

The processes of planning and nutrient analyses of diets for controlled feeding trials in free-living subjects.

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SUMMARY

Motivation:

There is an increased tendency in the field of nutrition research to conduct human feeding studies in order to test diet-disease hypotheses. Using well controlled feeding approaches subjects consume only foods that have been precisely formulated and prepared in a research kitchen. The development of these accurate experimental diets is essential in order to meet the study objective and provide valid scientific data. Research dieticians use computerised nutrient databases to design these diets that meet the study protocol diet specifications. In most trials the developed experimental diet is chemically analysed to validate the menu. Chemical analysis is an expensive and time consuming procedure and if analysis presents with different nutrient content than planned, adjustments to the menu will follow and a possible repeat of the chemical analysis for verification, adding to the costs of the trial. Limited information has been published regarding the procedures for the planning and nutrient analysis of diets for controlled feeding trials thus, research teams are depending on trial and error experiences in order to guide them in the processes of planning and nutrient analysis for controlled feeding trials in free-living subjects.

Objectives:

The main aim of this study was to describe the processes of planning and nutrient analyses of diets for controlled feeding trials in free-living subjects.

- The first objective was to develop appropriate methodologies for the planning of diets for controlled feeding trials in free-living subjects. Subsequently these recommended steps were used in developing a seven day menu cycle for a controlled feeding trial.
 - Secondly, the reliability of the two nutrient databases available in South Africa was tested by comparing the nutrient analysis of the menu as
-

calculated by the databases with each other, as well as comparing it to the standard reference of chemical analysis.

Methods:

- **The appropriate menu design methodology to be used in controlled feeding trials:** In this study a literature search was conducted using electronic scientific journal databases. This literature search was done in order to locate published controlled feeding trials which described the methodology used for menu design. The information was summarised and a flow diagram was compiled presenting the identified steps that will guide the research team.
- **The process of nutrient analysis for controlled feeding trials: A comparative study of two South African nutrient databases with chemical analysis:** A seven day menu providing 7500kJ/day (35% of the total energy as fat, 17% as protein and 48% as carbohydrates) was developed. The menu was then entered into FoodFinder3[®] and Dietary Manager Software programmes and nutrient analysis was done. Food prepared in the research kitchen, North-West University, Potchefstroom, South Africa, according to this menu was then chemically analysed for the macronutrient profiles (carbohydrate, fat, protein and fibre, soluble and insoluble fibre) and fatty acid distribution (saturated fatty acids, mono-unsaturated fatty acids and poly-unsaturated fatty acids) using standard methods. Differences between the different nutrient analyses were compared with non-parametric statistical tests by using the computer software program Statistica[®].

Results:

- **The appropriate menu design methodology to be used in controlled feeding trials:** Ten steps were identified and described in detail that will

guide the research team in menu development for controlled feeding trials in free-living subjects.

- **The process of nutrient analysis for controlled feeding trials: A comparative study of two South African nutrient databases with chemical analysis:** The nutrient content of the two nutrient databases did not differ significantly from each other, however, there were differences between the chemical analysed values and the databases calculated values. There were no significant differences between the amount of total energy, protein, carbohydrate, poly-unsaturated fatty acids and total fibre. The total fat, saturated fatty acids and mono-unsaturated fatty acids content using both FoodFinder3® and Dietary Manager were statistically and practically significantly higher than the chemical analysed values ($p < 0.05$). FoodFinder3® produced significantly lower levels of insoluble and soluble fibre compared to the chemical analysis. The main factors that were identified that could have contributed to these variations include the use of recipes and combination dishes not available on the database; variations in the fat content of meat dishes; and incomplete data of key nutrients in nutrient databases.

Conclusion:

The 10 recommended steps need to be followed by the research team in order to accurately formulate, plan, produce and deliver research diets. There are important considerations to remember that might influence the success of the menu and the feeding trial. The use of computerised nutrient databases in menu design for controlled feeding trials is functional and assists the research dietitian with this challenging task. However, computer nutrient databases are not reliable enough to exclude the step of menu validation by chemical analysis.

Afrikaanse titel: Die prosesse van beplanning en nutriëntanalises van diëte vir gekontroleerde voedingstudies op 'n vrylewende proefpersoonbasis.

OPSOMMING

Motivering:

Daar is toenemende tendens in die veld van voedingsnavorsing om meer gekontroleerde voedingstudies uit te voer, om sodoende dieet-siekte-hipotese te toets. Wanneer daar van hierdie gekontroleerde voedingstudies gebruik gemaak word, eet proefpersone slegs die voedsel wat presies geformuleer en voorberei word in 'n navorsingskombuis. Die ontwikkeling van hierdie akkurate eksperimentele diëte is dus belangrik ten einde die studiedoelwit te bereik en om geldige wetenskaplike data te verkry. Dieetkundige navorsers gebruik rekenaargebaseerde nutriëntdatabasisse om hierdie diëte te beplan volgens die studie se dieetspesifikasies. In meeste gekontroleerde voedingstudies word die eksperimentele diëte chemies geanaliseer om die geldigheid van die spyskaart te valideer. Chemiese analise is 'n duur en tydrowende proses in die uitvoer van gekontroleerde voedingstudies. Indien die resultate van die chemiese analise verskil van die beplande nutriëntsamesstelling, sal aanpassings aan die spyskaart gemaak moet word en die chemiese proses sal herhaal moet word om die samesstelling van die dieet te bevestig. Dit sal dan verder tot die kostes van die studie bydra. Die gepubliseerde inligting oor die prosedures vir die beplanning en nutriëntanalise in gekontroleerde voedingstudies is beperk en navorsingspanne maak staat op die probeer-en-tref-metode om hulle te lei gedurende hierdie proses van beplanning en nutriëntanalise van diëte vir gekontroleerde voedingstudies.

Doelwitte:

Die hoofdoelwit van die studie was om die prosesse van beplanning en nutriëntanalise van diëte vir gekontroleerde voedingstudies op vrylewende proefpersone te beskryf.

- Die eerste doelwit was om toepaslike metodologieë te ontwikkel vir die beplanning van diëte vir gekontroleerde voedingstudies. Vervolgens is hierdie aanbevole stappe gevolg om 'n sewedag-spyskaartsiklus op te stel vir 'n gekontroleerde voedingstudie.
- Tweedens is die betroubaarheid van die twee nutriëntdatabasisse wat tans in Suid-Afrika gebruik word, op die proef gestel deur dit met mekaar, sowel as met die standaard van chemiese analise, te vergelyk.

Metodes:

- **Die toepaslike spyskaartbeplanningsmetodologie om te gebruik in gekontroleerde voedingstudies:** In hierdie studie is 'n volledige literatuursoektog gedoen. Tydens hierdie soektog deur elektroniese wetenskaplike databasisse is gepubliseerde gekontroleerde voedingstudies gesoek wat die spyskaartbeplanningsmetodologie van die spesifieke studie beskryf. Die informasie in die studies is opgesom en gebruik om 'n vloeidiagram saam te stel met 'n uiteensetting van die aanbevole stappe om die navorsingsplan te lei in die proses van spyskaartbeplanning.
- **Die proses van nutriëntanalise vir gekontroleerde voedingstudies: Vergelykende studie van twee Suid-Afrikaanse nutriëntdatabasisse met chemiese analise:** 'n Sewedag-spyskaartsiklus wat 7500kJ/dag (35% van die totale energie vanaf vet, 17% vanaf proteïene en 48% vanaf koolhidrate) voorsien het, is ontwikkel en in die rekenaarprogramme

FoodFinder3® en *Dietary Manager* ingelees en nutriëntanalises is gedoen. Die maaltye is daarna in die navorsingskombuis van die Noordwes-Universiteit, Potchefstroom, Suid-Afrika, voorberei en chemies geanaliseer vir die volgende makronutriënte (koolhidrate, vet, proteïene, vesel, oplosbare en onoplosbare vesel) en vetsuurverspreiding (versadigde vet, mono-onversadigde vet en poli-onversadigde vet) deur gebruik te maak van gestandaardiseerde metodes. Verskille tussen die verskillende nutriëntanalises is met behulp van nie-parametriese statistiese toetse geanaliseer deur gebruik te maak van die rekenaar sagteware program *Statistica®*.

Resultate:

- **Die toepaslike spyskaartbeplanningsmetodologie om te gebruik in gekontroleerde voedingstudies:** Tien stappe is geïdentifiseer en volledig beskryf om die navorsingsplan te lei in die proses van dieetbeplanning vir gekontroleerde voedingstudies.
- **Die proses van nutriëntanalise vir gekontroleerde voedingstudies: Vergelykende studie van twee Suid-Afrikaanse nutriëntdatabasisse met chemiese analise:** Die nutriëntsamesstelling van die twee nutriëntdatabasisse het nie betekenisvol van mekaar verskil nie, maar daar was wel verskille tussen die chemies geanaliseerde waardes en die berekende nutriëntdatabasiswaardes. Daar was nie betekenisvolle verskille vir die totale energie, proteïen, koolhidrate, poli-onversadigde vet en totale vesel nie. Beide *FoodFinder3®* en *Dietary Manager* het statisties en prakties betekenisvolle hoër waardes opgelewer vir totale vet, versadigde vet en mono-onversadigde vet in vergelyking met die chemiese analise ($p < 0.05$). *FoodFinder3®* het ook – vergeleke met die chemies geanaliseerde waardes – betekenisvol laer waardes opgelewer vir oplosbare en onoplosbare vesel. Die geïdentifiseerde faktore wat kon

bydra tot hierdie verskille sluit in die gebruik van resepte en geregte wat nie beskikbaar is op die databasis nie, die verskille in die vetinhoud van vleis; asook onvolledigde inligting van spesifieke nutriënte in die databasis.

Gevolgtrekking:

Die aanbevole tien stappe moet deur die dieetkundige gevolg word ten einde akkurate dieet te formuleer, te beplan en te lewer. Daar is belangrike aspekte wat in ag geneem moet word om suksesvolle spyskaart en studie te beplan. Die rekenaargebaseerde nutriëntdatabasisse is funksioneel en help die dieetkundige met dié uitdagende taak van beplanning van die spyskaart. Tans is rekenaargebaseerde nutriëntdatabasisse egter nie betroubaar genoeg om die stap van chemiese analise uit te skakel nie.

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Chapter 2

Figure 1: The recommended steps for menu planning in controlled feeding trials in free-living subjects.

List of abbreviations

%E	Percentage of total energy intake
ANOVA	Analysis of Variance
BMR	Basal Metabolic Rate
CE	Capillary Electrophoresis
CHO	Carbohydrates
DASH	Dietary Approaches to Stop Hypertension
DELTA	Dietary Effects on Lipoproteins and Thrombogenic Activity
GC	Gas Chromatography
HPLC	High Performance Liquid Chromatography
MUFA	Mono-unsaturated fatty acid
NSP	Non-Starch Polysaccharides
PUFA	Poly-unsaturated fatty acid
SA	South Africa
SFA	Saturated fatty acid
SFC	Supercritical Fluid Chromatography
US	United States
USDA NDB	United States Department of Agriculture National Nutrient Database
WHO	World Health Organisation

Introduction

1. Background and motivation

Human feeding studies are one of the many techniques used to develop and test diet-disease hypothesis. It defines the relationship between dietary intake and changes in an outcome, typically a risk factor for disease, metabolic parameters and health outcomes. There is a tendency in the field of nutrition research to conduct more controlled feeding studies on an outpatient (i.e. free-living, non-residential) basis. Factors contributing to this trend are lower costs compared to residential studies and easier recruitment of volunteers due to minimal interruptions of subjects' lives (Clevidence, 1997).

