modified form of the dietary record questionnaire from the Danish National Dietary Survey 2000–2002<sup>(21)</sup>. The 24 h recall has been validated with an objective biomarker of fruit intake<sup>(22)</sup>. The questionnaire was completed on two non-consecutive weekdays, covering the dietary intake of the previous weekday, carried out by trained interviewers in closed rooms, at baseline and endpoint. The software program General Intake Estimated Systems (GIES) version 0.995a

(Danish Food Institute, Technical University of Denmark, Søborg, Denmark; released 26 June 2005) was used to calculate nutrient intake. Items included in the analysis were fruit, vegetables, total energy, fat, protein and total carbohydrates, as well as added sugar and dietary fibre separately. Added sugar was calculated as the sum of industrially manufactured refined sugars including sucrose, glucose, fructose and starch hydrolysates. The dietary fibre calculations were based on analytical values obtained by the AOAC method<sup>(21)</sup>.

### Background information

Background variables such as sex, age, education and occupation were assessed using a background questionnaire based on the validated questionnaire from the Danish National Dietary Survey 2000–2002<sup>(21)</sup>. Body weight and height were measured without shoes in light indoor clothing using a Soehnle Verona Quattrotronic digital scale (model 63686; Soehnle, Backnang, Germany) to the nearest 0.1 kg and a Soehnle 5001 Ultrasonic Height Measure to the nearest cm, respectively.

### Employee satisfaction

At endpoint, participants from the intervention group were asked about their satisfaction level with the fruit programme. There were four levels of response option: (i) very satisfied; (ii) reasonably satisfied; (iii) less satisfied; or (iv) not satisfied.

### Statistical analysis

Power analyses showed that with a mean expected difference of 100 (SD 220) g/d in fruit intake between intervention and control group, with a power of 80% and a significance level of 5%, at least seventy-five participants were necessary in each group. Paired *t* tests were performed in the intervention and control group separately

to evaluate changes in intake from baseline to endpoint. Two-sample *t* tests were performed to evaluate differences in changes from baseline to endpoint between the intervention and control group. The analyses were made using the Statistical Analysis Systems statistical software package version 9.1 (SAS Institute, Cary, NC, USA). Homogeneity of variance and normal distribution were confirmed by plots, histograms and Shapiro–Wilk's tests.

## Results

At endpoint, the total number of participants was reduced from 146 to 124, sixty-eight in the intervention and fifty-six in the control group, due to unexpected end of employment or pregnancy.

### Baseline characteristics

Baseline characteristics, including sex, age, educational level, occupation, smoking status and BMI, did not differ significantly between the intervention and control groups (Table 1). However, although non-significant, there was a larger proportion of women in the intervention group than in the control group. Additionally, participants in the intervention group tended to have a higher education than those in the control group. Both groups consisted predominantly of white-collar workers.

### Dietary intake

Table 2 shows mean daily intake values with their standard errors for the intervention and control groups at baseline and endpoint for fruit (exclusive of juice), vegetables (exclusive of potatoes), energy and macronutrients (including added sugar and dietary fibre), which were assessed by using the two 24 h recall questionnaires. At baseline, no statistically significant differences in consumption variables were found between the intervention

**Table 1** Baseline characteristics of intervention and control groups: employees from eight Danish workplaces enrolled in a workplace feasibility study of the effect of a minimal fruit intervention on fruit intake

	Intervention group (n 68)		Control group (n 56)	
	Mean	SD	Mean	SD
Age (years)	46.5	9.9	44.9	8.3
BMI (kg/m <sup>2</sup> )	26.2	5.2	25.2	4.0
	%		%	
Sex female	74		57	
Education				
Basic school	6		9	
Vocational education	22		36	
Short (<3 years)	13		16	
Medium length (3–4 years)	32		27	
Long (>4 years)	27		13	
Occupation				
Skilled	2		4	
Unskilled	9		16	
Office worker	90		80	
Smoker	18		14	

**Table 2** Daily intake values in the intervention and control groups before and after the intervention, a Danish workplace feasibility study of the effect of a minimal fruit intervention on fruit intake

	Intervention group (n 68)						Control group (n 56)					
	t = 0		t = 5		t = 5 - t = 0		t = 0		t = 5		t = 5 - t = 0	
	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Mean	SE
Fruit (g)	260	25	372 <sup>a</sup>	31	112	35	234	22	244	26	10 <sup>b</sup>	24
Vegetables (g)	192	15	209	20	17	15	210	15	206	17	-4	15
Energy (MJ)	8.9	0.4	9.0	0.4	0.1	0.4	9.0	0.3	9.2	0.5	0.2	0.4
Protein (g)	79.3	3.6	84.2	3.8	4.9	3.8	78.3	3.1	79.0	3.4	0.7	3.6
Carbohydrate (g)	249.2	10.7	251.7	10.7	2.4	11.3	267.9	9.7	273.0	13.2	5.1	11.4
Added sugar (g)	43.9	4.7	33.2 <sup>a</sup>	3.6	-10.7	4.4	50.4	4.1	45.3	5.3	-5.1	4.4
Dietary fibre (g)	20.1	1.0	23.2 <sup>a</sup>	1.2	3.0	1.1	22.6	1.1	23.3	1.3	0.7	1.0
Fat (g)	76.0	3.5	77.1	4.2	1.1	3.8	76.5	3.6	80.2	5.6	3.7	5.3

t = 0, intake at baseline; t = 5, intake at endpoint; t = 5 - t = 0, change from baseline to endpoint.

<sup>a</sup>Significant change from t = 0 in the intervention group (fruit, P = 0.002; added sugar, P = 0.019; dietary fibre, P = 0.007).

