

DASH Feasibility Study 2012/2013 Nurse Training Manual

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Chapter 1

Study Background

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1. Background to the DASH Study

DASH is a key element in our MRC funded research programme that focuses on how the timing and duration of social exposures are related to ethnic differences in health over the life course, and how these interact with biological influences. This approach should allow us to identify key time points when interventions to reduce ethnic inequalities in health could be most effective, but also gives insights into improving health outcomes for *the whole population*, especially where some ethnic groups do better than average. For more information about the research programme see <http://www.sphsu.mrc.ac.uk/research-programmes/eh/>

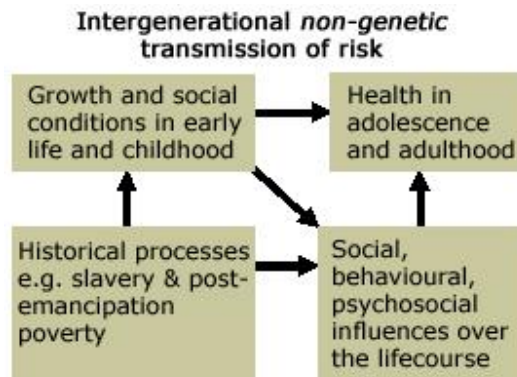
Addressing ethnic inequalities is a key aspect of major public health policy priorities in the UK (e.g. Choosing health; Ethnic Monitoring in the NHS; Department of Health Race Equality Scheme) and internationally (Commission on Social Determinants of Health 2008). The lack of longitudinal studies of ethnic minorities to date has made it difficult to consider when health differences emerge, and to understand the transmission of health potential across generations. The DASH study is a unique resource that has the potential to track ethnic differences in cardiovascular, respiratory and mental health from youth to adulthood.

The DASH Study started as a school-based study of adolescents from the main ethnic groups (White British, Black Caribbean, Black African, Indian, Pakistani and Bangladeshi) in 10 London boroughs. Wave 1 took place in 2002/03, when participants were aged 11-13 years (school years 7 and 8). Wave 2 took place in 2005/06 when they were 14-16 years (school years 9 and 10). In 2010/2011, at ages 19-21 years, participants were contacted via post and telephone. The cohort is now in their early 20s and the DASH tracing exercises have located to date 81% of the original sample.

The feasibility study uses a small sample of the DASH cohort to inform the design of the next full face-to-face follow-up of all study members. DASH will be the first large scale UK cohort of ethnic minority youths with both social and biological measures from childhood to early adulthood. It will allow detailed examination of ethnic differences in the social patterning of biological mechanisms and pre-clinical disease in young adulthood. DASH has shown ethnic differences in blood pressure trajectories in adolescence, with greater increases in systolic blood pressure, among ethnic minorities than Whites. Similarly, DASH showed that ethnic differences in BMI among boys emerged in adolescence, with Nigerian/Ghanaian boys being more likely to be obese than White boys by age 16 (Harding et al. 2010).

Compared with people born in England and Wales, those of South Asian origin have more than a 50% greater death rate from coronary heart disease and people of Black African origin more than double the death rate from stroke, than that of White Europeans. With continued follow-up, DASH will have the potential to study the social and biological

exposures that lead to ethnic differences in early vascular disease, and inform intervention strategies that produce greatly leveraged gains in cardiovascular outcomes in later life.



In spite of considerable work, the causes of ethnic differences in health (e.g. excess prevalence and deaths from hypertension in Black African origin and coronary events in South Asians) (Bhopal et al. 1999; Cappuccio 1997; Chaturvedi 2003; Cruickshank et al. 2001; Harding et al. 2008b) remain a scientific and policy challenge.

The conceptual underpinning of DASH draws on life course models (Kuh and Ben-Schlomo 2004). Considerable evidence indicates that experiences early in the life course (such as intra-uterine and childhood development) (Barker 1998) can have far reaching consequences for health in later life. Later events (such as change in socio-economic circumstances (SEC)) may also alter health trajectories initiated in early childhood. In addition, the cumulative exposure to adverse effects of deprivation in childhood and adulthood frequently erode health capital (physical and inherited resilience). The diagram illustrates these ideas, emphasising the intergenerational non-genetic transmission of health capital over the life course of many generations. It links social and behavioural processes to physical indices (e.g. early obesity) and to health at different stages of the life course. It signals that historical processes, such as slavery and post-emancipation poverty, may have a continuing legacy via compromised intrauterine and postnatal growth, which in turn may affect, for example, vascular health in later life. DASH allows comparisons of groups of potentially similar genetic background, whose previous generations were subject to such drastic selection processes with those who were not (for example young British born people of African-Caribbean origin compared with those of directly African origin). As well as an increasing awareness of the need to systematically explore differences in developmental experiences and socio-environmental exposures over the life course, it is becoming increasingly recognised that it is important to understand the interaction between genetic endowment and environmental interactions, to understand ethnic differences in health.

In this feasibility study we will assess whether data on biomarkers, as well as DNA, can be collected. The aim of collecting this in the full-follow-up will be to contribute more directly to current debates about the biological pathways between ethnic differences in social circumstances and health over time.

2. Recent research findings

DASH papers continue to provide insights about ethnic differences in exposures and mechanisms that are protective of and/or harmful for health.

Mental health remains a significant focus in our analyses (Maynard and Harding 2010a; Maynard et al. 2007; Maynard and Harding 2010b). We have been examining the

association between cultural integration and mental health (Bhui et al. In Press). The de/merits of multi-culturalism is a hotly debated issue with important policy implications for communities. Some argue that clustering of ethnic communities is associated with living parallel lives and more social inequity. In DASH, cultural diversity in friendships (as measured by the extent of friends of different ethnicity) appeared to be more protective of mental health than cultural homogeneity of friendships (friends of similar ethnicity). Diversity in friendships increased with age regardless of ethnic residential density. These findings could be taken to signal that the issue of cultural integration is perhaps a natural progression for the younger generations who are growing up in a very diverse environment. We have also been examining the effect of racism on mental and cardiovascular health (Astell-Burt et al. In press). Ethnic minority groups reported more racism than Whites at every age. Racism was associated with poorer psychological well-being regardless of ethnicity. Higher ethnic residential density was associated with less reports of racism but did not buffer the effect of racism on mental health.