Using well controlled feeding approaches, subjects consume only foods that have been precisely formulated and prepared in a research kitchen. Because of the detailed control of experimental diets, it is intellectually and logistically challenging to conduct (Most *et al.*, 2003). The process includes designing and selecting menus according to specific nutrient goals defined by the study protocol that promote participant adherence to the diet and that efficiently utilize the research kitchen staff and resources. Following the appropriate methodology and processes is essential for conducting well-controlled outpatient feeding studies that will assemble valid scientific data. This increased interest in conducting more controlled feeding trials consequently led to the necessity for information on planning successful trials. This information has recently become more available through publications (Most *et al.*, 2003); however, up to now no clear guidelines and recommendations have been documented on the ideal methodology for menu design in controlled feeding trials in free-living subjects.

Nutrient analyses also play a critical role in the practice of dietetics and nutrition research. Not only does one rely on nutrient analysis systems for the assessment of dietary intakes of individuals and groups, but it is also part of the development of carefully controlled menus for feeding studies (McCullough *et al.*, 1999). It is the research dietician's task to determine the correct types and proportions of foods needed to achieve diets that attain the study goals. Due to this, the day-to-day use of nutrient analysis led to the development of computerised nutrient databases. In South Africa use is made of the FoodFinder3® programme (Medical Research

Council of SA, Tygerberg SA) which is based on the South African food composition database where 41% of the foods in the database have South African analysed values as main reference source and the rest of the values are borrowed from United States Department of Agriculture National Nutrient Database (USDA NDB) (Sayed *et al.*, 1999), and Dietary Manager (Modified 2006, Scharf, Programme Management, Johannesburg, SA), which is primarily based on the USDA NDB including 200 South African foods (oral communication with Oskar Scharf), in order to calculate the diet composition. These databases contain the energy and nutrient composition of food items which have been chemically analysed except for carbohydrates which are calculated by the deduction from other constituents.

$$Carbohydrate(g) = Totalfood(g) - (Protein + Fat + Ash + Water)g \quad (Englyst \text{ et al.}, 1995).$$

The two important considerations when selecting nutrient database programmes to calculate research diets are 1) the reliability of the database and 2) the functionality of the programme. Both aspects are important but the reliability of the data is most important as inaccurate data would result in the research objective not to be achieved (Stumbo, 1996). According to McCullough *et al.* (1999), several articles have described essential characteristics of nutrient databases and practices of manufacturer; however, published tests of the reliability of nutrient databases are rare. This motivated the comparison of the two South African nutrient databases with each other as well as with the chemical analysis in order to evaluate the reliability of the data.

Results from this study will assist in the planning of all future controlled feeding trials. It gives clear guidelines on the methodology of menu design for the research dietician and determines the reliability of nutrient databases as compared to the actual chemical analysis. This will demonstrate whether a research diet's nutrient composition calculated by the nutrient database is accurate enough to exclude the step of chemical analysis.

2. Aim and objectives

The aim and objectives of this study were:

Aim

The aim of this study is to describe the processes of planning and nutrient analyses of diets for controlled feeding trials in free-living subjects.

Objectives

- To develop appropriate methodologies for planning diets of controlled feeding trials in free-living subjects.
- To compare the nutrient analysis of a seven day menu obtained from two nutrient databases available in South Africa.
- To compare the nutrient analysis from nutrient databases with the chemical analysis of a seven day menu.

3. Structure of this dissertation

This dissertation is presented in article format. This introductory chapter presents a brief background and rationale for the scientific value of this research. Subsequently, Chapter 2 describes the recommended steps of methodology for use by a research dietician when designing a menu for controlled feeding trials in free-living subjects. Each of the ten steps is discussed, explaining its importance and special considerations to keep in mind. One study was conducted and is presented in Chapter 3. Here the process of nutrient analysis for controlled feeding trials is investigated by determining the reliability of two South African nutrient databases' calculated values with the chemical analysis as standard reference. In Chapter 4 a general summary, conclusion and recommendations are given. The relevant references of Chapter 1, 2 and 4 are provided at the end of each chapter according to the mandatory style stipulated by the North-West University. The relevant references of Chapter 3 are provided according to the author's instructions of *Contemporary Clinical Trials* to which it is submitted.

4. Co-authors contributions

The study reported in this dissertation was planned and conducted by a team of researchers. The principle author of this dissertation is Izette van der Watt. In Table 1 the contributions of co-authors are given. Also included is the statement from the

co-authors confirming their role in the study and giving permission that the article may form part of this dissertation.

Table 1: Co-authors and their contribution

Name	Role in study
Ms I van der Watt (Dietician)	MSc student. Responsible for the design, planning, execution and documentation of the study. More specifically, responsible for literature searches, development of step-by-step methodologies for planning menus for controlled feeding trials, designing the menu, preparing the menu, chemical analysis of the fatty acid distribution of the menu, nutrient analysis with two nutrient databases and statistical analysis.
Prof. W Oosthuizen (Nutritionist)	Study leader. Supervised the design, planning, execution, statistical analysis of the study and writing-up of this dissertation.
Dr M Pieters (Dietician, Nutritionist)	Co-study leader. Assisted in designing and planning of the study, statistical analysis and writing-up of this dissertation.
Dr. Hanekom (Dietician)	Assistant study leader – Supervised the design of the menu plan.
Dr. Du Toit Loots (Biochemist)	Trained and supervised I van der Watt for the chemical analyses of the fatty acid content of the menu.

The following is a statement from the co-authors confirming their individual role in each study and giving their permission that the article may form part of this dissertation.

I declare that I have approved the above-mentioned article, that my role in the study, as indicated above, is representative of my actual contribution and that I hereby give my consent that it may be published as part of a M.Sc. dissertation of Izette van der Watt.

Wrote names Prof Oosthuizen

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Dr. M Pieters

SM Hanekom

Dr. SM Hanekom

D Loots

Dr. D Loots

5. References

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The appropriate menu design methodology to be used in controlled feeding trials.

1. Introduction

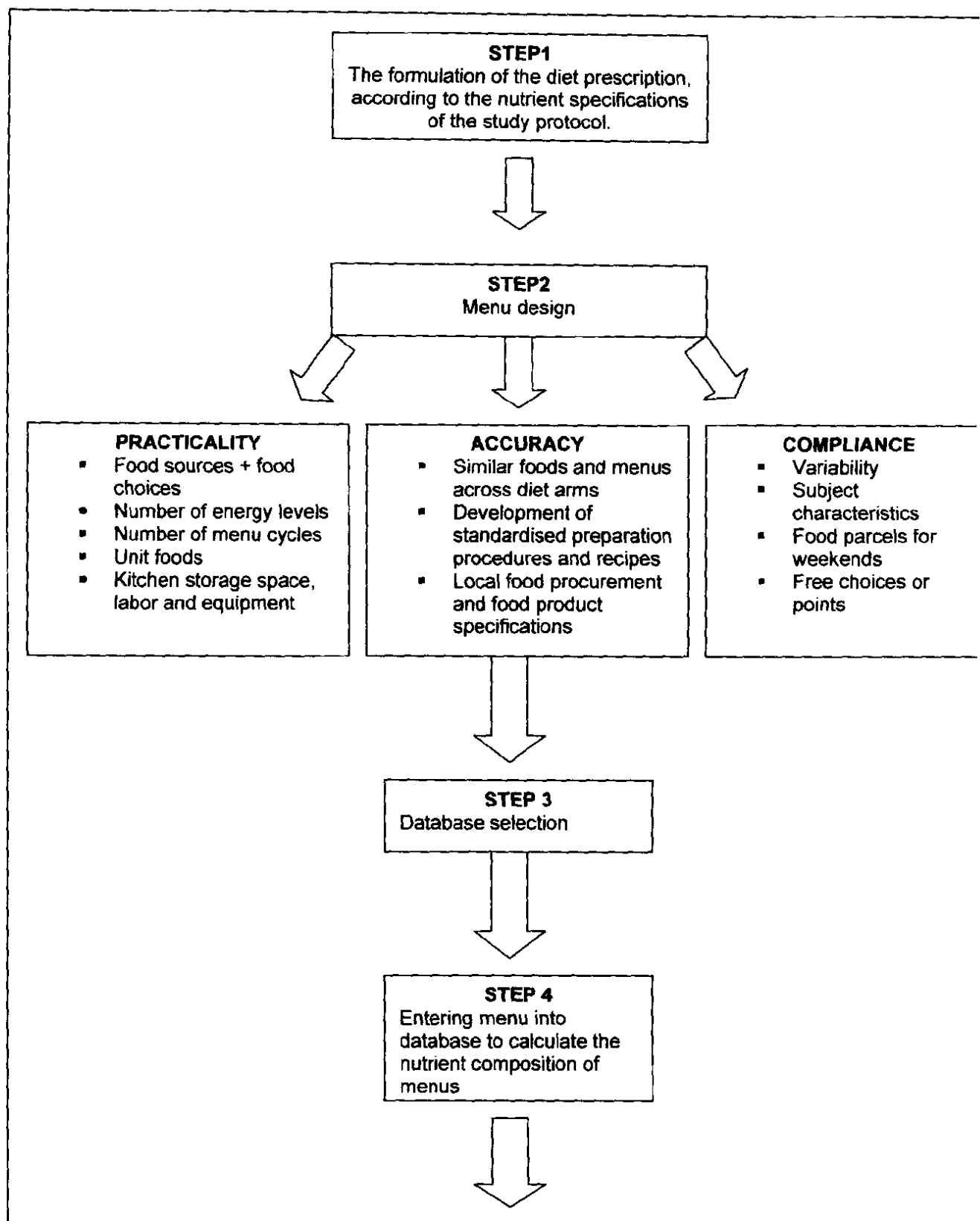
The aim of this chapter is to describe the recommended steps to use when designing accurate menus for controlled feeding trials. These recommendations will assist the research dietician in menu design, a process which is applicable to all controlled feeding trials. Outpatient feeding studies are challenging to conduct and require many skills. The research dietician responsible for the menu design needs to formulate accurately, produce and deliver these research diets in order to guarantee valid scientific data. The end goal of the menu design process is to produce a menu that matches the nutrient specifications of the study protocol, which is appetising and acceptable to the subjects in order to promote compliance, a menu that is cost effective as well as endorse efficient food procurement, production and delivery (Swain *et al.*, 1999). Thus, this chapter will describe the process of menu design for controlled feeding trials step-by-step, starting with the formulation of the diet prescription, menu development, database selection, chemical analysis and menu evaluation through to the production and delivery of the research diet.

2. The recommended steps for menu planning

In order to compile the ideal methodology for menu design in controlled feeding trials in free-living subjects, a literature search was conducted, using electronic scientific journal databases namely; Science Direct, Web of Science and Medline. This literature search was done in order to locate published controlled feeding trials which described the methodology used for menu design. Only three relevant controlled feeding trials were found and scrutinised to identify the procedure and lessons learned by each trial. These publications described the comprehensive procedure of diet design from the formulation of diet specifications to the delivery of the research diet. These trials included firstly: the Dietary Effects on Lipoproteins and Thrombogenic Activity (DELTA-1) programme, a multicentre feeding study to determine the effects of alterations in

the amount and type of fat on lipoproteins and selected hemostasis parameters. Three diets were fed randomly to 103 participants for three 8-week feeding periods (Dennis *et al.*, 1998). Secondly, the Dietary Approaches to Stop Hypertension (DASH) trial involving 4 clinical sites at which 459 participants (in 5 cohorts) were fed 3 dietary patterns over 11 weeks per cohort to test the effects of dietary patterns on blood pressure (Swain *et al.*, 1999). Thirdly, the NUT study, a single centre three 8-week feeding trial conducted by the co-investigators of the current study, investigating the effects of a high walnut diet and high unsalted cashew nut diet on markers of the metabolic syndrome in 64 subjects (Mukuddem-Petersen *et al.*, 2006). A self developed flow diagram compiled from identified steps used in the above mentioned studies and experience from co-investigators, is presented in Figure 1. A detailed description of each step and factors to consider follows.

It is important that time is set aside for the planning of the menus. The DASH trial allowed a planning period of 12 months to develop menus, standardise the procedures and to incorporate them into operational systems (Swain *et al.*, 1999). The DELTA programme used almost 9 months to calculate menus, validate menus, do sensory testing, analyse and to select the appropriate menu (Dennis *et al.*, 1998). During the NUT study developing menus, testing the procedures and acceptability of the menus in a pilot study and amending it took ± 5 months.