<sup>b</sup>t = 5 - t = 0 in the control group significantly different from t = 5 - t = 0 in the intervention group (P = 0.021).

and control groups. After the intervention, mean daily fruit and dietary fibre consumption increased significantly by 112 (SE 35) g (P = 0.002) and 3.0 (SE 1.1) g (P = 0.007), respectively, whereas there was a significant decrease of 10.7 (SE 4.4) g (P = 0.019) in the mean daily consumption of added sugar in the intervention group. Mean daily intakes of vegetables, total energy and macronutrients remained unchanged in the intervention group. In the control group, no changes in any of the intake variables were observed from baseline to endpoint. Only the change in fruit intake was significantly different between the intervention group and the control group (P = 0.021).

### Employee satisfaction

The satisfaction level in the intervention group was as follows: 50%, 41% and 9% of the participants chose the first (very satisfied), second (reasonably satisfied) and third (less satisfied) option, respectively. The fourth option (not satisfied) was not selected by any of the participants. The number of individuals who selected options (i) and (ii) was significantly higher than those who selected option (iii) (P < 0.001).

### Discussion

The present feasibility study has shown that the 'minimal intervention' method used at workplace settings is a relatively easy and low-cost way to increase the daily intake of fruit significantly. Simple and easy methods that can increase the consumption of fruit in the general population are greatly warranted since this could contribute to a better nutritional status and reduction in overweight and obesity, and thus an overall reduction in DALY lost.

A number of other workplace intervention studies, aiming to implement healthy dietary behaviour among the participants, have been performed<sup>(11-17)</sup>, including the relatively extensive American 'Treatwell 5-a-Day worksite study'<sup>(16)</sup>,

the 'Seattle 5-a-Day Worksite Project'<sup>(11)</sup> and a less extensive Danish workplace study<sup>(15)</sup>. These studies achieved successful results in increasing the average fruit intake of the participants through a range of determinants, such as education and counselling of the participants and in some cases also families of the participants or other staff at the workplace. However, the present study differs from these studies at various levels, including the adoption of a relatively simple approach. The novel idea behind the present study was to investigate if application of a relatively minimal intervention in the form of increased availability and accessibility of fruit at workplaces can be an effective strategy to enhance the average fruit intake of the participants. Our results indicate that this was possible. It cannot be excluded that the dietary pattern of the participants may also have been affected in that the participants' intake of added sugar was decreased, suggesting a potential substitution of a part of the sugar-sweetened food items in their diet with fruit.

In the study, no effect of increased fruit intake on the total energy intake was observed, which supports the suggestion that fruit was not added to the usual diet but may have substituted other food items in the diet. Other intervention studies have found an effect of increased fruit intake on total energy intake<sup>(23-27)</sup>. These intervention studies are either behavioural intervention studies, addressing several dietary and lifestyle factors among free-living individuals<sup>(24-26)</sup>, or clinical trials, implementing strict dietary regulations<sup>(23,27)</sup>. Common to all these studies is that participants were either overweight or obese and may thus have had a high motivation for weight reduction. It can be argued whether such intensive interventions are sustainable and possible to implement in everyday life. The present study explored if a minimal intervention was sufficient to generate a potential reduction in total energy intake among the participants. However, our participants were mainly of normal weight and may therefore not have had a strong incentive to reduce their total energy intake. Further, the participants had a relatively high baseline fruit intake and possibly

therefore increased their daily fruit intake by only one piece of fruit during the intervention. While a decrease in the consumption of added sugar was observed, the reduction was not adequate to affect the total energy intake of the participants. Individuals with a lower fruit and higher total energy intake than the participants in the present study might have increased their fruit intake more extensively and substituted a larger proportion of their usual diet with fruit, which potentially could have been reflected in their total energy intake.

Although the present minimal intervention has shown to be an effective initiative to increase participants' fruit intake at the enrolled workplaces, some limitations should be considered. Workplaces were all from the Copenhagen area and the majority of the participants consisted of white-collar workers. Hence, extrapolation of the results to other areas and to individuals with a different occupational profile should be done with caution. Because the workplaces purchased the fruit themselves, the allocation of the workplaces and the participants to the intervention or the control group was self-selected and not randomized. This reduces the generalizability of the findings because participants in the intervention group may have been more motivated to increase their fruit intake than participants at an average workplace. Moreover, due to the self-purchased fruit, only a small number of the workplaces, initially approached, chose to enrol in the study, increasing the risk of selection bias.

In conclusion, the current study suggests that it is feasible to increase the fruit intake of employees by increasing the availability and accessibility of fruit at workplaces, using a minimal intervention method. Additionally, dietary fibre intake of the participants was increased, whereas intake of added sugar was reduced and possibly substituted with fruit. One additional piece of fruit per day was not sufficient to affect total energy intake in this study population, suggesting a substitution effect. In future minimal interventions of this kind, it would be interesting to examine if inclusion of overweight or obese participants with a relatively low fruit intake prior to the study and a potentially greater incentive to reduce body weight would result in a change in total energy intake. Further, future intervention studies need to be randomized in order to provide more robust and generalizable results.