We had examined BP and related health behaviours in early adolescence (Harding et al. 2006; Harding et al. 2008a; Harding et al. 2008c; Harding et al. 2010). Recently we reported on the longitudinal trajectories in adolescence. Ethnic minority boys and girls generally had lower blood pressure than their White peers at age 12y but had greater age related increases in BP during adolescence. By age 16y, African boys had higher blood pressure than White boys (Harding et al. 2010). In contrast to mental health, racism did not affect these ethnic differences in blood pressure trajectories. Racism is hypothesised to be a psychosocial stressor affecting blood pressure, either directly or via factors that influence blood pressure (Lenguerrand et al. 2011). These findings raise questions about potential ethnic and gender differences in coping strategies that might buffer the impact of racism on BP in adolescence. We also examined the effect of physical exercise on blood pressure. Physical exercise has an independent reducing effect on blood pressure and hypertension in adulthood but we found no effect in adolescence, regardless of ethnicity.

We had reported that social factors (overcrowding and psychological well-being) explained about 10% of the ethnic differences in lung function and, contrary to what is expected in adulthood, there appeared to be an asthma advantage in early adolescence for most ethnic groups (Whitrow and Harding 2008, 2010). We have broadened this enquiry to examine the effects of traffic related pollution on respiratory health. We are currently examining the effect of PM10 (particulate matter <10µm) on ethnic differences in lung function and asthma (Astell-Burt et al. Submitted). We had also examined smoking patterns and reportage in early adolescence (Whitrow et al. 2010). We are now examining the increase in smoking in relation to school and neighbourhood environments.

Findings from DASH have been an important trigger for national and international collaborative studies: these include the Department of Health Public Health Consortium funded [DASH-DEAL](#) (Maynard et al. 2009) prevention of obesity study for which a proposal for Phase 2 is in preparation; a MRC funded study examining the impact of neighbourhoods on ethnic differences in cardiovascular risk in children, a Wellcome Trust funded study of ethnic differences in respiratory health in primary school children (led by Institute of Child Health, University College London), MRC funded international comparisons of ethnic differences in mental health with a similar study in South Africa, and a proposal to MRC for

prevention and control of hypertension in Jamaica (in collaboration with the University of the West Indies).

3. Aims of the feasibility study

(i) To conduct a feasibility study to establish the best methods for data collection, including the collection of physical and biological measurements, for subsequent face to face follow-up of the entire cohort.

(ii) To generate a proposal for subsequent follow-up of the entire cohort for submission to MRC, dependent on the findings of the postal and telephone surveys and proposed feasibility study.

4. Research questions

a. What will be the advantages and disadvantages of conducting the study in the different settings (GP surgeries, other NHS centres, homes)?

b. Do participants' response rates vary by setting?

- What will be the challenges faced by the nurses in the different settings?

- Will the quality of data collected (e.g. extent of missing data) vary by setting?

- Will the delivery of blood samples to the laboratory be reasonably straight forward in each setting?

c. What percentage of participants will agree to undertake bio-marker measures?

d. Are mental health measures for this age group, typically used with White European populations, culturally appropriate?

e. How will DASH participants' view feedback on their medical results (e.g. blood pressure, weight, blood lipids)?

f. How satisfied will participants be with the different components of the survey process – contact, consent, data collection?

g. What is the estimated length of time and the resources required for subsequent full follow-up of DASH study members?

5. Research plan

5.1 Outcome measures

These will be examined by setting (home visit, GP surgery, other locations) using a mixture of quantitative and qualitative methods and are as follows:

Percentage response rates – overall, per item/physical measure;

Percentage consistency of answers to questionnaire items;

Percentage physical measures within expected range e.g. spirometric measures;

Mean length of time for interview;

Mean length of time for taking physical/biological measures;

- I. Qualitative appraisal of cultural appropriateness of mental health measures and of participants' satisfaction with survey processes.

5.2 Sample

At the recent telephone survey, participants were asked if they would be willing to take part in a small feasibility study to prepare for a later full face-to-face follow-up. Almost all agreed and of those, a sample of 300 (40-50 in each of the main ethnic groups- White British, Black Caribbean, Black African, Pakistani, Bangladeshi, Indian) will be invited to complete a questionnaire, and have physical and physiological measures taken. Interviews will be conducted in GP surgeries, participants' homes or other chosen locations (e.g. King's College London) dependent on the preference of the participants. As this is a feasibility study, the sample size has been chosen pragmatically to give a reasonable spread, with equal gender representation across the 10 London boroughs that the whole sample was in at wave 2.

5.3 Main Questionnaire

The content reflects mainly questions that were asked in previous waves (general health; health behaviours; psychological well-being; SEC; social support; and relationship with parents). New items include parenthood; age appropriate mental health measures; own education, economic activity and occupation; job strain; caring; 'romantic' relationships; positive and negative emotions; views on their parents being invited to participate in DASH in order to examine generational influences.

5.4 Physical/physiological measures

As in waves 1 and 2, height, weight, arm, waist and hip circumference, lung function, blood pressure will be measured.

New measures include:

(i) Hand to foot bio-impedance

Reliable body composition measures are important for assessing ethnic differences in overweight, particularly in childhood when other factors, such as differences in the onset of puberty and hence adiposity rebound, occur. Body mass index, based on height and weight, is the standard measure used in population studies but has limitations. For example we know that for every unit of BMI, South Asians have more fat and Africans less fat (Deurenberg-Yap et al. 2002; Luke et al. 2002). Gold standard data (e.g. hydrodensitometry, bioelectrical impedance, dual energy X-ray absorptiometry) used in impedance equations to derive lean mass and fat mass in children are mainly based on Europeans. In wave 2, we collected leg-to-foot measure of bio-impedance. Here we propose to measure hand-to-foot BIA with the participant lying flat. This will be an improvement on the wave 2 measure as fat is differently distributed across the ethnic groups, more so around the hips than waist for Black African origin girls but more so around the waist than hips for Indians.