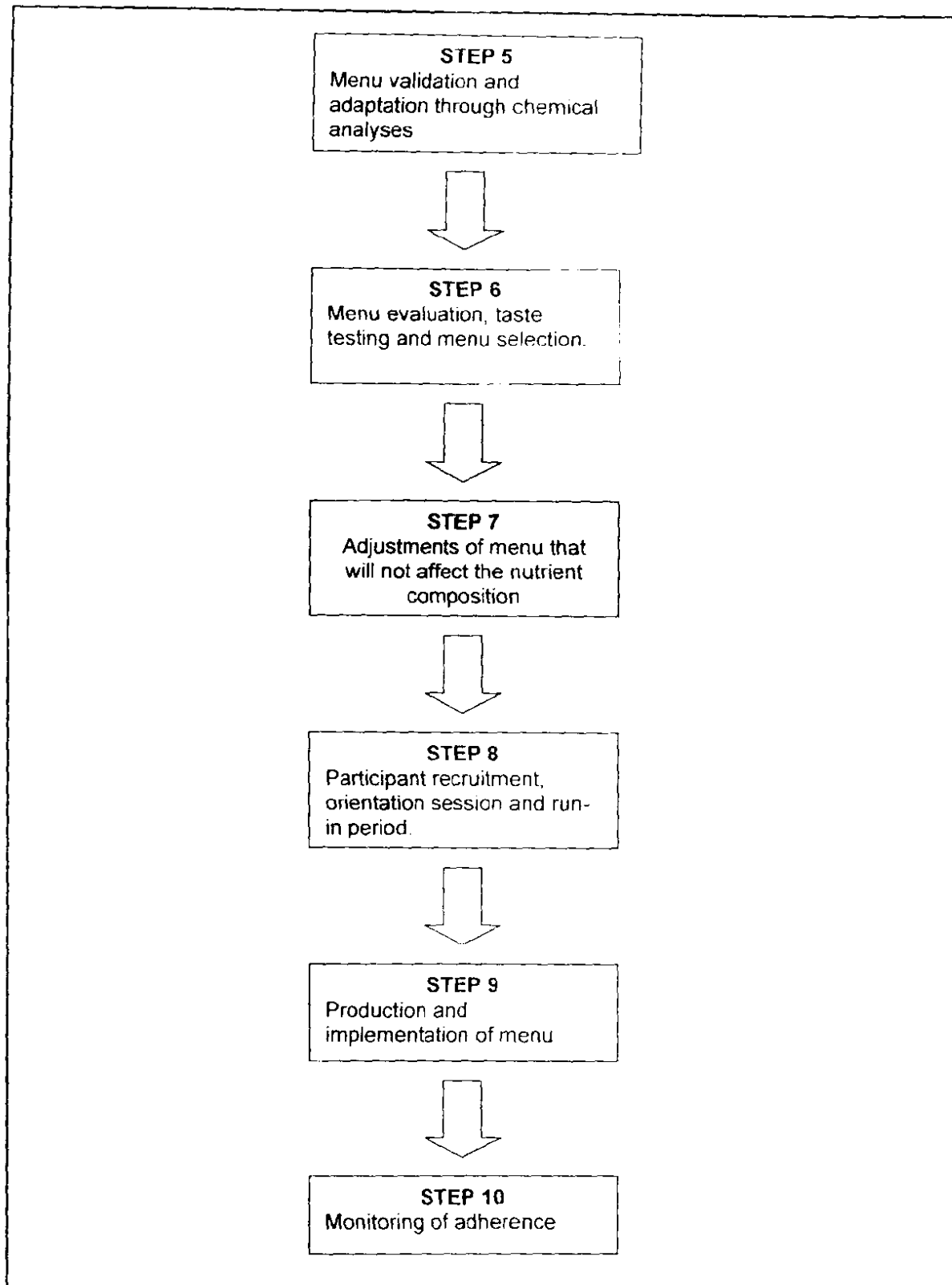


Figure 1 The recommended steps for menu planning in controlled feeding trials in free-living subjects.

2.1 Step 1: Formulation of the diet prescription

The first step in this process is the formulation of the diet prescription. The research dietician must create menus that match the specific nutrient specifications stipulated in the study protocol (Most *et al.*, 2003). The food provided to the subjects will then result in dietary modifications that will test the study hypothesis. In the past controlled diets often consisted of fluid mixtures of nutrients such as sugars, amino acids, different lipids and some vitamins and minerals. It is, however, more appropriate to prescribe diets that will not only contribute to the expected nutrient content of the study but that are also consistent with intended dietary patterns of consumption of free-living subjects continuing with their daily routine (Holden, 1995). Most of the studies have different dietary groups, either all having the same nutrient content but differing in food sources providing specific nutrients or components e.g. the NUT study where all the diets were identical except for the different type of nuts used in each respective group; or the dietary specifications are different in the dietary groups but they control for a specific nutrient, for example fat or sodium e.g. the DASH trial. In the end one has a diet that presents the nutrient specifications that vary with variables unique to that study design. If possible the diets are usually blinded in order to avoid bias. Participants will be informed that there are diet variables but they will not know which diet they are receiving. Meals provided should thus aim to appear identical for the different dietary groups and can be coded by colour, number or letters to differentiate (Clevidence, 1995).

Determination of energy requirements

All controlled feeding studies require accurate estimation of energy requirements for subjects in order to keep participants' weight stable and prevent weight fluctuation especially during specific studies where weight is a confounding factor. The components of energy expenditure are: Basal Metabolic Rate (BMR) (60-70%), the thermic effect of food (5-10%) and physical activity (Seagle, 1997;

Lin, 1996). The most accurate methods used for the determination of energy expenditure are with an indirect calorimeter for BMR, measuring total energy with a whole-room calorimeter or doubly labeled water, and measuring physical activity with heart rate or activity monitors (Lin, 1996; Dauncey *et al.*, 1979). However, this is expensive and not always available. As an alternative, formulas such as the Harris Benedict equation, the Bernstein equation and the FAO/WHO formulae can be used to estimate the BMR adding physical activity factors (1.4-2.2 multiples of BMR) or doing physical activity assessment questionnaires (Lin *et al.*, 2003). Food intake records can also be used but are not accurate predictors of energy requirements and should be used as additional information on dietary habits (Seagle, 1997).

BMR formulae (kJ/24hr):

1. Bernstein *et al.*, 1983: Women $7.84 (\text{kg}) - 0.42 (\text{cm}) - 3(\text{yr}) + 844$
 Men $11(\text{kg}) + 10.2(\text{cm}) - 5.8(\text{yr}) - 1032$
2. Harris Benedict, 1919: Women $655 + 9.5(\text{kg}) + 1.9(\text{cm}) - 4.7(\text{yr})$
 Men $66 + 13.8(\text{kg}) + 5(\text{cm}) - 6.8(\text{yr})$
3. WHO formulae (FAO/WHO/UNU, 1985)

Gender	Age range	Equation
Men	18-30	$(15.3 \times \text{kg}) + 679$
	>30-60	$(11.6 \times \text{kg}) + 879$
	>60	$(13.6 \times \text{kg}) + 487$
Female	18-30	$(14.7 \times \text{kg}) + 496$
	>30-60	$(8.7 \times \text{kg}) + 829$
	>60	$(10.5 \times \text{kg}) + 596$

All these equations may overestimate or underestimate the actual energy expenditure of individuals. Thus, after the determination of energy requirements of each participant, adjustments to the energy intake may be needed during the study period. Research diets are usually planned to provide a range of energy

levels at set intervals, so that every subject will receive his/her specific energy requirement to keep the weight stable. The range will be determined by the maximum and minimum energy requirements of the subjects (Van Heel, 1995a).

It is, therefore, important to monitor weight on a continuous basis throughout the study period, for example twice a week. When measuring weight, factors such as the time of day, clothing, reliability of the scale and accessories should be taken into consideration. Daily fluctuations are likely to be fluid retention; however, continuous weight changes of 1% or more over 3-5 days will need careful investigation and may require change to a lower or higher energy level. Participants are also expected to keep their level of physical activity the same throughout the study period. Unit foods, food modules or complete foods are all terms used for food products that are utilised to change the energy level to the subsequent level to meet energy requirements of a subject (Lin *et al.*, 2003; Van Heel, 1995a). This can include food products such as bread rolls, cookies and muffins. These recipes for the baked products can be adjusted to provide the same nutrient composition as the total diet for all relevant nutrients and can, therefore, be eaten to increase energy levels without changing the composition of the diet (Van Heel, 1995a). The other alternative that can be used to increase or decrease the energy to the next level is by controlling portion sizes of the recipes between the required levels, for example in the NUT study.

After the diet prescription has been formulated and energy levels determined according to the need of all subjects, the next step is designing the menu. There are certain factors that need consideration that will help develop a menu that is accurate, practical and promotes compliance.

2.2 Step 2: Menu development

Participants in controlled feeding trials must consume all study foods and abstain from all other foods. In outpatient feeding trials with their strict dietary requirements and free-living conditions, compliance is a challenge to the participants and the research team (Diller, 1996). The acceptability and type of menu served to the participants will contribute to the success of the study. When designing the menu the subjects' characteristics such as age, culture, religion, work schedule and lifestyles should be considered and will affect the lenience towards compliance. The variety of foods that is included in the menu is also important and will affect the participant's adherence to the diet (Swain *et al.*, 1999). Windhauser *et al.*, (1999) reported that lack of variety and too much food contributed to half of the participants failing to eat a study food at least twice in the 8 week intervention period of the DASH trial. The choice of the length of the menu cycle may also add to the variety of the diet and participant satisfaction. In the DELTA programme an 8-day diet cycle was used, DASH used a 7-day diet cycle and in the NUT study a wide variety was provided with a 14-day diet cycle. With an outpatient controlled feeding trial the ideal would be that subjects consume most of their meals at the feeding site, however, this is not always possible and take away meals will need to be included in the menu. In the NUT study it was expected that participants eat at least one meal of a week day at the feeding site for direct observation, whereas the rest of the meals were provided in take-away format to be consumed at home or at work (Mukuddem-Petersen, 2005). This will have to be taken into consideration when selecting meals for the menu. All other meals that are arranged to be eaten at home or work should be easy to prepare, transport and store. Weekend meals should include foods that adapt to weekend patterns. In the NUT study pre-packed food parcels such as barbeque packs were provided to comply with the South African tradition of barbequing (Mukuddem-Petersen, 2005). In the DASH trial, commercially prepared entrees, such as frozen lasagna and pizza were provided to enhance compliance over weekends (Swain *et al.*, 1999). Another method used to

improve adherence is the “Free Point or Free choice” system. In the NUT study, 10% of the total energy intake was calculated in the form of “Free Points” to be eaten daily. Participants received a list of foods with an associated number of points. Participants thus had the freedom of choice from this list everyday as long as the total number of points added up to the prearranged number of points for the respective energy level for that day (Mukuddem-Petersen, 2005). In the DASH trial and DELTA programme, a number of servings of soft drinks and coffee or tea were allowed as well as alcoholic beverages. In addition breath mints, sugar free gum and selected spices were permitted (Dennis *et al.*, 1998; Swain *et al.*, 1999). In the DELTA programme, a self selected Saturday night meal that met the guidelines of the National Cholesterol Education Programme step 1 diet was allowed, this enhanced the long-term compliance (Dennis *et al.*, 1998).

For the menu to be accurate, similar foods for the different dietary groups should be procured and standardised preparation procedures should be set. The variability in composition of unprocessed or raw foods and nutrient changes resulting from different cooking methods can cause nutrient intake to differ from the planned diet prescription. Many natural and processed foods vary with season, lot number and brand name. It is thus advisable to purchase single lot foods centrally for targeted nutrients to limit the nutrient variability. In the DASH trial all sources of fat and cholesterol were purchased in single lots and then transported to the different feeding sites (Swain *et al.*, 1999). For the other food products standardised specifications should be stipulated and can then be procured locally at different sites. Food specifications should include a description of the food product, brand name, size and packaging as well as amount needed (Kris-Etherton *et al.*, 1996).