## Acknowledgements

*Sources of funding:* European Commission. *Conflicts of interest:* None. *Author contributions:* A.D.L. and K.S.K. were involved in planning the study and recruitment/interview of the workplaces/participants. T.C. performed the nutrient calculations. O.H.H. conducted the statistical analyses. I.T. contributed to planning of the study. All co-authors contributed to the writing process of the manuscript. *Acknowledgements:* This study is part of the ISAFRUIT project, funded by the European Commission under

'Thematic Priority 5 – Food Quality and Safety' of the 6th Framework Programme of RTD (contract no. FP6-FOOD-CT-2006-016279). The views and opinions expressed in this publication are purely those of the writers and may not in any circumstances be regarded as stating an official position of the European Commission. The authors are grateful to the leadership and the employees of all worksites who participated in this study. Furthermore, the authors thank Dr Amelia A. Lake, Research Fellow at the Human Nutrition Research Centre, IHS, Newcastle University, for her contribution and proofreading of the manuscript.

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## **Paper IV**

**The effectiveness of a free fruit, workplace intervention on body weight, dietary intake and blood pressure**

## **The effectiveness of a free fruit, workplace intervention on body weight, dietary intake and blood pressure**

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Running title: Workplace intervention and body weight

Key words: BMI; overweight; obesity; dietary change

## **Abstract**

**Objective:** To investigate the effectiveness of a simple workplace intervention on: 1) changes in BMI and blood pressure (BP); 2) changes in overall dietary intake, including fruit, sweets and snacks, soft drinks, dietary fibre, fat and total energy (TE).

**Design:** An 18-week, cluster-randomized, parallel-design intervention. Intervention group (IG) received daily access to free fruit while control group (CG) did not. Participants completed validated FFQ at baseline and end of intervention. Anthropometric and BP measurements were collected at baseline, midway and end of intervention.

**Setting:** An office-based workplace near Newcastle, UK.

**Subjects:** 409 men and women (BMI=26.4), aged 39.5 years.

**Results:** 351 participants (IG: n=186, CG: n=165) completed the study. No differences in anthropometric or BP measurements were seen between the two groups at the end of intervention. Within IG, diastolic BP fell by (mean±SE)  $-2.07\pm 0.52$ mmHg,  $P=0.0001$  and fat mass by  $-0.41\pm 0.16\%$ ,  $P=0.0104$ . BMI showed a reducing trend ( $-0.12\pm 0.06$ kg/m<sup>2</sup>,  $P=0.0515$ ). In CG, diastolic BP fell by  $-1.41\pm 0.54$ mmHg,  $P=0.0093$ . Compared to CG, consumption of fruit ( $+0.4\pm 0.2$ portion/d,  $P=0.0254$ ) and dietary fibre ( $+1.9\pm 0.6$ g/d,  $P=0.0013$ ) was significantly higher in IG at the end of intervention. TE remained unchanged in both groups. Within IG, consumption of sweets and snacks decreased by  $-0.3$ servings/d,  $P=0.0038$  and fatE% by  $0.8\%$ /d,  $P=0.0015$ . In CG, consumption of soft drinks increased by  $0.1$ glasses/d,  $P=0.0014$ .

**Conclusions:** This simple workplace intervention seems insufficient to substantially change BMI, while effective in increasing fruit intake. Future interventions may need to include more than one single food group and consider a larger study size and longer time-frame.

## Introduction

Overweight and obesity are some of the most prevalent and increasing public health challenges worldwide, in particular due to their contribution to the increasing risks of non-communicable diseases including type 2 diabetes, cardiovascular diseases and some cancer types<sup>(1)</sup>, which bring substantial human and economic costs for society. Cost-effective strategies, aiming to promote healthy lifestyle choices in the general population need to be developed in order to reduce risk of diseases linked to diet and body weight.

Increased fruit and vegetable consumption is identified as an important strategy to prevent weight gain or reduce obesity<sup>(2)</sup> in addition to other health benefits. A significant determinant in this process is the relatively low energy density of fruit and vegetables due to their high water and dietary fibre content.

Prospective observational, intervention and cross-sectional studies have demonstrated a positive role of fruit and vegetables in preventing or reducing overweight and obesity<sup>(3,4)</sup>. However, a distinction between the roles of fruit and vegetables is wanted for a number of reasons. The culinary use of fruit is different from that of vegetables. Typically, fruit has a sweet taste and can therefore be an alternative to potentially more energy-dense sweets and desserts. Most fruit do not need any preparation and are found in various physical forms, including fresh, dried or canned, making them convenient to consume as a quick snack between meals. Unlike fruit, vegetables mostly need cooking before use and are sometimes prepared with the addition of fat. The relatively low energy density and high dietary fibre content give fruit a potential role in substituting more energy-dense food items. This may facilitate a decrease in total energy intake and thereby have a positive effect on body weight and other health related parameters including body composition and blood pressure.

Very few randomized clinical trials have explored the separate effect of fruit intake on body weight<sup>(5-7)</sup>. However, the majority of these show that increased fruit intake is able to reduce body weight. A number of prospective observational and cross-sectional studies have also indicated an inverse association between fruit intake and body weight<sup>(8)</sup>.

Various approaches can be made in order to increase consumption of fruit among free-living individuals across the life course. One is provision of free fruit, which in general has shown promising results among school children<sup>(9-12)</sup>. A novel approach would be to use this model of free fruit provision within workplaces. These environments are considered as appropriate settings for

health promotion strategies, as they provide a suitable environment to address large groups of individuals<sup>(13)</sup>.

Previously, several health promotion interventions at workplaces have been conducted<sup>(14-21)</sup>. These have generally focused on the effectiveness of the intervention on changes in dietary intake and/or lifestyle of the participants. Potential changes in body weight or other health indicators were not assessed. Furthermore, most of the studies have aimed to improve the dietary habits of the participants through delivery of relatively comprehensive interventions including education or counselling of the participants or canteen staff. Although these interventions may achieve successful results, our focus in the present study was to conduct a low cost intervention, demanding only simple structural modifications and minimal resources from the workplace, by addressing only two determinant factors to increase fruit consumption: availability and accessibility<sup>(22)</sup>. The rationale behind this intervention design was that fruit can be distributed with relative ease to a large number of employees only requiring minimal demands from other staff and with few modifications to the physical structure of the workplace. Further, fruit is relatively cheap and ready to eat almost without any preparation.