(ii) Accelerometry

To date subjective measures of physical activity have been collected in DASH. Here we will use the ActivPal (PAL Technologies Ltd., Glasgow, UK) to obtain an objective measure of physical activity. ActivPal gives a direct output of steps and step rate, and information about time spent in different postures (sitting/lying, standing, and stepping) are provided in real time. The software provides an indirect estimate of metabolic equivalent based on steps. Participants will wear for 5 days including days in the week and at the weekend.

(iii) Arterial stiffness

Artery stiffness is an established marker of cardiovascular (CV) risk beyond other traditional factors such as age or blood pressure, and has recently become part of the European Society of Hypertension guidelines for stratifying cardiovascular risk. Pulse wave velocity (PWV), the time the pulse takes to travel between two sites in the body, is the recommended measure of arterial stiffness. We plan to use the Arteriograph to measure PWV. This machine gives a measure of PWV, central (cBP) and brachial blood pressure (baBP), and augmentation index (AiX). Participants will wear the Arteriograph for most of the interview – about 1 hour, which will yield about 6 readings.

(iv) Bio-markers

In previous surveys of the DASH cohort we avoided conducting any invasive measures that might compromise response rates in teenage years. We will now ask the participants permission to take a blood sample of 25ml. Major blood measures of interest are levels of potassium (K⁺) and sodium (Na⁺) (Palacios et al. 2010; Vaidya et al. 2011; Melander et al. 2007), creatinine (kidney function (known to generate blood pressure (BP)), lipid markers (for early tendency to atheroma which deposits on and narrows arteries which may then block causing heart attacks, strokes etc.), blood glucose markers, but in addition the hormone systems known and only now becoming known to be related to blood vessel function and disease (whether 'hypertension' whose early signs we may detect, diabetes, even osteoporosis, Alzheimer's etc). These hormones include vitamin D, already known to be reduced well below recommended levels in minority ethnic groups whose melanised skin limits its synthesis in poor sunlight (Moreno-Reyes et al. 2009; Rezai et al. 2011; Vaidya et al. 2011), plasma renin which generates other factors raising BP (Melander et al. 2007; Vaidya et al. 2011), nitrates and nitrite which reflect green leafy vegetables and reduce BP (Kapil et al. 2010; Webb et al. 2008), gut hormones which may reflect appetite and its control (Bansal et al. 2011; Brownley et al. 2004), etc. We are therefore asking each participant whether they will donate their sample for such assays, including for potentially relevant substances not yet known but which we may develop reasons for thinking are relevant to chronic disease development. Such blood constituents include those found by the modern metabolomic and proteomic methods, which use mass spectrometry for their analysis, generate many molecules or peptides whose roles are not yet discovered.

5.5 Dietary assessment

Our [DASH-DEAL](#) intervention study highlighted the need for developing appropriate dietary assessment methodology for ethnic minority groups. We aim to use the method developed

to examine dietary patterns and health in the full follow-up. Participants will be invited to complete 24 *hr* recalls and food portion exploration. Food records will be coded and nutrient intake and dietary pattern computed.

5.6 Qualitative assessment

Semi-structured interviews will be conducted with participants to obtain feedback on the process of follow-up – what worked well, how best to improve the process, what was un/acceptable etc. A similar evaluation will take place with the nurses with the aim of identifying best practice in clinics and homes.

5.7 Quantitative assessment

Descriptive statistics will be used to look at the general distributions and quality of the data collected. Outcomes measured as rates will be examined by data collection setting (GP surgeries vs. home visits), ethnic group and socio-demographic characteristics using standard comparisons technique such as Chi-square test or logistic regression. Mean length of time and any continuous outcomes will be compared using linear regression. In addition, although the sample size of each ethnic group is small, the total sample will allow analyses of the potential social patterning of biological mechanisms in a diverse sample in young adulthood.

6. Consent

Participants consented to take part in the recently completed telephone and postal survey. They gave their written (postal survey) or oral (telephone interview) consent. In the main therefore we see no problem with continuing to facilitate the majority of these participants giving informed consent (in writing) to take part in this feasibility study. Participants will be sent the information sheet about the study two weeks before a nurse contacts them to try to arrange an interview. Before beginning the interview the nurse will discuss the study with the respondent, ensuring that any questions they have are answered effectively, that the respondent understands what they are consenting to, and that they know they can refuse any question or measure and withdraw at any time.

Consent will be gained in two stages. First at the start of the interview, the nurse will seek consent to conduct the interview; to carry out the physical measures; to contact them for further follow up in the future; for their permission to access their medical data and to send some of their test results to their GP (Consent Form 1, attached). After the main interview has been conducted, the nurse will seek consent to collect the three blood samples (Consent Form 2, attached): for immediate analysis; for DNA; and for storage. Consent for the focus groups will be conducted prior to start of the focus group discussions (see Information Form 2 and Consent Form 3, attached).

The DASH cohort is relatively young and only recently consented to take part in the feasibility study, but there is always a possibility that some might have become incapacitated and therefore are not able to give informed consent. Interviews will not be conducted if the respondent is unable to give informed consent.

7. Sub-studies

All of the sub-studies will use the data that will be collected as part of the main feasibility study and additional activity may include further data collection (e.g. ambulatory blood pressure monitoring) and/or additional visit (e.g. to the Clinical Research Facility at St Thomas' Hospital).