When designing a menu it should be practical. Menus should be planned to utilise the seasonal abundance of specific food items fully. The food choices used in the menu should take into account the local and seasonal availability of

food products. Thus, the knowledge regarding fruits and vegetables and their seasons enables a planner to include the best quality in the menu and to pay the most affordable price. The equipment and kitchen facility used should also be taken into consideration. The menu planned for any given day must be one that can be produced in the available work space with the equipment (Payne-Palacio & Theis, 2001:96-97). The inclusion of too many foods at one meal that require the same equipment can cause an overload or complicate production schedules. Storage space, for example refrigerator and freezer space should also be considered when planning the menu and purchasing food products. The availability and skills of the personnel may also affect the complexity and variety of the menu. Workloads should be spread evenly throughout the day. Properly planned menus increase the productivity and quality of the service (Payne-Palacio & Theis, 2001:96-97).

Developing a menu that promotes adherence by the participants, that meets the study diet prescription and is practical can be achieved if all of the above mentioned factors are taken into consideration. The use of a computerised nutrient database can assist the research dietitian in meeting these goals. Step 3 involves the selection of the most appropriate nutrient database for this challenging task.

2.3 Step 3: Database selection

The number of computer software programmes for use in nutrition and dietetics has increased markedly. Several programmes are available for rendering different nutrition services but one of the most important applications of computer technology is the computerised nutrient intake analysis (Lee *et al.*, 1995). Computerised nutrient analysis plays a critical role in the practice of dietetics and nutrition research. Not only does one rely on nutrient analysis systems for the assessment of dietary intakes of individuals and groups, but it is also part of the development of carefully controlled menus for feeding studies (McCullough *et al.*

1999). It is the research dietician's task to determine the correct types and proportions of foods needed to achieve diets that attain these study goals. Choosing the best system is important but it is complicated by the large availability of programmes as well as differences in the quality of each programme's database and operating features (Lee *et al.*, 1995). As mentioned previously the two important considerations when selecting a nutrient database are the reliability of the database and the functionality of the programme (Stumbo, 1996).

Under functionality the programme features of software programmes that are important to researchers include the ease of data entry and analysis, software functions that facilitate calculation of diets, data export systems, the ability to assign volume and weight measures to food items, ease of editing the food list and ability to print reports (Lee *et al.*, 1995; McCullough *et al.*, 1999). With reliability the nutrient analysis calculated by the nutrient database should be accurate and as close as possible to the chemical analysis. Both aspects are important but the reliability of the data is most important as inaccurate data would result in the research objective not being achieved (Stumbo, 1996).

The accuracy can be influenced by many factors namely, the source of nutrient information, the number of foods and nutrients included in the database, completeness of the database and the frequency of updating the programme. Generally the food component database contains estimates which represent the approximate nutrient content of a food sampled across national or regional supply. The most used source of nutrient information for database manufacturers is the United States Department of Agriculture (USDA) National Nutrition Database (NNDB). This provides means of food compositions across varieties, brands, seasons, growing conditions and locations. Thus, these are only estimates of the nutritional content of foods and the variability in the food supply will have an impact on the accuracy of data displayed (McCullough *et al.*, 1999). It is, therefore, important to use the same brand and lots when planning and

producing the menu. The use of a nutrient database that is mainly based on the USDA NNDB outside of the United States may also influence the reliability of the data due to the natural change of food composition across countries. Thus, it is recommended that if a local nutrient database is available that includes the specific country's food composition values, it is chosen above a USDA NNDB based nutrient database to decrease the factors contributing to the deviation between the chemically analysed values and the nutrient database values (personal experience from the study reported in Chapter 3).

Developers of dietary analysis software will continue to be challenged by the change in food products, new product introductions, new ingredients and technologies as well as consumers changing their food habits and behaviours. In the United States during the middle 80's, 6000 new foods were introduced annually and it increased to 13000. It is thus expected that software programmes be updated yearly to keep the data up to date (Lee *et al.*, 1995). However, with the frequent changes in the nutrient content of processed foods they sometimes still lag behind (McCullough *et al.*, 1999). This trend has led to many databases being incomplete meaning that partial data is added to the database, for example, a manufacturer of a new product may only analyse for the nutrients required on the label, thus only this information will be available when the food is added to the database. This contributes to a database being incomplete. This information on the completeness is, however, difficult to obtain so the user must beware of this possible inaccuracy (Stumbo, 1996).

Selecting the most appropriate computerised nutrient database to meet the needs and objectives of the user requires careful consideration. Buzzard *et al.* (1991) published questions to consider in evaluating a nutrient database. The following six questions can be used as a guide to evaluate the nutrient database:

1. Does the database contain all of the foods and nutrients of interest?
2. Is the database complete for the nutrients of interest?

3. Do the foods included in the database provide adequate specificity to accurately assess the nutrients of interest?
4. Is the nutrient database kept up to date with the changing marketplace and the availability of new nutrient data?
5. Are manufacturers contacted routinely for new information of existing products?
6. What quality control procedures are used to ensure the accuracy of the nutrient database?

The only two available computerised nutrient databases in South Africa are FoodFinder3® (Medical Research Council of SA, Tygerberg SA) and Dietary Manager 2005 (Modified 2006, Scharf, Programme Management, Johannesburg, South Africa). These databases are both primarily including USDA NNDB data. Dietary Manager contains a total of 7748 foods and 77 nutrients. Its main source of information is the USDA composition data (7146 foods), where 200 South African foods' analysis have been added through the use of product labels. These include fortified maize products such as breads and flours. The food descriptions have been changed to South African English in order to ease the data entry. These food names are used to find food codes and to use when entering data. The programme runs on MS Dos and can be exported to MS Word (oral communication with Oskar Scharf, Programme Management, Johannesburg, South Africa). FoodFinder3® (2002) data is based on the South African food composition database where 41% of the foods in the database have South African analysed values as main reference source (Sayed *et al.*, 1999) thus, being more South African than the above mentioned. The rest of the data is mainly obtained from the USDA NNDB 1998. Other sources of information include McCance and Widdowson 1991, scientific publications, food industry data as well as chemical analysis. The programme runs on Windows. Both of these software programmes were functional and assisted the research dietician in developing the menu (personal experience from the study reported in Chapter 3). The research dietician must choose which nutrient database to use that will

assist him/her the best in menu development taking into account programme features as well as the reliability of the database.

After the most appropriate nutrient database has been selected according to the above mentioned questions, the process of data entry into the nutrient database follows. Data entry contributes to the reliability of the data and the research team should recognise the importance of this step in the process of menu design.

2.4 Step 4: Entering the menu into the database to calculate the nutrient composition of menus

The first consideration is the importance of identification of food products and substitutions used for a product. Substitutions should be closest to the nutrient content of the actual food product available for use. Foods used in controlled feeding trials include unprocessed items, processed foods, fresh, canned, dried, frozen and mixed dishes or recipes. Computerised databases usually provide a specific description to the user when selecting a food product. It is thus important to make the right decision as the nutrient content differs between the options. Another consideration is the use of composite recipes. The menus are not restricted to single food items but also contain combinations of foods from simple to complex recipes (Vasilopoulou *et al.*, 2003). It is thus important to compare the composite recipes available on the software programme with the planned recipe that will be used with the feeding trial. If the nutrient content differs it is best to enter the raw ingredients and amounts used for that specific recipe into the database using the recipe function on the programme. The amount of moisture lost from raw to cooked food products then needs to be corrected. This calculation is important as cooking methods can lead to moisture loss and thus a change in concentration of nutrients. All food products raw weight and cooked weight need to be recorded during the preparation. The total day's moisture loss is then determined by subtracting the total cooked weight from the total raw weight for the day. The ratio between the two weights is then determined and used to calculate the actual nutrient concentration taking into account the

moisture loss for the day (personal experience from the study reported in Chapter 3). Care should be taken to ensure that foods used in the diet composites are identical to the foods prepared, served and consumed by the study participants and are handled in a manner to optimise subsequent analysis of nutrients of interest.

These four steps will proceed to a designed menu with calculated nutrient composition from the chosen computerised nutrient database. The next step includes validation of the menu. Chemical analyses are used to verify that diets consumed by study participants meet the nutrient specifications dictated by the study design.

2.5 Step 5: Chemical analysis

The calculated nutrient composition of the menu needs to be validated by chemical analysis before the trial starts because food tables, as mentioned previously, provide estimates only and the nutrient composition of individual food items can vary from database values (Most, 2003; Swain, *et al.*, 1999).

Food products are complex mixtures that contain nutrients of organic (lipids, proteins, carbohydrates, vitamins) and inorganic nature (water, minerals, oxygen). Analysis of food products is mainly aimed at the determination of nutritional value and content of the food sample. In the last decade chromatography (gas chromatography (GC)), high performance liquid chromatography (HPLC), and supercritical fluid chromatography (SFC) and capillary electrophoresis (CE) have been largely used in the analysis of food products. Because of the complexity of the food matrices a sample preparation step is usually included before the actual analysis process is done (Mondello *et al.*, 2002).

Chemical analysis needs to be conducted before the feeding trial begins in order to have time to adapt the menu if the need arises. It is not practical to analyse all the energy levels due to the time and cost involved in chemical validation. Only one or two energy levels can be selected to be analysed chemically (Phillips *et al.*, 1999). Food procurement should be done according to the specifications. The menus must be prepared in the research kitchen using the standardised recipes, preparation methods and precision weighing to minimise variability. The key nutrients to be analyzed should be determined by the research team, but it usually includes the macronutrients (protein, carbohydrates and fats) and if important for the specific study hypothesis, certain micronutrients that need to be controlled for.

Daily samples of the food prepared for one individual at a specific energy level should be collected and homogenised. The aliquots of the daily samples should be stored at -80°C until ready to be transported or shipped to the designated laboratory. Some laboratories request samples to be in freeze-dried form. It is important for the reliability of the chemical measurements that investigators are educated on analytical methodologies required for the analyses and that analytical results are accompanied by quality control results (Holden, 1995).

After the menu has been validated by chemical analysis and the required changes have been made to the menu, it should be evaluated for sensory acceptance.

2.6 Step 6: Menu evaluation, sensory palatability and menu selection.

Palatability of meals in controlled feeding trials is important because participants can only consume the foods provided and no other foods. Thus, menu evaluation is an important part of menu planning and should be an ongoing process. The menu as planned should be reviewed prior to its use. This can be done through sensory evaluation prior to the trial. If more than one menu has been planned this

evaluation can also be used to decide which menu to use (Swain *et al.*, 1999; Payne-Palacio & Theis, 2001:105).

The following check list can be used for menu evaluation:

1. Does the menu meet nutritional specifications according to the study hypothesis and protocol?
2. Are the in-season foods that are offered available and within the available budget?
3. Do foods on the menu offer contrasts in colour, texture, flavour, consistency, shape or form?
4. Can the foods be prepared with the available equipment and number of personnel available with appropriate skills?
5. Are the workloads balanced for the equipment and personnel?
6. Is any one food item or flavour repeated too frequently during the menu cycle?
7. Are the meals made attractive with suitable garnishes?
8. Will the meals served be acceptable to the participants? (Payne-Palacio & Theis, 2001:105).

The DASH trial conducted sensory evaluation on 11 to 17 entrees or side dishes. Non-professional tasters similar to the DASH study population rated each food on a 9-point hedonic scale (1=very undesirable, 5=neither desirable nor undesirable, 9 = very desirable). They evaluated the food according to the appearance, aroma, texture, flavour and overall acceptability. Menus were also evaluated for ease of production (complexity of recipes), food availability (seasonal and geographic), nutritional composition according to chemical analyses and cost. Field dieticians then ranked the menus. The menus with the lowest scores were then discarded (Swain *et al.*, 1999).