The primary aim of the present study was to investigate the effectiveness of a simple, single-factor workplace fruit intervention in changing body weight, BMI, adiposity and blood pressure, and the secondary aim was to investigate the intervention effectiveness in changing dietary intake, including fruit, sweets and snacks, soft drinks, dietary fibre, fat and total energy.

## **Materials and methods**

This study was an 18-month, cluster-randomized, parallel-design, controlled intervention study, performed in a workplace setting. It was conducted according to the guidelines determined in the Declaration of Helsinki and all procedures involving human subjects/participants were approved by the Newcastle University Research Ethics Committee (CL08/09/15).

### *Workplace and participants*

The study took place at a regional local government office close to Newcastle upon Tyne, UK, with over 1000 employees. The large number of employees within one building made this workplace suitable for the intervention. Furthermore, employees consumed most meals at the workplace due to the building's location at the periphery of the city and therefore away from food stores and restaurants.

Employees were invited to participate in the study through posters displayed throughout the workplace and a notice sent on the office intranet. Researchers gave brief oral presentations at the individual offices and distributed information sheets summarizing the study and its background to the employees, who also were given the opportunity to ask questions.

All employees were eligible for the study except women who were pregnant or lactating and individuals expected to be away from the workplace for extended periods or absent at the end of the intervention. A total of 441 employees enrolled for the study during recruitment and written informed consent was obtained from 409 employees before the start of the intervention.

Following recruitment, participants were randomized into either intervention or control group, where possible ensuring a matching number of males and females in each group. The physical structure and layout of the workplace determined the allocation of participants to the intervention or control arm of the study, aiming to maximize the separation of participants in different groups. The randomization resulted in 206 participants in the intervention group and 203 in the control group.

Each participant was given a unique code and password that enabled them to securely log on to the study website ([www.fruitatwork.org](http://www.fruitatwork.org)) where they also were able to contact study researchers and complete on-line questionnaires.

### *Intervention*

The intervention took place over an 18-week period (February 2009 - June 2009). For each participant in the intervention group, two free pieces of fruit were made available for collection at a designated point daily during the working week (Monday – Friday). The types of fruit were rotated on a weekly basis; typically participants received two different types of fruit (e.g. apples (range of varieties), oranges, pears, bananas and Kiwi fruit). The fruit was provided by a regional fruit distributor three times a week (Monday, Wednesday and Friday). Discussions were held with the building management team of the workplace and participants about the best location for the fruit collection points. This exploratory work established that the foyer area of each intervention floor was the most suitable area to maximize access to the fruit whilst considering workplace health and safety guidelines. After the intervention, to support compliance, the control group received the same amount of fruit for 18 weeks as that given to the intervention group.

### *Demographic details*

Demographic details including age, gender, education level, income, occupation and smoking status were collected at baseline. Socio-economic status (SES) was derived from the demographic questionnaire, where respondents recorded their job title. The job titles were subsequently coded into the categories of the nine major group coding levels, using the Standard Occupational Classification (SOC) 2000<sup>(23)</sup>. The nine major groups are as follows: 1: 'managers and senior officials', 2: 'professional occupations', 3: 'associate professional and technical occupations', 4: 'administrative and secretarial occupations', 5: 'skilled trades occupations', 6: 'personal service occupations', 7: 'sales and customer service occupations', 8: 'process, plant and machine operatives' and 9: 'elementary occupations'. Due to small numbers, the groups 'skilled trade occupations', 'personal service occupations' and 'sales and customer service occupations' were combined. Hence, the respondents were classified into groups 1-7.

### *Dietary Assessment*

Participants' dietary intake was assessed at baseline and at the end of the intervention, on-line, using a validated food frequency questionnaire (FFQ)<sup>(24)</sup>, covering food consumed during the previous week. Participants were able to complete the questionnaires through the study website. Reminders to complete the FFQ were sent to participants by email. Daily frequency of food group consumption was calculated from the FFQ data. Estimates of nutrient intake were calculated from frequencies using estimates of portion size and frequency of food consumed within each category based on National Diet and Nutrition Survey (NDNS) data<sup>(25)</sup> and nutrient composition from standard food tables<sup>(26)</sup>.

### *Anthropometric and blood pressure measurements*

Anthropometric measurements, referred to as 'health checks', including height, body weight, bio-impedance (using a portable Tanita body composition analyser (BC-420MA and TBF300MA)) and seated blood pressure measurements were collected at baseline, midway through the intervention and at the end of the intervention by the researchers and trained assistants. The interim health checks had a dual purpose in that they also motivated the participants to continue with the study.

### *Sample size calculations*

Respondent numbers required for assessment of changes in body weight were calculated from other similar intervention studies. Based on a two sample t-test it was estimated that in order to detect a significant ( $p < 0.05$ ) mean change of 1.25 kg in body weight from baseline to the end of the intervention with a power of 0.80 and a standard deviation of 5 kg, 252 participants would be needed in each group, which was the target for recruitment.