Evaluation of the impact of feedback to participants

During the study participants will receive initial, limited feedback of results and, within two months of the Nurse Interview they will receive additional feedback on selected specific results from the blood assays (e.g. total and HDL cholesterol) and their BMI together with some healthy eating and active living advice. Little is known about ethnic differences in the acceptability of such feedback and advice and/ or the likelihood that such feedback will influence subsequent behaviour change. These issues will be explored with a mixed method approach of qualitative interviews and measures of food choice and physical activity behaviours among a sub-sample of the feasibility participants.

Collaborators: Dr Michaela Benzeval, Dr Shona Hilton, MRC SPHSU.

Appropriateness of mental health/cognitive measures

There has been very little qualitative exploration of the cultural appropriateness of mental health and cognitive measures for minority ethnic young adults in the UK. For the new mental health/cognitive measures included in the feasibility study, we will conduct focus group vignette assessment, based on explanatory model and illness perception theories. This will be carried out in a small sub-sample (6 participants per ethnic group and allowing for 2 gender-specific groups; n=48). Analysis of these data will focus on narratives about the signs and symptoms of different aspects of mental health in the different ethnic groups. These data will provide valuable insights about the appropriateness of measures, usually validated with European populations, for ethnic minority groups.

Collaborator: Prof Kam Bhui (Barts and The London School of Medicine & Dentistry, Queen Mary University of London)

Dietary intake and vascular function

Emerging evidence suggests that different types of nutrient intake affect gut motility, local gut hormone production and resulting changes in blood flow, locally and systemically. This sub-study will examine how specific dietary intakes and patterns common to particular ethnic groups affect gut hormone production, measured in a blood sample. Variation in blood flow and pressure will be assessed by validated 24-hour monitoring.

Collaborators: Dr Louise Goff and Prof Kennedy Cruickshank, King's College London.

Psychosocial stress and cardiovascular health

There is a well recognised association between psychosocial stress and cardiovascular risk but the mechanisms underlying this relationship are unknown. Psychosocial stress has been hypothesised to account for ethnic differences in cardiovascular health, particularly between migrant and host populations in the same environment. Nitric Oxide (NO), a key signalling

molecule within the cardiovascular system, provides a potential link between psychosocial stress and cardiovascular disease. This sub-study will take advantage of the multi-ethnic feasibility sample, which is well characterised in terms of psychosocial stress, to examine the hypothesis that chronic psychosocial stress reduces NO with resultant harmful effects on sodium retention, vascular tone, endothelial function, platelet function and myocardial function. Methods include central BP, pulse wave velocity and echocardiography.

Collaborators: Prof Phil Chowienczyk, Prof Kennedy Cruickshank, King's College London.

8. Dissemination and research feedback to participants

A feedback leaflet of the broad results from this feasibility study will be sent to all participants by Spring 2013, signalling potential later full follow-up. Study members will continue to receive their annual calendar and all efforts will be made to stay in touch with them. Between 2013 and 2015, findings will be published in peer review journals.

9. Ethical approval for DASH Feasibility study

Approval for this phase of the study has been obtained from the South East Scotland Research Ethics Committee. As some of the data collection will be done on NHS premises, local NHS permissions are required, currently in process. DASH has been included in the NIHR CLRN portfolio, London South being our lead CLRN, which is supporting DASH through the NHS Coordinated system for NHS permissions.

10. DASH Governance arrangements

The study continues to develop with the guidance of a highly qualified and experienced technical advisory group consisting of members both internal and external to the Unit. The group members and their particular expertise are outlined below. In addition, there has been extensive discussion with, and considerable support from communities including civic leaders, head teachers and MPs.

The advisory team includes:

Name and institution	Relevant specialism
Professor Sally Macintyre (MRC SPHSU; Director)	Area/ neighbourhood effects on health
Geoffrey Der (MRC SPHSU)	Sampling methodology and medical Statistician
Michaela Benzeval (MRC SPHSU)	Cohort studies, health inequalities
Catherine Ferrell (MRC SPHSU; survey manager)	Survey methods
Professor Angela Dale (chair) (University of Manchester)	Ethnicity and well-being
Professor J Kennedy Cruickshank (Kings)	Diabetes and hypertension related

College, University of London	epidemiology
Professor Kamaldeep Bhui (Queen Mary College, University of London)	Social Psychiatry
Dr Maria Jackson (University of the West Indies)	Nutrition; social epidemiology
Mr Devon Hanson (Principal Walworth Academy, London)	Youth and ethnicity
Dr Charles Agyemang (University of Amsterdam)	Ethnicity and health; international comparisons
Dr Tracey Reynolds (Families & Social Capital Research Group, London South Bank University; Co-director)	Sociology of family life
Dr Kirsty Winkley (King's College & Institute of Psychiatry, University of London)	Diabetes and Psychology; community based studies

11. MRC audit and review

In addition to study specific governance arrangements, the SPHSU is audited annually by the MRC and this includes the conduct of DASH. The DASH Study is scientifically reviewed as part of the MRC five yearly review of the SPHSU Unit. Plans for this feasibility study were reviewed and approved at the Unit's last review in 2009.

12. Timetable

Training of nurses/researchers – March 2012 onwards; fieldwork in April 2012 – March 2013; Data cleaning and coding – ongoing during fieldwork, completed March 2013; Analysis, writing up and dissemination – January – June 2013; Proposal for full follow-up – Spring 2013.

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Chapter 2

Preparing for the Nurse Interview

Chapter 2. Preparing for the Nurse Interview

This chapter outlines the process leading up to the nurse interview; the overall fieldwork plan, contacting participants to arrange their appointments, and preparing equipment and materials ready for the interview.