The chemical analysis and sensory evaluation of the menus will lead to Step 7. This step includes the final adjustments that may enhance accuracy and the palatability or presentation of meals without changing the nutrient composition.

2.7 Step 7: Adjustments of menu that will not affect the nutrient composition

Final adjustments of the menus according to sensory testing can be made to enhance acceptability, ease production and standardise procedures. Herbs can be added or dishes can be distributed differently on a specific day in order to enhance the palatability. These changes should not affect the nutrient composition (Swain *et al.*, 1999). If the chemical analyses results differ from the study nutrient requirements, menu changes should be made in order to ensure the accuracy of the menu. Many changes to the menu may lead to repeating the chemical analysis.

2.8 Step 8: Participants recruitment, orientation programme and the run-in period

Participant adherence to the research diet is critical to the success of the study. As mentioned before, well controlled feeding approaches require that subjects consume only foods that have been precisely formulated and prepared in a research kitchen. However, the free-living conditions complicate the adherence to the strict dietary requirements of a controlled feeding trial. Screening for the “perfect” participant, orientation sessions, having a run-in period for subjects to familiarise themselves with the feeding protocol and using motivational and educational techniques during the intervention trial will advance successful participant adherence (Windhauser *et al.*, 1999).

During the recruitment phase the potential participants should be screened in order to enhance participant adherence to the demands of the study. In the DASH study the screening process was divided in three steps. With the first

screening the participants had to complete a general dietary questionnaire. Information such as food allergies or any personal food dislikes that could add to difficulty in adhering were identified. With the second screening step a food frequency questionnaire was completed in order to obtain an idea of the participant's food habits and patterns. Those participants still eligible were then asked to indicate on a study food list which study foods he/she will not be able or are unwilling to consume. Other information gathered included the eating environment, possible transport, storing and reheating problems. Any activities like birthdays, holidays or change at work that may occur during the study were identified. Study dietitians then reviewed this information in order to recruit the "perfect" participant for the study (Windhauser *et al.*, 1999). With the DELTA programme potential participants were shown a complete set of menus. They also participated in a 3-day pre-randomisation trial of the experimental diet protocol during which those not able to comply could resign (Dennis *et al.*, 1998).

After the screening sessions the eligible participants should attend an orientation session. The participants should be informed of the monitoring and compliance expectations, the study purpose, implementation and crucial role of the participant. Participants should also be provided with adherence guidelines. These guidelines should state information regarding limitations of any foods or beverages, restrictions on use of medication, feeding site attendance, study programme and routines as well as expectations not to change physical activity level throughout the study (Van Heel, 1995b).

Following the selection of the eligible and interested candidates, a diet *run-in* period should be used to allow chosen individuals to experience the feeding centre atmosphere, menus, limitations and expectations. Individuals will then be evaluated regarding the degree of commitment to the study feeding protocol (Van Heel, 1995b). Subsequent to the run-in period the study intervention will start. Food production and delivery of the carefully designed menu will determine the success of the controlled feeding trial.

Step 9 describes the factors to consider when procuring, preparing and delivering the menu.

2.9 Step 9: Production and delivery of menu

2.9.1 Procurement

The guiding aim of procuring foods for research diets is to meet the nutrient specifications of the experimental diets and to minimise the nutrient variability. Today's market offers a large variety of products from which well-informed selections must be made. As mentioned in Step 2 the procurement of food products for the production of the research diets should be done using product specifications to ensure accuracy of the menu's nutrient composition by minimising the nutrient variability, especially in target nutrients. First, a list of all the food products needed should be compiled. Then the specifications should be written. A description of the food product, brand name, size, type of packaging and amounts needed must be included in the specifications (Kris-Etherton *et al.*, 1996). The quantities of food needed for production of the planned menus are identified from the menus and from the recipes used to prepare them. Then a purchase order can be developed (Payne-Palacio & Theis, 2001:119). It is also advised to purchase single lot foods centrally, or to buy from the same provider throughout the research trial for those food products containing targeted nutrients in order to limit the nutrient variability. Another approach used to minimise the nutrient variability is the procurement of all food sources that are needed for the whole study a few weeks before the study begins all at the same time. In the case where the food products' shelf life is shorter than the duration of the study, procurement can be done more than once during the trial to ensure food product freshness and quality (Kris-Etherton *et al.*, 1996).

2.9.2 Food deliveries

Before delivery it is important to identify and specify the exact area where foods should be delivered. The availability of appropriate storage space should also be considered. Most bulk food vendors pack food in large quantities that are difficult to handle, thus the size of packages needs to be specified. When food products are delivered at the research kitchen a specific, competent, well-trained person must receive the foods and ensure that the foods match the established quantity and quality specifications (Payne-Palacio & Theis, 2001:155).

2.9.3 Food production

Food production procedures must be standardised. All procedures should be defined, written down, and followed by the entire staff in exactly the same manner. This includes preparation methods, cooking times, temperature used and careful weighing of all ingredients. To achieve nutrient consistency, ingredients and foods should be weighed on an electronic scale. Guidelines for weighing vary, however, foods >10g may have a variance of 0.5g and food <10g a variance of 0.1g (Swain, 1996). Batch recipes can be developed in order to maintain uniform composition. This allows all ingredients to be proportionately mixed and dispensed. Commercially available portion control packages of syrup, jelly, and condiments can be used where possible. This will help reduce labour and staffing. The use of fresh fruits and vegetables are often avoided because of the difference in nutrient composition. However, if it has little effect on the nutrients being studied it can be provided. Depending on the elements studied, distilled water will at times be necessary (Swain, 1996).

2.9.4 Attractive and tasty meals

When designing research diets researchers focus more on the specific nutrient requirements than on flavour and appeal of the foods. These diets are usually

restricted in fat and sodium that also result in reduced palatability. Thus, the research dietician will have to use more herbs, spices and different cooking techniques in order to maintain the flavour and appeal while adhering to the nutritional specifications (Patrick, 1997).

2.9.5 Emergency situations

A contingency plan is advisable. For the locally procured food products a second vendor and brand name should be identified in cases where a problem develops with the provisioning. For centrally procured foods the storage and handling should be monitored. If possible the stock of the same product can be divided between different storage units in order to decrease the risk of losing all stock when temperature control fails in one unit. Back up power supplies should be ready in case of power failure and emergency meals must be available (Kris-Etherton *et al.*, 1996).

Participant emergencies or obligations that can interfere with scheduled meals should be planned for. In the DASH trial one emergency menu was designated for each dietary group. This consisted of a complete day's food intake. It was prepared, packaged and given to participants at the beginning of the feeding period. These meals were only consumed when approved by the DASH dieticians (Swain *et al.*, 1999).

2.10 Step 10: Monitoring of adherence

Promoting, documenting and monitoring adherence are necessary throughout the intervention period. Approaches of evaluating the compliance in a controlled feeding trial can be objective or subjective (Windhauser *et al.*, 1999).

Objective methods include collection of urine, stool and blood samples. The biological markers used to measure dietary adherence include urine excretion of

electrolytes, urea nitrogen and urine osmolality as well as blood levels of fatty acids and some vitamins and minerals. Body weight monitoring also gives an indication of compliance and should be measured weekly. These methods can be used in order to determine the general group adherence. It may, however, be invasive for some participants. Another method used is direct observation during one meal per day at the feeding site, staff confirmed meal attendance and complete consumption of the meal provided. Waste containers should be removed from the dining area to prevent omission of food or containers. Individual spatulas or bread may be provided at each meal to facilitate the consumption of gravies, sauces, oils and remnants of food remaining on plates or in containers (Van Heel, 1995b; Windhauser *et al.*, 1999). Tray checks were also conducted after meals were eaten in the DELTA programme and daily food record check sheets were used to verify that each participant received the correct diet and that it was consumed (Dennis *et al.*, 1998). The subjective methods include oral and written self reports. With these methods one has to rely on the honesty of every participant. An example is the use of daily food diaries, all study foods, non-study foods and beverage intake should be recorded by the participants themselves (Windhauser *et al.*, 1999). In the NUT study information regarding use of medication, changes in activity level, or any other information relating to compliance was also included in the diaries. These diaries were reviewed by the investigators during the study (Mukuddem-Petersen, 2005:50).

Further evaluation of compliance is dependant on participant contact with study staff. Any questions, problems or concerns should be discussed regularly. Participants should be encouraged and counseled daily to reinforce protocol issues. Deviations from the protocol should be handled discreetly with a sincere understanding of the situation. Counseling regarding alternative future adherence behaviour will improve adherence in the future. Training staff in motivational interviewing techniques will add to improved motivational communication and trust. Weekly newsletters, parties, t-shirts, contests and invitations to bring a friend to dinner adds to the fun and increases the compliance to the study

protocol (Van Heel, 1995b; Windhauser *et al.*, 1999). Weekly newsletters and invitations to bring a friend to dinner were successful methods used in the NUT study to promote a positive attitude among the study participants.

3. Conclusion

The recommended methodology for menu design can be described in 10 steps. It will assist the research team to design and deliver accurate menus in order to conduct a successful controlled feeding trial.

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3

The process of nutrient analysis for controlled feeding trials: A comparative study of two South African nutrient databases with chemical analysis.

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ABSTRACT

Background: There is an increased tendency in the field of nutrition research to conduct more outpatient controlled feeding trials. The formulation of accurate diets is essential in order to assemble valid scientific data, which will substantiate hypothesised relationships between a nutrient variable and an outcome. Research dieticians rely on the accuracy of computerised nutrient databases when designing the menu.

Objective: The reliability of the two computerised nutrient databases available in South Africa were investigated, comparing them with each other and with the reference standard of chemical analysis.

Methods: A seven day menu providing an energy level of 7500kJ/day was entered into FoodFinder3® (2002) and Dietary Manager (modified 2006 version) Software programmes. Food prepared according to this menu was chemically analysed for the macronutrient profiles (carbohydrate, fat and protein), fatty acid distribution (saturated fatty acids, mono-unsaturated fatty acids and poly-unsaturated fatty acids) and total fibre, insoluble and soluble fibre in order to compare data.

Results: The two nutrient databases values did not differ significantly from each other, however, there were differences between the chemical analysed values and the databases calculated values for selected nutrients. There were no significant differences between the amount of total energy, protein, carbohydrate, poly-unsaturated fatty acids and total fibre. The total fat, saturated fatty acids, mono-unsaturated fatty acids content using both FoodFinder3® and Dietary Manager were statistically and practically significantly higher than the chemical analysis ($p < 0.05$). FoodFinder3® produced significantly lower levels of insoluble and soluble fibre compared to the chemical analysis.

Conclusion: The use of computerised nutrient databases in menu design for controlled feeding trials is functional and assists the research dietician with this challenging task. However, computer nutrient databases are not reliable enough to exclude the step of menu validation by chemical analysis before the start of the intervention.

KEY WORDS Controlled feeding trial, menu design, chemical analysis, nutrient database, diet validation, nutrient analysis.

Introduction

There is an increased tendency to conduct more outpatient controlled feeding studies in the field of nutrition research [1]. These controlled human feeding studies are used to test the diet-disease hypothesis [2]. It defines the relationship between dietary intake and changes in an outcome typically a risk factor for disease, metabolic parameters and health outcomes [1].

The formulation of diets that are accurate is essential in order to assemble valid scientific data which will substantiate hypothesised relationships between a nutrient variable and an outcome. This optimal control of experimental diets is achieved through the challenging task of menu design. Research dieticians use computerised nutrient databases in order to design these diets that meet the study protocol diet specifications [3, 4]. Two important considerations when choosing a database are the reliability of the data determined as well as the functionality of the programme. However, the most important aspect is the reliability of the data as inaccurate data would result in a research objective not to be achieved [5]. Researchers use chemical analysis to verify the diets consumed by study participants [6]. This is an expensive step in the execution of human feeding studies which may possibly be unnecessary if data presented by nutrient databases are accurate.