### *Statistical analysis*

Baseline characteristics for the intervention and control group were compared univariately. T-tests were used to compare continuous variables and within contingency table analysis for comparing categorical variables. Unadjusted changes in food and nutrient intake, including fruit intake, and anthropometric measures from baseline to the end of the intervention were estimated for each group and tested, using paired t-tests. Adjusted differences between the intervention and control group were obtained using multiple linear regression models. In this analysis we controlled for age, gender, education, SES, smoking status and baseline values. The analyses were carried out after the principle of intention to treat, applying last value carried forward in order to increase the probability of the changes observed to be true, since intention to treat analyses yield the most conservative estimates. In all statistical tests a significance level of 5 % was applied. The Statistical Analysis Systems statistical software package version 9.1 (SAS Institute, Cary, NC, USA) was used for all statistical analysis.

## **Results**

A total of 351 participants (186 in the intervention group and 165 in the control group) completed all aspects of the study. Of the 58 participants who dropped out of the study, 26 did so due to lack of time, 12 due to end of employment, 10 due to illness, four due to pregnancy, two due to dislike of fruit, one due to concern about a high blood pressure reading at the first measurement and one, who failed to remember to complete the questionnaires. Two of the dropouts did not state a reason.

### *Baseline characteristics*

The intervention and control group were matched for age, gender and education level, whereas SES and smoking status differed significantly between the two groups (table 1). Due to small numbers in some groups, SES groups 4, 5, 6 and 7 were combined. Compared with the control group, a higher proportion of the participants in the intervention group were in the SES group 3 (33% vs. 18%),

while a smaller proportion were in the SES group 4 to 7 (42% vs. 61%). There were more smokers in the intervention group compared with the control group (12% vs. 3%).

### *Measurements*

Anthropometric and blood pressure measurements were similar for the intervention and control groups at baseline (table 2). Participants from both the intervention and control group were slightly overweight and had a fat mass of 28-29%. Systolic and diastolic blood pressures were within acceptable ranges for this age group. At the end of the intervention, participants in the intervention group tended to have a lower BMI compared with baseline ( $-0.12 \pm 0.06 \text{ kg/m}^2$ ,  $P=0.0515$ ). This trend was due to a small, non-significant reduction in body weight for those in the intervention group ( $-0.31 \pm 0.17 \text{ kg}$ ,  $P=0.0675$ ). Fat mass and diastolic blood pressure were significantly lower for the intervention group compared with baseline ( $-0.41 \pm 0.16\%$ ,  $P=0.0104$ ;  $-2.07 \pm 0.52 \text{ mmHg}$ ,  $P=0.0001$ , respectively). Diastolic blood pressure also fell in the control group ( $-1.41 \pm 0.54 \text{ mmHg}$ ,  $P=0.0093$ ), but the fall was less than in the intervention group. Changes from baseline were not significantly different between the intervention and control group for any of the anthropometric or blood pressure measurements.

### *Dietary intake*

Total energy and macronutrient intake were not different between groups either at baseline or at the end of the intervention (table 3). Within the intervention group, daily E% from fat decreased significantly at the end of the intervention compared with baseline ( $-0.9 \pm 0.4 \text{ E\%}$ ,  $P=0.0154$ ), whereas daily E% increased significantly for carbohydrate ( $1.1 \pm 0.4 \text{ E\%}$ ,  $P=0.0049$ ). In the control group, daily E% from protein rose significantly at the end of the intervention compared with baseline ( $0.3 \pm 0.2 \text{ E\%}$ ,  $P=0.0211$ ). Dietary fibre intake was not different between the two groups at baseline but rose significantly by  $1.4 \pm 0.4 \text{ g/d}$  ( $P=0.0003$ ) in the intervention group at the end of the intervention, while remaining unchanged in the control group. The adjusted difference in dietary fibre intake between the two groups at the end of the intervention was  $1.9 \pm 0.6 \text{ g/d}$  ( $P=0.0013$ ).

Fresh fruit intake at baseline was similar in both groups at about 1.65 portions per day (table 4). This increased significantly in both groups at the end of the intervention, but the increase in the intervention group was greater ( $0.7 \pm 0.1 \text{ portions/d}$ ,  $P<0.0001$ ) than the increase in the control group ( $0.3 \pm 0.1 \text{ portions/d}$ ,  $P=0.0159$ ), resulting in an adjusted significant difference between the two groups at the end of the intervention ( $0.4 \pm 0.2 \text{ portions/d}$ ,  $P=0.0254$ ). Average daily consumption of

sweets and snacks, and soft drinks was not significantly different between the two groups at baseline. Within the intervention group, consumption of sweets and snacks fell significantly at the end of the intervention ( $-0.3\pm 0.1$  servings/d,  $P=0.0038$ ), while consumption of soft drinks increased significantly in the control group at the end of the intervention ( $0.1\pm 0.0$  glasses/d,  $P=0.0014$ ). Changes from baseline were not significantly different between intervention and control groups for either sweets and snacks or soft drinks.

## **Discussion**

This relatively simple workplace fruit intervention demonstrated only a small within-group, and not between-group, improvement in the anthropometric and blood pressure values among the participants. Participants in the intervention group showed only a borderline significant mean reduction in BMI and a significant mean reduction in their adiposity and diastolic blood pressure from baseline to the end of the intervention period. In the control group diastolic blood pressure fell significantly over the time course of the study, but to a lesser extent than the intervention group. Comparisons of the changes in the anthropometric and blood pressure measurements between the two groups were not significantly different. The modest effectiveness of the present intervention on the anthropometric and blood pressure outcomes may be attributed to a type II error due to limited power. The number of respondents was smaller than the number required to achieve the intended 80% power. However, it may also be due to the fact that it was aimed to keep the study as simple as possible. Attempting to modify only one single, potentially determinative, factor may be insufficient for body weight reduction purposes among free-living individuals. Multifactorial interventions focusing on additional important determinants in relation to body weight than only fruit, such as vegetables, dietary fat and information to the participants of the weight-reducing aim of the study may serve as more effective strategies<sup>(3)</sup>. Furthermore, especially given the simple and minimal nature of the intervention, longer study duration may have influenced the outcomes.