2.1 Overall Fieldwork Plan

London based personnel

Strategic management of the study will be provided by Seeromanie Harding. Dr Elli Enayat, project manager, will be responsible for the day to day study management, helped by Mr Aidan Cassidy, part time project administrator. An MRC Career Development Fellow will conduct the qualitative examination of various aspects, including assessing the cultural appropriateness of psycho-social measures of the study. The project team will be based in the DASH Study Office in the Diabetes and Nutritional Science Division at Kings College, Room 4.21, 150 Stamford Street, London. Telephone number is **0207 848 4505** and email is **dash@sphsu.mrc.ac.uk**

The study will be take place in nine London boroughs. The main data collection will be conducted by nurses in GP surgeries, nurses that work directly for the Primary Care Research Network (PCRN), and Katherine Twist, a Senior Researcher working for the Clinical Research Network (CLRN). Hayley Brown, (Research Officer), and Jo Burns (Research Manager), from the PCRN, advised on potential research active GP surgeries in the South East, South West and Brent and recruited surgeries into the study.

Support from MRC SPHSU, Glasgow

Erik Lenguerrand and Karen Maxwell will provide scientific input. Additional support for the fieldwork process (e.g. mailings to participants; database provision and maintenance; training) will be provided by the Unit's Surveys Team, led by Catherine Ferrell. Telephone number is Freephone **0800 389 2129** and email is **dash@sphsu.mrc.ac.uk**

2.2 The Fieldwork Process

Participants will be contacted by letter to invite them to this current phase of the study. Nurses and Researchers will be assigned participants and are responsible for contacting the participants by phone to arrange an appointment (termed the 'Nurse Interview'). Participants will be allocated a GP surgery appointment, other NHS centre, or a home visit according to their preference.

Each stage of the research process will have detailed protocols and field guidelines to assist the team in completing data collection and physical measures. Quality assurance is a very important part of the fieldwork and will be continuously monitored by RAs and senior research staff. All members of the team are encouraged to seek assistance if they do not understand or are struggling with the role assigned to them during fieldwork.

The protocols are appropriate for Nurse Interviews in GP surgeries and for home/ other non-GP venues.

The recording of data during data collection will be on a CAPI (Computer Assisted Personal Interview) system for which laptops will be provided. Please refer to the section of this manual on CAPI for further details on how to use this system.

2.3 Making Appointments

Letters of invitation, the Main Questionnaire, the self-complete 24 hour dietary recall and an information sheet will be sent out to participants by the Survey Office in Glasgow.

The Survey Office will alert Nurses in the GP surgery/ DASH Study Office by email to let them know that participant contact details are available to download on the study laptop. Aidan Cassidy will then contact the surgery to check that surgeries/ nurses have received the details. If surgeries don't have WiFi access, a member of the study team will visit the surgery to download the contact details.

The Surgery Nurse will then contact the participants by phone to arrange the Nurse Interview.

If a nurse from a GP surgery is in contact with a participant who would like a home visit, they should note this in CAPI and the participant will be re-assigned by the database manager to a PCRN nurse or Katherine Twist.

Telephone contact procedure

All attempts to contact the participant should be recorded on CAPI

Number of attempts

Telephone the participant on the number provided. Try the number 6 times. If there is no reply after the first two attempts but there is the option for voicemail, leave a short message

Voicemail Script

- *"This is a message for (name of participant). My name is XX and I am phoning from the DASH Study. We recently sent you a letter and I am following this up. I will try again to contact you in the next 2-3 days but, if you would prefer to call me, my number is (use MRC mobile number) If you prefer, you can call the DASH Freephone number 0800 389 2129 and leave me a message there".*

If there is no response to the voicemail message and no contact has been made with the participant after 6 attempts spanning morning, afternoon and evening, you should contact the DASH Study Office to refer this participant back to the study team for review.

Once you get through to someone on the phone

Follow the telephone script for introducing yourself.

Introductory script

"Hello, my name is XX and I am working on the DASH Feasibility Study. May I speak to (name of the participant)?" If the participant is not available, ask *"when would be a suitable time to call back"* and record this in CAPI. If it is the participant, continue:

Participant

- *"Recently, you should have received a postcard and then a pack from us, telling you about the study and inviting you to take part. Did you receive the pack? I am based at XXX Surgery (provide address). I'd like to arrange a time for you to come and see me. The interview will take about an hour to an hour and a half."* Suggest a suitable time. If the participant is unable to make that time, ask what day and time is best until an agreement can be reached.
- Confirm that the participant knows how to find the surgery, that travel expenses will be arranged (receipts required for public transport) and that there is a £25 voucher to thank them for the time they are giving us. Say that you will confirm the appointment by sending a short letter with the details of the interview attached.

If the participant requests a call back, agree a suitable time which is convenient for you and arrange to call back and update CAPI to reflect the contact with the participant.

If the only time the participant can attend is when the surgery is closed, please notify the DASH Study Office. And if the participant would prefer a home visit, please update CAPI with this information and let the Study Office know. Thank the participant and say that someone will be in touch from the study to arrange an appointment to suit them.

If contact has been made three times and an appointment has not been made, please note the reasons that the participant has been unable to commit to an appointment and let the Study Office know.

Also, if you only have a landline number for the participant, check if there is a mobile number that we can contact them on at this point. Note this number on CAPI. This will allow us to send text reminders to the participant.

Query Participant Identity

If, for any reason, you suspect that the person you are talking to is not our participant, you could use the following 3 checks for confirmation

- *"Please can you tell me your postcode?"* If postcode agrees with CAPI records, continue. If not, ask if they have moved recently. If they have, ask for previous postcode. If this matches the record we hold, continue. If not, say that there is an issue with our records and that you will check with the Study Office and call back.
- *"I'd just like to check your date of birth"* If correct, continue. If not, ask the following:
- *"Your details don't totally agree with our records. Can I please ask what school you were attending at age 16?"*

If in doubt at any point, say you will just check with the DASH Study Office and call them back. Although we believe this is most unlikely, it may happen on occasion.

Not participant


If the person answering is not the participant and they can't arrange for the participant to phone back, ask if they have an alternative number for the participant e.g. mobile number and then attempt to reach the participant using this new number, leaving a voicemail message if no contact can be made. (See voicemail script above)

If the person answering has no contact details for the participant or says that they don't know the participant, please update CAPI and contact the DASH Study Office for further instructions.