Limited data are available in the literature investigating the reliability of these nutrient databases using the criterion standard of chemical analysis. This need for more information, the cost associated with chemical analysis and previous experiences in conducting a controlled feeding trial [7] were the motivation to conduct this study in order to determine the reliability of the two databases available in South Africa, comparing them with each other and with the reference standard of chemical analysis.

Methods

Menu development

A seven day menu cycle providing an energy level of 7500kJ/day was developed according to balanced dietary principles [8]. The menu was planned to provide 35% of the total energy intake (%E) as fat, 17%E protein and 48%E carbohydrate (CHO) by using a combination of food groups and exchange lists [8]. The menu was based on a Westernised diet and consisted of commonly consumed South African meals. All foods were purchased locally according to set product specifications. The menu for 7 days was prepared in the research kitchen of the Department of Nutrition at the North-West University (Potchefstroom Campus), South Africa. See Table 1 for the seven day menu cycle developed and used. Standardised recipes were used and all portions were weighed to the nearest gram.

Database analysis of the menu

For this study the menu was analysed by the two available software programmes in South Africa namely FoodFinder3® (Medical Research Council of SA, Tygerberg, South Africa) and Dietary Manager, modified 2006 version (Scharf, Programme Management, Johannesburg, South Africa), that vary with the proportion of South African data and sources used. When the exact food product was not available on the database an alternative food closest to the nutrient content of the specific food was used. Recipes of baked goods were entered into the database, using the recipe function according to the listed raw ingredients and amounts on the recipe. A calculation was used to determine the amount of moisture lost through the baking process and the nutrient content was adjusted to be closest to the nutrient content of the cooked product. Recipes of the combined dishes were also entered into the database by using cooked ingredients. The results of the chemical analysis were only received after the period of data entry in the databases. The database analysis included all macronutrients, CHO, protein and fat as well as different fatty acid distribution,

specifically mono-unsaturated fatty acid (MUFA), poly-unsaturated fatty acid (PUFA) and saturated fatty acid (SFA). Total fibre was analysed in both the nutrient databases, however, soluble and insoluble fibre were only analysed by FoodFinder3®.

Chemical analysis of the menu

The macronutrient profiles (CHO, protein and fat), fatty acid distribution (SFA, MUFA and PUFA) and total fibre, insoluble and soluble fibre of the diet were analysed chemically to validate the diet composition. Portions of the 7500kJ diet's breakfast, lunch and supper (see Table 1) for the 7-day menu were collected daily, homogenised, pooled in a container and aliquots of the food were frozen at -84°C until the analysis was done. Carbohydrate (fructose, glucose, sucrose, lactose, maltose, total starch) [9] and non-starch polysaccharides (NSP) soluble and insoluble composition [10] of the diets were determined with the Englyst method by Englyst Carbohydrates Research and Services Ltd, Southampton, U.K. The data received represented g/100g of wet sample. This amount was then multiplied by the factor of 0.95 in order to convert the sugars to carbohydrates as in product labels. Protein and total fat were analysed by a general combustion method (AOAC Method 992.23) and acid hydrolyses (AOAC 935.39/948.15) respectively by Muller Laboratories-Analytical chemists, Paarden Eiland, South Africa. These protein and fat analyses were carried out in accordance with SANAS accredited test methods. Total energy (kilojoules) for each day was calculated using Attwater general factors of 17kJ/g for protein, 37kJ/g for fat and 16kJ/g for total carbohydrate [11]. Fatty acid analysis was done in triplicate using a GCMS as described below.

Fatty acid analysis

Briefly, 18-methylnonadecanoic acid (72mM), as an internal standard was added to 25µg of lyophilised food sample followed by 100µL of a 45mM solution of

butylated hydroxytoluene and 2ml methanolic HCL (3N). The samples were then vortexed and incubated for 4h at 90°C. After cooling to room temperature, the sample was extracted twice with 2 ml of hexane, dried under a nitrogen stream and finally re-suspended with 100µl of hexane, of which 1µL was injected onto the GCMS via splitless injection. An Agilent 6890 GC ported to a 5973 Mass Selective detector (Agilent, California, USA) was used for identification and quantification of individual fatty acids. For the acquisition of an electron ionization mass spectrum, an ion source temperature of 200°C and electron energy of 70 eV was used. The gas chromatograph was equipped with a SE-30 capillary column (Chemetrix, USA), a split/splitless injection piece (250°C) and a direct GC-MS coupling (260°C). Helium (1 ml/min) was used as the carrier gas. An initial oven temperature of 50°C was maintained for 1.5 min and then allowed to increase to 190°C at a rate of 30°C / min. The oven temperature was maintained at 190°C for 5 minutes and then allowed to increase to 220°C at a rate of 8°C / min. The oven temperature was again maintained for 2 min and finally ramped to 230°C at a rate of 3°C / min and maintained for 24 minutes at this temperature.

Calculations used for moisture loss adjustments

The amount of moisture lost from raw to cooked food products of each day was determined. This calculation is important as cooking methods can lead to moisture loss and thus a change in the concentration of nutrients. All food products' raw weight and cooked weight were recorded during the preparation. The total day's moisture loss was then determined by subtracting the total cooked weight from the total raw weight for the day, using all cooked and uncooked food products of the specific day. The ratio between the two weights was then determined and used to calculate the actual nutrient concentration taking into account the moisture loss for the day.

$$\text{Ratio} = (\text{Cooked weight of total day (g)} / \text{Raw, uncooked weight for total day (g)}) \times 100$$

$$\text{Reported nutrient concentration} = \text{Ratio} \times \text{Nutrient concentration calculated by database}$$

Statistical analyses

The computer software programme Statistica® (Statsoft.Inc, 2004, Tulsa, OK, USA) was used for the analyses of the data [12]. Data from the 7 days are expressed as medians and 25, 75 percentiles. Differences between the groups were determined using the Kruskal Wallis ANOVA for nonparametric data. Results were considered significant at the $p < 0.05$ level. When significance between the groups was indicated, a post-hoc test was done where two groups at a time were compared using the Mann Whitney U test in order to determine between which groups the differences occurred. The Bonferroni adjustment was done to maintain p at 0.05. Differences between the chemical analysis and FoodFinder3® for insoluble and soluble fibre were analysed using the Mann Whitney U test. For variables that differed significantly, practical significance based on effect sizes was calculated. Pearson's correlation coefficient r was used as an effect size measure, $r = \frac{Z}{\sqrt{n}}$ where Z is the approximate Z statistic and n is the total number of subjects. The following guidelines for interpretation of r were used: $r = 0.1$ a small effect, $r = 0.3$ a medium effect and $r = 0.5$ a large effect, where the large effect is seen as practical significant [13]. The effect size guides the researcher to decide whether a statistically significant difference between the means is in fact an important difference in practise [13]. Absolute differences were calculated between the software databases and chemical analyses for each specific day in order to determine which days contributed most to the differences.

RESULTS

Table 2 summarises the average macronutrient content for the 7-day menu per 100g of food sample, as analysed using the two software nutrient databases and by chemical analysis. The variables did not differ significantly between the two nutrient databases, however, there were differences between the chemical analysed values and the nutrient databases. The total energy, protein, CHO,

PUFA and total fibre content did not differ significantly between the different methods of nutrient analysis. The total fat, SFA and MUFA content using both FoodFinder3® and Dietary Manager were statistically and practically significantly higher than the chemical analysis. FoodFinder3® produced significantly lower levels of insoluble and soluble fibre compared to the chemical analysis.

Table 3 summarises the average macronutrient content expressed as percentage of total energy of the 7-day menu. The dietary specifications for the study were not achieved according to the results of the chemical analysis. The percentage of energy from total fat for the menu was lower with a value of 27.7% compared to the planned 35%. CHO resulted in a higher percentage with a value of 55.6% compared to the planned 48%. The nutrient database nutrient percentages of total energy were closer to the planned dietary specifications. The same differences as described in Table 2 are reflected in this table, except for % total fat (FoodFinder3® did not differ significantly from the chemical analysis) and %SFA (the two nutrient databases did not differ significantly from the chemical analysis).

Table 4 summarises the absolute differences between the two nutrient databases and chemical analysis for each day for all nutrients analysed. For total fat, SFA and MUFA the greatest deviation was seen on days 3, 6 and 7. Insoluble fibre deviated the most on days 5, 6 and 7 and soluble fibre on days 2, 5, 6 and 7.

DISCUSSION

This study contributes to the important research question regarding the reliability of computerised nutrient databases for the use of menu design in controlled feeding trials. Even though the accuracy of experimental diets for controlled feeding trials is of importance, limited literature is published on the validity of nutrient databases [14]. Menu validation by chemical analysis has been used in most trials to verify the estimated database nutrient content followed by

adjustments to the menus [15]. However, the cost associated with chemical analysis is high. Thus, if nutrient databases compared well with chemical analysis, repeats of this expensive and time consuming step would not be necessary. In the current study the macronutrient content of a 7-day menu was analysed using two South African nutrient databases and compared to the chemical analysis of the menu that was used as the standard reference. No significant differences between the two nutrient databases were seen. The two nutrient databases produced results similar to the chemical analysed values for energy, protein, CHO, PUFA and total fibre. However, total fat, SFA, MUFA, insoluble fibre and soluble fibre differed significantly, indicating overestimation of these databases for total fat, SFA and MUFA as well as underestimation for insoluble and soluble fibre by FoodFinder3®.

Both the databases, FoodFinder3® (2002) and Dietary Manager 2005 (modified 2006), are mainly based on the USDA NDB data, but vary with the proportion of South African data and sources used to add South African foods to the programme. Dietary Manager's main source of information is the USDA NDB (7146 foods), with 200 South African foods added through the use of product labels. These include South African fortified maize products such as breads and flours. FoodFinder3® (2002) data is based on the South African food composition database where 41% of the foods in the database have South African analysed values as main reference source [16] thus being more South African than the above mentioned. The rest of the data is mainly obtained from the USDA NDB 1998. Other sources of information include McCance and Widdowson 1991, scientific publications, food industry data as well as chemical analysis [11]. Even though the two programmes differed considerably with regard to the sources of information, the values obtained were similar between the two nutrient databases for macronutrients and fatty acid distribution investigated. As mentioned previously the functionality of the programme is also important in choosing a computerised nutrient database. Different features presented in the programme might influence the ease of utilization, such as name or code search, print/export

systems, number of food components, recipe entry and analysis, ease of editing the food list as well as comparing results with a variety of dietary recommendations [17]. Both the nutrient databases used in this study were found to be functional.

McCullough *et al.* [14] reported similar deviations between the nutrient database values and the chemical analysis for SFA, MUFA and protein as the current study. The deviations between the nutrient databases and the chemical analysis for CHO and PUFA's were smaller in the current study. McCoullough *et al.* [14] furthermore reported higher chemically analysed fat values than the database value which is in contrast to the current study. The similarities seen between the two studies can probably be related to the Westernised diet prescribed in the current study. Even though the menu included South African foods, most were available on the USDA based databases. These nutrient databases may, however, not be as accurate when using a true indigenous menu including foods like morog, mopanie worms and other root vegetables found in Africa which are not available on the USDA NDB. This issue highlights the importance of having an indigenous nutrient database that contains truly South African foods and values.