The potential independent effect of fruit intake on body weight and other health related parameters has previously only been examined in a few clinical trials under strict dietary conditions<sup>(6,27,28)</sup>. The majority of these trials showed a reduction in body weight and other measurements, such as adiposity and waist circumference. However, there are limitations in these studies, including missing information on the energy content of the diet together with the use of energy-restricted diets making it difficult to determine the contribution of the fruit intake *per se* to the changes reported. Furthermore, it is unlikely that the strict dietary conditions applied can be implemented in everyday

life. These trials, therefore, are very different from the present study, which was carried out in a workplace-based setting among free-living individuals, and hence may form a more realistic basis for developing strategies to reduce the global public health challenge of overweight and obesity. Even though the observed change in BMI was relatively small, this change shows that simple structural modifications within the workplace setting, such as increasing access to, and availability of fruit, can result in positive progress in an overall public health context.

The increased fruit intake of the participants in the intervention group by 0.7 portions per person per day was significantly higher than the increase seen in the control group. Participants in the intervention group had free access to, on average, two pieces of fruit per person per day at the workplace. Thus, the increase in fruit intake over the whole day was less than half of the available fruit, indicating a replacement of fruit already consumed by those in the intervention group prior to the study, since all fruit was taken from collection points each day. A general intervention effect, causing changes in dietary and lifestyle patterns across the whole study sample, including those in the control group, may have occurred, explaining the small increase in fruit intake observed in the control group.

While the intervention influenced food at work, the results indicate a broader effect. Hence, the daily intake of dietary fibre increased significantly in the intervention group compared to the control group. Moreover, daily intake of sweets and snacks decreased significantly within the intervention group, whereas intake of soft drinks increased significantly within the control group. These changes may suggest that this simple workplace intervention may have motivated participants in the intervention group to make an attempt to improve their broader eating patterns, as well as increasing their fruit intake. Increased consumption of soft drinks in the control group may reflect a seasonal shift in intakes of foods and drinks from winter to summer. The absence of such an increase in the intervention group supports the interpretation of an attempt in this group to follow an overall healthier lifestyle. Alternatively, substitution with available and accessible fruit, providing fullness and hydration, may have caused the reduction in intake of sweets and snacks and prevented an increase in consumption of soft drinks among those in the intervention group.

Total energy intake was not altered in either group, indicating that the increased fruit intake was not added to the usual diet but may have substituted other components of the diet, which is also supported by the increase in E% from carbohydrate and decrease in E% from fat by the intervention group. The stability in total energy intake also supports the suggestion that some of the fruit

provided at work substituted for fruit normally brought from home. Therefore, the observed trend for a reduction in BMI in the intervention group cannot be explained by a decrease in total energy intake. However, the observed improvements in dietary intake and potentially other, not measured overall lifestyle habits, such as increased level of physical activity, may explain the falling trend in BMI, as taking part in the intervention may have triggered changes toward a healthier lifestyle, affecting body weight.

A series of lifestyle measures, including increased fruit intake, are widely recognized to reduce blood pressure<sup>(29,30)</sup>. The blood pressure lowering effect of fruit may potentially be due to its relatively high content of flavonoids, dietary fibre and certain minerals<sup>(31-33)</sup>. Our findings support the blood pressure-lowering effect of fruit, as diastolic blood pressure among participants in the intervention group was lower at the end of the intervention. In addition to increased fruit intake, increased intake of dietary fibre along with decreased BMI and adiposity may also in part explain the reduced diastolic blood pressure in the intervention group. A smaller decrease in diastolic blood pressure was also observed in the control group. This reduction in blood pressure is unlikely to be due to the smaller increase in fruit intake by the control group, but is more likely due to the participants taking part in the intervention and becoming used to the measurement procedures<sup>(34,35)</sup>.

Other workplace intervention programmes have been conducted, exploring the effectiveness of the workplace as a setting to increase consumption of fruit and vegetables or promote generally healthy dietary and lifestyle choices<sup>(14-21)</sup>; for example the large-scale, randomized, controlled Seattle 5 a Day Worksite Program<sup>(14)</sup>. This study aimed to implement changes at two levels: the workplace environment and individual behaviour. The intervention resulted in a significant increase in fruit and vegetable consumption of the intervention group by 0.5 servings daily compared with the control group. A smaller-scale study in a Danish workplace also succeeded in significantly increasing fruit and vegetable consumption of the participants by 70 g daily by educating the canteen staff to increase availability of fruit and vegetables in the canteen<sup>(19)</sup>. At follow-up, four months after the end of the intervention, the consumption of fruit and vegetables had increased further to +95 g daily compared with baseline. In these studies, the main outcome of interest was the effectiveness of the intervention in changing dietary habits of the participants. The present study explores for the first time the effectiveness of a relatively simple, single factor workplace fruit intervention in changing body weight and other health-related parameters as well as the diet of the participants. This intervention was designed, as far as possible, to be simple, low-cost and with

minimal demands on the workplace and the intervention team, because restriction of resources is an important determinant in developing workplace-based strategies for improvement of public health.

Strengths of this study included its cluster-randomized, controlled design, ensuring limitation of selection bias and confounders. Performance of intention to treat analyses reinforced the credibility of the changes observed after the intervention in each group. The low-cost intervention, involving only simple structural changes, posed minimal demands on the management and other staff at the workplace. Furthermore, the workplace setting among free-living individuals is applicable to other organizations, and hence may be more helpful in planning of health promotion strategies, which are much needed worldwide.