Confirmation of the Appointment

Among the documents sent to the surgery will be a mail-merge letter giving the surgery address and the mobile and addressed to the participant. There will be spaces for the nurse to add the date and time of the appointment and send to the participant as soon as the details are confirmed.

Nurses and researchers will be issued with a study mobile phone to call participants. The day before the appointment, we would ask that nurses send the participant a text message reminder and suggest typing "Reminder of DASH appointment – Time, Date, Surgery".



2.4 Checklist of Materials and Equipment

- Study Laptop, charger and carry bag
- Consent Forms 1 & 2
- Information Sheets 1 & 2
- Dispatch Notes
- Participant Immediate Feedback Cards and Blood Pressure Letters for GPs
- Spare Main Questionnaires
- Spare 24 hour Dietary Recall Questionnaires
- Folders for collection of: Main Questionnaire; Consent Forms; 24 hour recall
- Sheet of barcodes for participant
- Digital Thermometer
- Timer
- 1 Buckle Tape measure
- 1 metal tape measure
- 1 plastic ruler
- Skin marker pen
- Blood Pressure Monitor – OMRON (plus 2 sizes of cuffs) or SPHYG
- Arteriograph equipment
- Callipers
- ActivPAL device
- Nitrile sleeves for water-proofing the ActivPAL
- ActivPAL set-up equipment – USB connection cable
- At least 7 10cm x 13cm strips of waterproof hypafix transparent dressing (2 for attaching ActivPAL device and at least 5 spares for giving to participant)
- At least 7 10cm x 13cm strips of flexifix transparent dressing (as an alternative to hypafix for those with allergies or sensitive skin)
- Weighing Scales and board for even measurement
- SECA Leicester Height Measurement tool (Stadiometer)
- Stool – for taking sitting height measurement
- BodyStat – bioimpedance tool plus electrodes, screwdriver, plastic mat and pillow
- Spirometer and calibration syringe
- Backpack and wheeled suitcase
- Screech alarm
- Mobile phone
- Spare batteries
- Phlebotomy equipment including for each participant:
 - two 4ml purple tubes
 - one 5ml gold tube
 - one 3.5ml blue tube
 - one 9ml purple tube
 - one Mailsafe box
 - Butterfly needles
 - Vacutainer holder
 - one Tourniquet
 - Yellow bag for waste
 - Set of gloves
 - Anti-bacterial wipes
 - Hand gel

2.5 On the day before

Make sure that:

- the ActivPAL device has been **fully charged** (allow 2-3 hours charging time)
- the ActivPAL device has been programmed (see section 2.6 below - 'Preparing the ActivPAL')
- the ActivPAL device has been securely waterproofed (put in nitrile sleeve and secured with one strip of hypafix dressing – see below) and you have written down the inventory number of the monitor and the participant IDNo on the front of the device sleeve
- the rechargeable batteries for the arteriograph have been fully charged (allow 2-3 hours charging time)
- all equipment which requires it (the scales and the spirometer) has been correctly calibrated (see chapter on Equipment Checking and Calibration)

2.6 Preparing the ActivPAL

Charging the ActivPAL

In order to set up and charge the ActivPAL monitor, connect the ActivPAL device to the laptop with the micro USB cable, and leave connected for a minimum of **two hours** to fully recharge the battery.

Programming the ActivPAL

1. With the ActivPAL connected to the computer, open the ActivPAL3 software on your laptop.
2. In the ActivPAL software, from the file menu, select 'Connect to ActivPAL'.
3. The software will search for the connected device. Once it finds the connected ActivPAL, a pop-up window will appear showing the serial number of the device and the level of remaining battery power.
4. Click on 'Setup New Recording'.
5. The software will ask you to enter the start condition, number of days, start time, stop time and recording identifier (see table).

Field	Info to enter:
Start condition	'Future time'
Number of days	5
Start time	12.00am on day after appointment
Stop time	<i>(automatically updates)</i>
Recording Identifier	Participant's IDNo

The start condition should be set to 'future time' and the number of days is 5. The start time should always be 12.00am on the day after the participant's appointment time (e.g. if appointment is 10am, 14th March, the start time should be set to 12.00am, 15th March). This ensures that 5 complete days worth of data are collected. The stop time should automatically update to 5 days after the start time. The Recording Identifier should be entered as the participant's IDNo.

Please note: It is essential that you enter the participant's IDNo in the box marked 'recording identifier' as this is the only way of identifying the data collected at a later date.

6. To complete the programming of the ActivPAL, check that you have entered all the fields correctly and select 'Program'.
7. A box will appear indicating that the ActivPAL has been programmed successfully. Click on 'ok'. An orange light on the monitor will begin to flash intermittently as the memory status is verified. At this stage the monitor can be disconnected from the computer. The ActivPAL monitor is programmed.

Water-proofing the ActivPAL

Before the device is attached to the participant, it must be prepared and covered, in order to waterproof the device and protect it from damage.

1. Place the programmed and charged ActivPAL device inside a protective nitrile sleeve, by rolling the sleeve up from the man's "feet" to his "head" to cover the device.
2. Fold over the end of the sleeve at the top of the device.
3. Using a biro or marker pen, write the inventory number of the device and the participant's IDNo on the front of the nitrile sleeve for ease of identification of the device.
4. Draw an arrow on the front of the monitor sleeve pointing **upwards** (from the man's feet to his head), to signify the correct positioning of the device (i.e. which way up to place it on the thigh). *(A useful guide is that the 'man' on the front of the device should always be standing upright, therefore draw the arrow from his feet to his head)*
5. Next, take a strip of waterproof hypafix transparent dressing, 10cm x 13cm in length. Remove each of the four corners of this strip with a pair of scissors. This strip will be used to wrap the ActivPAL device and make the ActivPAL waterproof.
6. Place the ActivPAL in its nitrile sleeve in the centre of the dressing strip. Then fold each edge of the dressing in (sides first) ensuring that this creates a completely sealed cover for the device.
7. Peel the backing of the dressing off.
8. Fold the top edges of the dressing strip over to completely cover the ActivPAL.
It is essential that each monitor is entirely covered in order to provide a complete waterproof barrier.
9. Make sure that there are no sharp edges sticking out which may cause irritation or discomfort to the participant when stuck on to the thigh.
10. Once you have done this, the ActivPAL is ready for use.