Some comparative studies where the nutrient database values were compared to the hand calculated values from the USDA NDB only entered basic food items and purposely avoided the use of recipes and combination foods not found in the USDA NDB as this increases the variation [17]. In the current study combination foods were included as people do not restrict their food intake to single foods but also combination of foods from simple to complex recipes [18]. In addition to this the menu included South African dishes such as Bobotie which were not available on the database or differed from the recipe used in the database. This may possibly explain the greater differences observed in fat values (total fat, SFA and MUFA) in the current study because on the days when the greatest variations were reported more meals from recipes (quiche, bobotie, pizza) were

included (see Table 1 & Table 4). Even though care was taken in the entering of the recipes to ensure consistency, use was not made of the composite recipes available on the software programme and raw ingredients and amounts used for the specific recipe were entered into the database and adjusted for the moisture loss during the baking process, we still observed greater variance. Another possible reason for the deviations observed in the total fat, SFA and MUFA values between the nutrient database and chemical analysis may be the variance found between the fat content of meat and meat products between South Africa (SA) and other countries. Sayed *et al.* [16] reported that the average South African beef carcass contains less than 13% fat and virtually no trimming is practiced, while beef carcasses in other countries on average have a fat content of more than 30% and fat is trimmed. This can be associated with the different breeding, feeding, production and fat trimming techniques in SA resulting in the unique nutrient composition of South African beef. Sayed *et al.* [16] reports specifically on the different values of visible intramuscular fat (marbling) found. In SA 1 to 2% is found while in the US marbling scores vary from 1.8 to 10.4%. In the FoodFinder3® database the beef values are based on South African products, however, USDA values are still used for mutton, pork and some meat products such as sausages. On day 3, 6 and 7 the greatest deviations were observed and were the days where grilled pork chops, sausage and lamb chops were served. Thus it can be associated with the possible difference of fat content in these meat products between SA and US as already observed with beef products.

Differences observed in the current study in the values of soluble and insoluble fibre can be directed to the lack of information in the computerised nutrient database. According to the joint FAO/WHO expert consultation on CHO in Human Nutrition (1997), the terms of soluble and insoluble dietary fibre or NSP should gradually be phased out because of a lack of clear distinction in analytical methodology and physiological effects. Due to this, data were not included on soluble, insoluble or NSP in the FoodFinder3® database [19]. According to the

EC Community Bureau of Reference the method of Prosky (AOAC, 1990) as well as the Englyst chemical procedure (1994) have been widely accepted for the determination of dietary fibre [20]. However, differences have been reported between these methods for total dietary fibre as well as soluble and insoluble fibre. Reasons documented were the difference in definitions and constituents used for dietary fibre as well as the pH used for separation into soluble and insoluble fibre and extraction of the soluble fibre [20]. The results found in the current study emphasize that for some nutrients the nutrient databases are incomplete. It is thus important that the research team determine beforehand possible missing values for key nutrients. Information on the specific nutrient needs to be added to the database particularly in the case of a study focusing on insoluble and soluble fibre.

Other possible reasons that could lead to differences reported between chemically analysed values and databases calculated values include the natural variation in nutrient content of food products as well as different factors associated with the software nutrient databases. Most food composition data available on databases are based on chemical analyses of food products. This data provides the mean values of food products' nutrient content across different varieties, seasons, growing conditions, year round availability and locations. Differences may occur in the chemical analyses, as this represents a specific variety or brand [21]. Thus, these are only estimates of the nutritional content of foods and the variability in the food supply will have an impact on the accuracy of data displayed [14]. Other differences may be due to processing and preparation methods of foods. Nutrient database factors that may contribute to the variance include the continuous development of new products, the change in nutrient content, new ingredients and technologies. Thus, developers of these dietary analysis software programmes will **always** be challenged to keep up to date [22]. A manufacturer of a new product may **also** only analyse for the nutrients required on the label, so only this information **will** be available when the food is added to the database. Thus, even though **software** database developers have regular

updates they may still lag behind and be incomplete. This information on the completeness, is however, difficult to obtain thus the user must be aware of this possible inaccuracy [5].

One might argue that even though the chemical analysis is seen as the criterion standard, some limitation through potential errors may add to uncertainty about the analysed values. McCullough *et al.* [14] reported these critical risk factors to be sample collection, method of homogenising, storage and handling, skills of the analyst and methodology used. In this study the chemical analysis was done by accredited laboratories and AOAC standardised methods for the analysis of specific nutrients were used. Additionally, the fatty acid distribution and total fat content that were analysed with different methods by two different laboratories, showed the same trend, highlighting that the fat was measured correctly.

In summary, the results found in this study show comparable accuracy in energy, protein, CHO, PUFA and total fibre values between the nutrient databases and the chemical analysed values. However, total fat, SFA, MUFA, insoluble fibre and soluble fibre significantly differed, indicating overestimation of these databases for total fat, SFA and MUFA as well as underestimation for insoluble and soluble fibre. The main factors that could have contributed to the differences observed in the current study include the use of recipes and combination dishes not available on the database, even though correcting for moisture loss during the cooking procedures; using nutrient databases that are not truly indigenous (in the current study meat products that differ between countries were of particular concern) and missing values or incomplete data in the nutrient database on key nutrients analysed. To decrease these deviations certain considerations should be kept in mind. It is important to compare the composite recipes available on the software programme with the planned recipe that will be used with the feeding trial. If the recipe content differs or it is not available, it is best to enter the ingredients and amounts used for that specific recipe into the database using the recipe function on the programme. When entering baked products, recipes' raw ingredients

should be entered and the amount of moisture loss during the baking process should be determined and used to adjust the nutrient content. Limit the use of complex recipes to the minimum or if possible analyse those key recipes chemically, especially those recipes that may lead to large deviations. It is also essential to select the most appropriate computerised nutrient database to meet the needs and objectives for the specific trial. If available, a local database that includes indigenous foods' nutrient content should be used, especially when developing a more traditional diet. To exclude the factor of missing values or incomplete data, the completeness of targeted nutrient values in the database should be confirmed by the researcher and if incomplete, data should be added by using other sources of information. These factors and guidelines should be taken into consideration since accurate formulation, production and delivery of research diets are major components in assuring scientific integrity of a controlled feeding study [4].

From the results in this study it could be recommended that chemical analyses should first be done in order to validate the data before conducting a controlled feeding trial. This study also verifies the need to conduct more such studies using the criterion standard of chemical analysis as the standard reference, due to the limited information published in the literature. Additional information on this subject will identify other possible reasons for deviations in order to take future precaution. It will assist the research team by providing suggestions to follow for menu design and nutrient analysis, therefore, diminishing trial and error experiences. The nutrient database analysis is usually the first step to test if the menu meets the study specifications. Chemical analysis is an expensive and time consuming procedure and if analysis presents with different nutrient content than planned, adjustments to the menu will follow and a possible repeat of the chemical analysis for verification, adding to the costs of the trial.

To conclude, the use of computerised nutrient databases in menu design for controlled feeding trials is functional and assists the research dietician with this

challenging task. However, computer nutrient databases are not reliable enough to exclude the step of menu validation by chemical analysis before the start of the intervention. The results of this study helped to identify some of the factors responsible for the observed differences between the nutrient databases and the chemical analysis.

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Table 1: Seven day menu for 7500kJ diet.

Mealplan	Day1	Day2	Day3	Day4	Day5	Day6	Day 7
BREAKFAST***							
Cereal/Porridge	Oats porridge 60g	Soft cooked maize porridge 60g	Oats porridge 60g	Corn Flakes 60g	Weet Bix 60g	All Bran 60g	Stiff cooked Maize porridge 60g
Milk, full cream	500ml	500ml	500ml	500ml	500ml	500ml	500ml
Sugar	10g	10g	10g	10g	10g	10g	10g
Bread	1 slice	1 slice	1 slice	1 slice	□	1 slice	1 slice
Margarine	8g	16g	8g	8g	8g	8g	8g
Jam/Filling	10g	10g	10g	10g	10g	10g	10g
	Unbelievable muffins	Croissants	Whole wheat Rusks	Scones	Raisin muffins	Unbelievable muffins	Whole wheat rusks
Side dish	60g	35g	2x20g	60g	60g	60g	2x20g
Fruit juice	125ml	125ml	125ml	125ml	125ml	125ml	125ml
LUNCH ***	Day1	Day2	Day3	Day4	Day5	Day6	Day7
Starch	Mashed potato 180g	Yellow Rice 50g	Potato 90g	Tasty Rice 50g	Corn on the cob 80g	Hotdog 40g	Porridge 100g
Protein	Mince balls 2x50g	Bobotie 170g	Grilled Pork chops 150g	Grilled Chicken 65g	Beef Pot Roast 100g	Beef Sausage 70g	Barbeque Lamb chops 90g
Gravy	Tomato & Onion 60g	Chutney 20g		Sweet & Sour 50ml	Meat gravy 60ml	Tomato, mayonnaise & Chutney 10ml	Tomato & Onion 60g
Vegetable A	*Mix Salad 70g	Tomato slices 80g	Cole slaw 80g	Cauliflower 80g	Broccoli 75g	*Mix salad 70g	Cole slaw 80g

Vegetable B	Sweet Peas 170g	Green beans 160g	Butternut with cinnamon sugar & margarine 200g	Carrots 75g	Sweet pumpkin 100g	Beetroot salad 100g	Carrot salad 80g
Fruit	Apple 100g	Banana salad 75g 8g mayonnaise		Apple 100g	Pear 100g	Pear 100g	-
Pudding			Fruit salad 100g				Chocolate Pudding 50g
Sauce			Custard 50g				Custard 50ml

SUPPER ***	Day1	Day2	Day3	Day4	Day5	Day6	Day7
Starch & Protein	Macaroni & Cheese 230g	Haddock roll 100g	‡Quiche 100g	Hamburger 75g patty Bun with 16g margarine	Whole wheat roll (60g) with Tuna salad 100g	Italian roll (40g) with **pizza filling 150g	Quiche 100g
Vegetable/Salad	Cucumber slices 120g	Carrot & Orange salad 80g	*Mixed salad 70g	Mixed salad for Burger50g	Cucumber slices 40g	†Banana salad 50g	Tomato slices 80g
Fruit juice	125ml	125ml	125ml	125ml	125ml		125ml

*Mixed salad: Lettuce, tomato, cucumber

†Banana salad: Bananas, low-fat yoghurt, coconut

‡ Quiche: Margarine, wheat flour, leavening agents, salt, milk, egg, cheese, pepper, onions, bacon, vienna

**Pizza filling: Baked beans, margarine, onions, green peppers, garlic, tomatoes, pumpkin, bacon, cheese

Table 2: Average daily macronutrient content, determined by chemical analysis and two computerised South African nutrient databases ^a.

Nutrient (100g wet food sample)	Chemical analysis	Food Finder	Dietary Manager
Total energy (kJ)	403 (386, 452)	486 (428, 489)	465 (397, 467)
Protein (g)	4.40 (3.22, 5.09)	4.22 (3.92, 4.47)	4.10 (3.98, 4.32)
Carbohydrate (g)	12.6 (11.2, 14.9)	12.3 (11.4, 14.6)	13.5 (12.0, 15.9)
Total fat (g)	2.96 (2.73, 3.16)	*†3.98 (3.56, 5.18)	*†3.53 (3.49, 4.59)
SFA (g)	1.09 (1.01, 1.11)	*†1.39 (1.28, 1.84)	*†1.29 (1.25, 1.68)
MUFA (g)	0.45 (0.39, 1.11)	*†1.10 (0.91, 1.60)	*†1.24 (1.19, 1.65)
PUFA (g)	0.72 (0.66, 0.79)	1.08 (1.01, 1.12)	0.82 (0.66, 0.86)
Total fibre (g)	1.00 (1.00, 1.50)	1.06 (0.81, 1.93)	0.89 (0.82, 1.91)
Insoluble fibre (g)	0.60 (0.40, 1.00)	*0.37 (0.3, 0.52)	NA
Soluble fibre (g)	0.50 (0.50, 0.60)	*0.33 (0.23, 0.35)	NA

Variables expressed as median (25, 75 percentiles)

^a The two databases used were FoodFinder3® and Dietary Manager

* Significant differences between nutrient database and the chemical analysis, adjusted p-value for multiple comparisons - $p < 0.05$.

† $r > 0.5$, large effect, significant in practice.

NA= Not analysed

Table 3: Average daily nutrient content expressed as percentage of total energy, determined by chemical analysis and two computerised South African nutrient databases ^a.