Limitations of this study include insufficient power, which may have masked potential significant differences in BMI, adiposity and diastolic blood pressure between the two groups. However, considering the severity of the problem, even small changes are of substantial importance from a public health point of view. Floor-based randomization by group caused significant differences in SES between groups, as there was an association between occupational profile and floor. The analyses were therefore controlled for SES as well as smoking status, which also differed significantly between the two groups.

In conclusion, the key findings of this study are that a simple, single factor workplace fruit intervention can successfully increase fruit intake of the participants but may be insufficient as an effective strategy to reduce BMI, adiposity and diastolic blood pressure, substantially. The lack of change in total energy intake, despite the increase in fruit intake, indicates that the extra fruit intake was not added to the usual diet but may have substituted other food items. Future interventions among free-living individuals may consider including additional factors than only fruit, a larger study sample and a longer time frame.

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**Table 1** Baseline characteristics of intervention and control group (n=351)

	Intervention group (n=186)	Control group (n=165)	<i>P</i> value*
Age (yrs) (mean (SD))	40.5 (11.0)	38.6 (11.1)	0.1063
Gender (% female)	60	59	0.7857
Education (%)			0.2323
<i>School/college aged 18</i>	7	12	
<i>College post 18</i>	38	40	
<i>University degree</i>	30	29	
<i>Postgraduate qualification</i>	25	18	
SES (%)			0.0012
<i>Group 1</i>	13	9	
<i>Group 2</i>	12	12	
<i>Group 3</i>	33	18	
<i>Group 4, 5, 6, 7†</i>	42	61	
Smoking status (% smokers)	12	3	0.0006

\* Difference between intervention and control group. †SES-groups 4, 5, 6, and 7 were combined due to small numbers.

**Table 2** Anthropometric and blood pressure measurements (mean and SE) in the intervention and control group at baseline (t=0 wks) and at the end of the intervention (t=18 wks), and group differences at t=0 wks and t=18 wks (n=351)

	Intervention group (n=186)			Control group (n=165)			Group difference*†		
	mean	SE	P value‡	mean	SE	P value‡	mean	SE	P value§
BMI (kg/m <sup>2</sup> )									
t=0	26.6	0.4		25.9	0.4		0.5	0.5	0.3751
t=18	26.5	0.4	0.0515	25.8	0.4	0.3645	-0.1	0.1	0.5660
BW (kg)									
t=0	75.9	1.2		73.2	1.2		2.3	1.7	0.1650
t=18	75.5	1.2	0.0675	73.1	1.2	0.4300	-0.2	0.3	0.5445
FM (%)									
t=0	29.1	0.7		27.5	0.8		0.9	0.9	0.2878
t=18	28.6	0.7	0.0104	27.2	0.8	0.1269	-0.1	0.3	0.6805
SBP (mmHg)									
t=0	127.0	1.1		126.8	1.3		0.0	1.5	0.9777
t=18	125.4	1.0	0.0773	126.9	1.3	0.9116	-1.5	1.1	0.1784
DBP (mmHg)									
t=0	79.0	0.7		77.7	0.8		1.1	1.0	0.3048
t=18	76.9	0.7	0.0001	76.4	0.9	0.0093	-0.5	0.8	0.4815

BW, body weight (kg); FM, fat mass (%); SBP, systolic blood pressure (mmHg); DBP, diastolic blood pressure (mmHg). \*Adjusted (for age, gender, education, SES, and smoking status) difference between intervention and control group (intervention group – control group), using multiple linear regression analysis. †Difference at t=18, also adjusted for t=0 value. ‡Change from t=0 to t=18 within intervention and control group, using paired t-test. §Difference between intervention and control group at t=0 and t=18.

**Table 3** Daily intake values for total energy and macronutrients (mean and SE) in the intervention and control group at baseline (t=0 wks) and at the end of the intervention (t=18 wks), and group differences at t=0 wks and t=18 wks (n=351)

	Intervention group (n=186)			Control group (n=165)			Group difference*†		
	mean	SE	<i>P</i> value‡	mean	SE	<i>P</i> value‡	mean	SE	<i>P</i> value§
Energy, total (MJ/d)									
<i>t=0</i>	8.94	0.23		8.89	0.24		-0.04	0.33	0.9144
<i>t=18</i>	8.96	0.24	0.9623	8.59	0.24	0.0724	0.29	0.22	0.1882
Carbohydrate (g/d)									
<i>t=0</i>	242.5	5.9		244.0	6.2		-2.0	8.6	0.8136
<i>t=18</i>	248.0	6.4	0.1984	235.5	6.7	0.0886	11.2	6.4	0.0821
Carbohydrate (E%/d)									
<i>t=0</i>	46.7	0.4		47.1	0.5		-0.1	0.7	0.8896
<i>t=18</i>	47.7	0.5	0.0049	46.9	0.5	0.7041	0.9	0.5	0.1054
Fat (g/d)									
<i>t=0</i>	93.5	2.8		94.0	3.0		-1.4	4.3	0.7428
<i>t=18</i>	91.8	3.0	0.3168	89.8	2.8	0.0791	2.5	2.8	0.3653
Fat (E%/d)									
<i>t=0</i>	38.2	0.4		38.7	0.4		-0.5	0.6	0.3669
<i>t=18</i>	37.4	0.4	0.0154	38.4	0.4	0.8397	-0.5	0.5	0.2460
Protein (g/d)									
<i>t=0</i>	71.9	1.8		72.6	2.0		-1.2	2.8	0.6643
<i>t=18</i>	72.0	2.0	0.9305	71.9	2.1	0.5365	1.1	2.0	0.5661
Protein (E%/d)									
<i>t=0</i>	13.8	0.1		14.0	0.2		0.2	0.2	0.4809
<i>t=18</i>	13.8	0.2	0.9276	14.4	0.2	0.0211	-0.4	0.2	0.0561
Dietary fibre (g/d)									
<i>t=0</i>	17.7	0.5		18.2	0.5		-0.8	0.7	0.2920
<i>t=18</i>	19.1	0.6	0.0003	17.4	0.6	0.0747	1.9	0.6	0.0013

\*Adjusted (for age, gender, education, SES, and smoking status) difference between intervention and control group (intervention group – control group), using multiple linear regression analysis.