This set-up process must be done prior to the nurse interview. The devices can be charged, programmed and prepared up to 2 days before the nurse interview.

2.7 On the day

Make sure that all items are ready for the visit i.e.

- all calibration checks have been completed as per the protocol (see chapter 3: Equipment Checking and Calibration)
- the measurement equipment is assembled and ready for the visit
- the room thermometer is set up
- all consent documents have barcode labels attached and that the ID number is correct for the participant
- all phlebotomy items i.e. dispatch note and tubes are correctly labeled
- the laboratory address label (for blood delivery by courier) is attached to the Mailsafe box as well as the surgery address on the back

Courier Procedure

When the visit is completed, call the courier on **0845 020 3000** and provide the following information to the booker:

- DASH Study
- Account Number **M70132**
- Purchase Order **4050149366**
- Details of the booking i.e.
- From:
 - Your GP Surgery (please provide full name and address)
- To:
 - Special Processing Unit, 5th floor North Wing, St Thomas's Hospital, Westminster Bridge Road, London SE1 7EH

The Mailsafe box can be given to the Reception staff to hold until the courier arrives if this is more convenient. Pick-up times will depend on courier availability.

Chapter 3

Equipment Checking and Calibration

Chapter 3. Equipment Checking and Calibration

	Frequency of verification	Other Considerations
1. Tape Measures	Not Applicable	-
2. Tanita HD-352 Scales	Weekly	Wipe with a damp, clean cloth
3. Stadiometers	Not Applicable	-
4. OMRON M5-1	Every year by Omron	Periodically wipe with a damp clean cloth
5. ActivPALS	Not Applicable	Wipe with a Steret alcohol swab after each use to remove adhesive
6. MICRO PLUS MS03 spirometer	Before each interview	Wash transducer after use with warm soapy water, and sterilize monthly using sterilizing tablets
7. Bodystat 1500MDD	Weekly – by DASH Project Manager	Periodically wipe with a damp clean cloth

Note spare batteries for each piece of equipment will be provided, if you require more please contact the DASH Study.

1. Tape Measure

No calibration/maintenance required, if equipment becomes damaged in any way please notify the DASH Study Office ASAP.

2. Tanita HD-352 Scales

- Measure your own weight, firstly on a hard surface with no legs attached to scales, secondly on a carpeted surface with the legs attached and check that the value for your weight is the same. If it is not, please return it to the DASH Study ASAP.
- Note: Legs “pop” on/off. Push firmly to remove. Tap button on front of the scales to start machine.
- Tanita HD-352 requires 6 “AA” batteries.

3. SECA LEICESTER Height Measure

No calibration/maintenance required, if equipment becomes damaged in any way please return it to the DASH Study ASAP.

4. OMRON M5-1

- No calibration/maintenance required, if equipment becomes damaged in any way please notify the DASH Study ASAP.
- OMRON M5-1 should be periodically wiped with a damp clean cloth.
- OMRON M5-1 requires 4 “C” batteries.

5. ActivPAL

No calibration/maintenance of the ActivPAL is required. If the equipment becomes damaged in any way, please notify the DASH Study Office ASAP. In order to prepare the ActivPAL, please see chapter on 'Preparing for the Nurse Interview'.

6. MICRO PLUS MS03 Spirometer

The spirometers need to be verified every time a participant is being seen by the nurse, this should be done prior to the interview.

- Ensure that the syringe and the spirometer have been in the same temperature environment for at least an hour.
- Circulate the room air through the 3 litre calibration syringe and the spirometer. To do this, connect the syringe to the flow head and simply pump through a few litres of air.
- Next fully extent the syringe piston, the handle of the spirometer should be pointing upwards.
- Next switch the spirometer to the "blow" position.
- Push the syringe arm into the syringe in a smooth swift stroke, pump the air from the syringe through the spirometer taking approximately 1 second to do so. Be careful not to occlude the outlet of the spirometer with your hand.
- Wait for a double beep, then withdraw the piston fully.
- Slide spirometer to the "view" position.
- Record the values in the Spirometer Calibration Record, the **FVC** value should be within a range of **2.97** and **3.15**.
- Repeat twice (**three times in total**).
- Slide spirometer to the "off" position.
- If the FVC value remains outside the range return it to the DASH Office ASAP for replacement.
- Maintain the calibration records. These will be checked monthly by a DASH Study researcher.
- MICRO PLUS MS03 spirometer requires 1 "PP3" battery.

Cleaning of Spirometers

- The transducer must be cleaned following each participant interview, and sterilized once a month. To clean after use, immerse the transducer in warm soapy water for 10 minutes.
- To clean monthly, make up a sterilizing solution by dissolving half a tablet in water. Immerse the transducer in the solution for 10 minutes. Sterilizing tablets will be provided by the DASH Study Office, please contact them if you need more.
- **IMPORTANT** – do not use alcohol or chloride solutions to clean the transducer).
- After cleaning/sterilizing, the transducer should be rinsed in water and dried.

7. Bodystat 1500MDD

Calibration of the Bodystat 15MDD will be undertaken by a member of the DASH Study Office team.

Chapter 4

The Nurse Interview

Chapter 4. The Nurse Interview

In preparation for the Nurse Interview you should read the chapter on 'Preparing for the Nurse Interview' and check that you have all the items on the checklist at the end of this chapter.

This chapter will take you through the process of conducting the Nurse Interview.