Nutrient (% total energy per day)	Chemical analysis	Food Finder	Dietary Manager
Protein	16.4 (15.2, 21.7)	15.1 (14.4, 17.3)	16.0 (14.0, 18.0)
Carbohydrate	55.6 (54.2, 57.3)	51.9 (49.2, 55.1)	52.0 (51.0, 54.0)
Total fat	27.7 (25.7, 29.0)	33.5 (29.2, 35.1)	* [†] 33.0 (31.0, 36.0)
SFA	10.1 (8.6, 11.1)	12.3 (9.7, 13.0)	12.0 (10.0, 13.0)
MUFA	3.8 (3.4, 4.3)	* [†] 9.2 (8.0, 12.0)	* [†] 12.0 (10.0, 13.0)
PUFA	6.34 (6.22, 6.77)	8.53 (6.77, 9.32)	6.00 (6.00, 7.00)

^a The two databases used were FoodFinder3® and Dietary Manager

* Significant differences between database and chemical analysis, adjusted p-value for multiple comparisons - $p < 0.05$.

[†] $r > 0.5$, large effect, significant in practice.

Table 4: Absolute nutrient deviations for each day of the two computerised South African nutrient databases from the chemical analysis ^a

Nutrient per 100g	FoodFinder3®								Dietary Manager							
	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Total	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Total
Total energy (kJ)	26.8	52.9	41.6	34.0	59.1	80.8	84.4	83	16.9	21.6	10.4	12.6	37.0	55.8	62.8	62
Protein (g)	0.74	1.25	-1.29	0.10	-1.17	-0.25	-0.27	-0.18	0.90	1.10	-1.28	-0.08	-1.14	-0.37	-0.42	-0.3
Carbohydrate (g)	-1.05	-0.69	0.17	-0.70	1.38	-0.38	-0.30	-0.3	0.16	-0.27	0.79	-0.66	2.72	1.02	0.87	0.9
Total fat (g)	0.47	0.82	1.24	0.72	0.83	1.79	2.22	1.02	0.44	0.37	0.71	0.85	0.76	1.65	1.63	0.57
SFA (g)	0.21	0.35	0.49	0.26	0.12	0.53	0.74	0.3	0.22	0.18	0.36	0.24	0.09	0.42	0.58	0.2
MUFA (g)	0.50	0.55	0.74	0.69	0.45	1.31	1.21	0.65	0.68	0.69	0.79	1.03	0.73	1.36	1.27	0.79
PUFA (g)	-0.06	0.39	0.51	0.33	0.37	0.2	0.52	0.36	-0.20	0.00	0.09	0.12	0.13	0.05	0.09	0.1
Total fibre (g)	0.00	-0.19	0.06	-0.04	0.43	0.32	-0.25	0.06	-0.20	-0.18	-0.13	-0.01	0.41	1.19	-0.27	-0.11
Insoluble fibre (g)	-0.18	-0.05	-0.23	-0.02	-0.7	-0.68	-0.37	-0.23	NA	NA	NA	NA	NA	NA	NA	NA
Soluble Fibre (g)	-0.23	-0.26	-0.07	-0.20	-0.29	-0.25	-0.27	-0.17	NA	NA	NA	NA	NA	NA	NA	NA

^a The two databases used were FoodFinder3® and Dietary Manager

NA=Not Analysed

General summary, conclusions and recommendations

1. Introduction

In this final chapter a summary of the general findings and conclusions will be given. Chapters 2 and 3 reported the aforementioned issues in detail thus combined general findings, conclusions and final recommendations regarding this study will be given.

The purpose of this study was to investigate and describe the processes of planning and nutrient analysis of diets for controlled feeding trials in free-living subjects. In this regard the first objective was to describe the recommended steps to use when designing accurate menus for controlled feeding trials in free-living subjects. This objective was realised by summarising the procedure and lessons learned from two identified trials as well as using personal experience to compile the ten steps that will assist the research dietician in menu design, a process which is applicable to all controlled feeding trials.

Two of the steps discussed in Chapter 2 include planning diets with the use of computerised nutrient databases as well as the validation of the planned menu by chemical analysis. These steps contribute to the accuracy of the nutrient content of the diet which is essential for the achievement of the research objectives. This was motivation to set the study's second objective to investigate the reliability of the two available South African computerised nutrient databases by comparing them with each other as well as the reference standard of chemical analysis.

2. Summary of main findings

2.1 The appropriate menu design methodology to be used in controlled feeding trials.

The research team should set enough time aside for the planning of menus as it is a challenging task. The methodology to be used can be summarised in 10 steps.

- The formulation of the diet prescription according to the set study specifications will result in a menu with a specific nutrient content that is unique to each specific study design.
- Deciding on the different energy levels will depend on the study participants and study aims. Identifying the energy needs of the participants, the research team can use energy equations combined with dietary and physical activity questionnaires.
- The end goal of the menu development process is to produce an accurate menu that matches the nutrient specifications of the study protocol. Plan a menu which is appetising and acceptable to the subjects in order to promote compliance, which is practical and cost effective and which will endorse efficient food procurement, production and delivery.
- A reliable and functional computerised nutrient database should be selected to assist the research dietician with menu design. Evaluate the nutrient database in order to determine whether the database will meet the needs and objectives of the study.
 - Evaluate the nutrient database for reliability on the source of information used, the number of foods included, complete data on key nutrients to be investigated, an up to date database and quality procedures used to ensure the accuracy of the nutrient database.
 - Evaluate the nutrient database on the functionality. Look at programme features that will ease the process of menu

development such as quality of help screens and user's manual, name or code search, print and export systems, recipe entry and analysis, ease of editing the food list and the ease of assigning volume and weight measures to food items. These databases contain only estimates but are functional tools that can be used.

- Entering the menu into the database is an important step. Identify and choose the food product from the database closest to the food that will be provided to the participants. When the food product is not available use substitutions closest to the original product. When using composite recipes enter raw ingredients into the database and correct for moisture lost during preparation.
- Validating the menu with chemical analysis needs to be conducted before the feeding trials begin. If the need arises changes to the menu can then be done before the trial begins. Choose an accredited laboratory and skilled personnel to do chemical analysis according to AOAC standardised methods.
- The research team can arrange an evaluation session to test the palatability of the diet. Adjusting the menu to enhance the acceptability without changing the diet composition is the last step of menu planning before the feeding trial starts.
- Choose the "perfect" study participant. Participant recruitment, an orientation programme and run-in trial will promote participant adherence to strict dietary recommendations.
- After the menu planning is finalised the next step is preparing the diet. Procure the correct foods according to set specifications and brand names, produce the diets according to standardised procedures and deliver the research menu to the study participants.
- The success of the study will depend on the adherence of the participants, therefore, the research team needs to promote, document and monitor the adherence throughout the intervention period.

2.2 The process of nutrient analysis for controlled feeding trials: A comparative study of two South African nutrient databases with chemical analysis.

- Results from this study showed no significant differences between the nutrient analyses of the two South African nutrient databases even though the one was primarily based on the United States Department of Agriculture Nutrient Database (USDA NDB) with only 200 South African foods and the other 41% South African and the rest of the values mainly from the USDA NDB (1998).
- Results showed differences between the chemical analysed values and the databases calculated values for total fat, mono-unsaturated fatty acids (MUFA) and saturated fatty acids (SFA). The calculated database values were significantly higher compared to chemical analysis.
- There were no significant differences between the amounts of total energy, protein, carbohydrate, poly-unsaturated fatty acids (PUFA) and total fibre between the chemical analysis and the nutrient databases.
- The chemically determined values for insoluble fibre and soluble fibre were significantly higher than the value provided in the nutrient database FoodFinder3®.
- The main factors contributing to the differences observed in the current study include the use of recipes and combination dishes that were not available on the database, even though correcting for moisture loss during the cooking procedures, using nutrient databases that are not truly indigenous and mainly based on USDA NDB as well as missing values or incomplete data in the nutrient database on key nutrients analysed.

3. Conclusions

Research dieticians and nutritionists are challenged by conducting controlled feeding trials on a free-living basis in order to test diet-disease hypotheses. In order to conduct a well controlled feeding study successfully the research dieticians and nutritionists must use an array of skills and specialised knowledge. For years little information on controlled feeding studies existed, thus the need was identified to document data on the processes of planning and nutrient analysis of diets. The results of this study are, therefore, valuable to increase the knowledge in this field.

This study resulted in 10 steps to be followed by the research team in order to accurately formulate, plan, produce and deliver research diets. It describes the most important considerations that might influence the success of the menu and the feeding trial. This ideal methodology was summarised from selected published controlled feeding trials that reported on the methodology used for menu planning and lessons learned, as well as personal experience of the co-authors of this study. This ideal methodology will be used in the planning of all future controlled feeding trials in this Nutrition Department and hopefully many others.

The computerised nutrient databases are functional tools that will assist the dietician in designing the menu, but results from this study found significant differences between calculated nutrient values and chemical analysis. Even though great care was taken in entering composite recipes, using raw ingredients with baked goods and correcting for moisture loss, greater deviations were still observed on those days where composite recipes were used. Another possible factor that contributed to the deviations observed on those days was the natural variance between the fat content of South African meats such as pork, mutton and sausage compared to US meats, as already reported on beef. Thus the use of

nutrient databases mainly consisting of USDA NDB data and not truly South African food compositions adds to the deviations observed. The similarities observed between the current study and McCullough *et al.*, 1999, are due to the Westernised diet prescribed in this study. Thus, one might question the reliability of these databases when designing a more indigenous African diet consumed in other parts of South Africa. The deviations reported on the values for insoluble and soluble fibre between FoodFinder3® and the chemical analysis were due to incomplete data on these nutrients in the database. This highlights the importance of evaluating the database on key nutrients to be analysed or investigated.

Computer nutrient databases are not reliable enough to exclude the step of menu validation by chemical analysis before the start of the intervention. The research team should take great care to design a menu using a nutrient database that will be as close as possible to the diet consumed by the participants and thus compare well with the chemical analysis. Chemical analysis is an expensive and time consuming procedure and if analysis presents with different nutrient content than planned, adjustments to the menu will follow and a possible repeat of the chemical analysis for verification, adding to the costs of the trial. These results support the use of a nutrient database as a functional tool for menu planning but it emphasises the importance of chemical analyses to validate the menu before conducting a controlled feeding trial.

4. Recommendations

The results from this investigation provide the impetus for conducting more research. Future comparative studies need to be conducted using the criterion standard of chemical analysis as the standard reference. More information will result in decreased trial and error experiences by the research teams. It is recommended that enough time be set aside for the

planning of the research menu. There is more to menu development for controlled feeding trials than previously realised. Dieticians and nutritionists using these computerised nutrient databases should be conscious about factors that may lead to a greater variance in data.

- With data entry the identification of food products, substitutions used for a product as well as the use of recipes should be closest to the nutrient content of the actual food product provided to the participants. Limit the use of recipes that are not available on the database, as this will increase the deviations between the database and chemical analysis.
- The loss of moisture due to the cooking process should be corrected for. Enter raw ingredients and amounts as specified in the recipe into the nutrient database. Weigh baked goods before and after cooking as this will allow one to determine the correct nutrient concentration.
- The author strongly recommends the development of a nutrient database that is based on the chemical analysis of South African foods, baked goods, combined dishes, all meat products and dietary habits. This will eliminate the factor of using food products from a nutrient database from another country as there is a natural variance in composition between countries. This will also decrease the use of recipes and combination dishes not available or different from those used on the database.
- Choosing the most appropriate nutrient database for the needs and objective of the study is advisable. The team should evaluate the computerised nutrient database beforehand to determine the quality of the software programme and identify missing values for the nutrients of interest.

- When conducting a study that investigates soluble and insoluble fibre, data will need to be added to the nutrient database as it is incomplete for these nutrients.
- Chemical analysis should be included as a step of menu validation before the trial begins.
- Instead of dieticians and nutritionists gaining knowledge by trial-and-error experience, documented reports and training on the logistical dimensions of human feeding studies need to be developed and published.

Addendum



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