†Difference at t=18 also adjusted for t=0 value. ‡Change from t=0 to t=18 within intervention and control group, using paired t-test. §Difference between intervention and control group at t=0 and t=18.

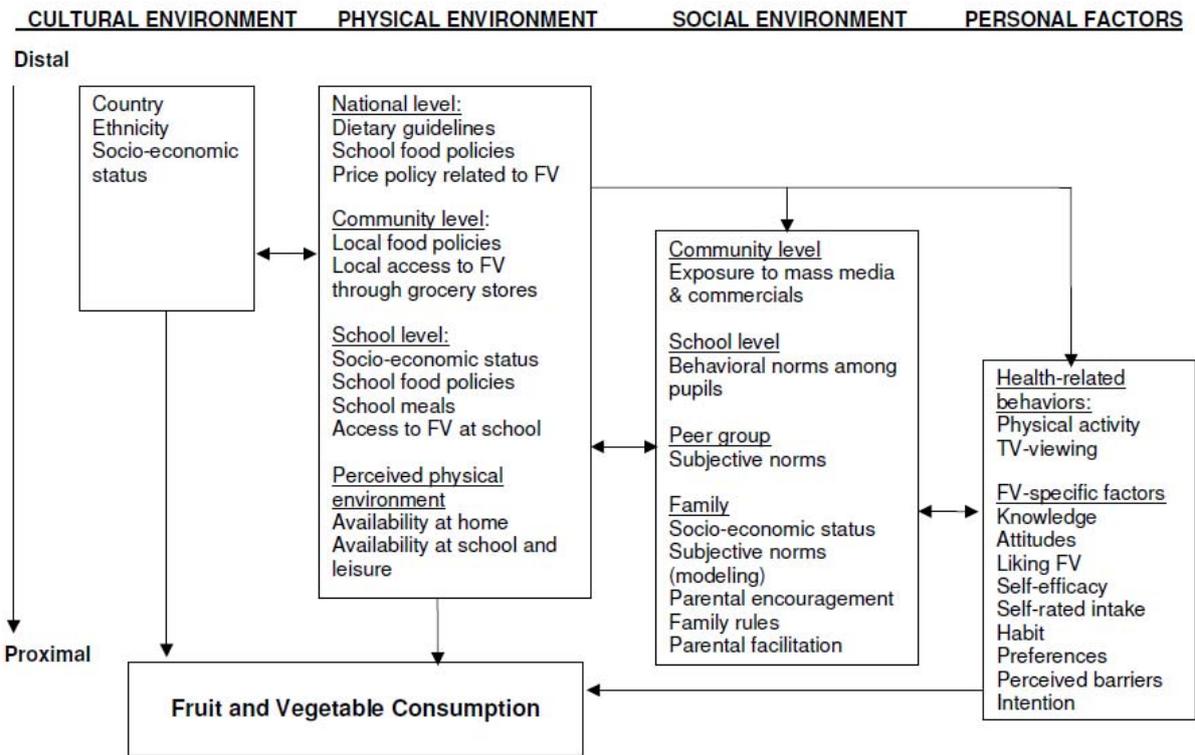
**Table 4** Daily intake values for selected foods (mean and SE) in the intervention and control group at baseline (t=0 wks) and at the end of the intervention (t=18 wks), and group differences at t=0 wks and t=18 wks (n=351)

	Intervention group (n=186)			Control group (n=165)			Group difference*†		
	mean	SE	<i>P</i> value‡	mean	SE	<i>P</i> value‡	mean	SE	<i>P</i> value§
Fruit (portions/d)									
<i>t=0</i>	1.7	0.1		1.6	0.1		0.1	0.2	0.7098
<i>t=18</i>	2.4	0.1	<.0001	1.8	0.1	0.0159	0.4	0.2	0.0254
Sweets & snacks (servings/d)									
<i>t=0</i>	2.24	0.15		2.19	0.16		0.04	0.24	0.8761
<i>t=18</i>	1.97	0.13	0.0038	1.96	0.16	0.0654	-0.06	0.13	0.6283
Soft drinks (glasses/d)									
<i>t=0</i>	0.09	0.02		0.06	0.01		0.04	0.03	0.1544
<i>t=18</i>	0.09	0.02	0.7841	0.11	0.02	0.0014	-0.04	0.03	0.1222

\*Adjusted (for age, gender, education, SES, and smoking status) difference between intervention and control group (intervention group – control group), using multiple linear regression analysis.

†Difference at t=18, also adjusted for t=0 value. ‡Change from t=0 to t=18 within intervention and control group, using paired t-test. §Difference between intervention and control group at t=0 and t=18.

## **Illustration, Conceptual framework**



**Figure 1**  
Conceptual framework applied to children's fruit and vegetable consumption: the Pro Children Project [16].

Source: Rasmussen *et al.*, (2006)