4.1 Taking Informed Consent and Checking Details (Stage 1)

Starting the Interview

- 1) Open CAPI on your study laptop (please refer to the CAPI User Guide for detailed notes on using the CAPI system)
- 2) Please note: You should keep the laptop plugged into the mains power at all times during the interview if possible.**
- 3) The system will prompt you to enter the participant's ID Number.
- 4) Enter today's date and the time.
- 5) The system will then prompt you to enter your worker reference number.

Taking Consent

- 1) Confirm the participant's name; check ID on CAPI, insert name on top of the **Consent Form 1** and check that the number coincides with the barcodes you have out for that person. Add a barcode to the top copy of the consent form.
- 2) Ask the participant if s/he has read and fully understands the information sheet and if they have any questions.
- 3) Once questions are answered, ask them to complete **Consent Form 1**.
- 4) Go through each item on the consent form requesting that the participant initials each box if they agree.
- 5) Once the boxes are completed, ask the participant to complete their name, the date and their signature in the space provided. Without a signature the consent form is invalid.
- 6) Complete the consent form with your name, the date, and your initials and ID number.
- 7) On CAPI, enter which consents the participant has agreed to by cross-checking against their form. Also double-check at this stage that the form is signed and dated in all places it should be.
- 8) Once completed, detach the yellow copy and give it to the participant and place the white top copy with the barcode in the Consent Folder.

Checking Details

- 1) The system will ask you to check the participant's details. To do this, you should click on the "Respondent" tab at the top of the screen. This will take you to a screen with the participant's details.
- 2) Please confirm with the participant their: name, address, telephone number and date of birth. If the participant has changes to any of these fields please click on either 'AMEND DETAILS' (to make changes to name, address, telephone number and date of birth) or 'NEW DETAILS' (to enter a completely new address). Enter the new information in the appropriate field and click 'OK' to save your updates.

- 3) You can click on the "Survey" tab at the top of the screen at any point to get back to the survey and continue with the interview.
- 4) **If the details of the person who has turned up at the interview do not seem to match on a number of the details we hold for them on the system (e.g. DoB and name have changed (excluding because of reasons like marriage), and they cannot confirm the school they were at during DASH), politely say to them that we can only interview those for whom we already have confirmed details. You should then pass the details of that person back to us at the DASH study office.**
- 5) The system will then ask you to repeat this process for the participant's 'link' person. You can view the 'link person' details by clicking on the "Link Person" tab at the top of the screen. If there are any changes to this person's details or the participant would like to add a new Link Person, click on the appropriate button and enter the new details. Click 'OK' to save your updates.

4.2 Weight and Height

Weight

Weight measurement is standardised by height to give BMI, the standard measure of body size that can be categorized to indicate overweight or obese status.

Equipment

The Tanita HD-352 scales are turned on by pressing the "ON" button on the back of the scales. Batteries should be inserted into the scales before the interview and removed after the interview to ensure that they do not lose power too quickly.

Exclusion Criteria

Participants are ineligible for this measure if they are a) chair bound, b) pregnant. The maximum limit of the Tanita scales is 31st 6lb. If the participant is heavier than this, the scales will show an error which should be recorded at the appropriate point in CAPI.

Procedure

- 1) Place the scales on a flat and hard surface. If you are measuring the participant in a carpeted room attach the support feet by inserting them into the holes at the four corners on the bottom of the scales. Place the wooden board under the scales and check that there is no movement of the scales.
- 2) Ask the participant to remove shoes, heavy outer garments such as jackets and cardigans, heavy jewellery, loose change, phones and keys.
- 3) Turn "ON" on the back side of the scales.
- 4) Gently tap the button at the bottom right of the scales, "88888" will appear on the display. When "0.0" appears ask the participant to stand on the scales.
- 5) Ask the participant to stand with their feet together in the centre and their heels against the back edge of the scales. Arms should be hanging loosely at their sides and head facing forward. Ensure that they keep looking ahead - it may be tempting for the participant to look down at their weight reading. Ask them not to do this and assure them that you will tell them their weight afterwards if they want to know. The posture of the participant is important. If they stand to one side, look down, or do not otherwise have their weight evenly spread, it can affect the reading.
- 6) The display will show the reading in 'kg' on the upper row and 'st-lb' on the lower row. Record the reading in 'kgs' to one decimal place e.g. 74.3 kgs, before the participant steps off the scales.
- 7) You will be prompted by CAPI to check the measure if what you have input is not within reasonable limits. Should this occur, check first that you have typed the data in correctly. If you have, measure the participant's weight again and enter the second measurement in CAPI.
- 8) When the participant steps off the scales the display reading will return to "0.0" and the scale will turn off automatically.

- 9) Remember to turn the scales off after use and remove batteries.

Summary of data to be recorded in CAPI

- 1) Enter the inventory number of the equipment.
- 2) Enter the participant's weight in CAPI in kgs
- 3) If weight not measured, select an appropriate missing code in CAPI and record the reason in the notes section at the end.
- 4) Similarly, if there are any problems or issues with weight measurement (e.g. participant refusal to remove heavy items of clothing), record this in the notes section in CAPI (as above).

Feedback to participants

Record the weight on measurement card. CAPI will convert it to stones and pounds for you.

Height

Height sums up the cumulative effect of your health, nutrition and environment since childhood. It is also an important way of standardising other health measures. For example, the ratio of weight relative to height (body mass index or BMI) is used to indicate whether someone is under/overweight.

Equipment

Portable SECA LEICESTER Height Measure or Stadiometer – a collapsible device with a sliding head plate, a base plate and a vertical rod marked with a measuring scale. Open the SECA LEICESTER carry case and ensure that all parts of the equipment are present i.e. the base, 4 measurement sections, two plastic spacers and a head plate.

Find a section of wall which is flat and upright with no protrusions, against which to place the SECA LEICESTER Height Measure and ensure the floor has a hard and flat surface. Assemble the SECA LEICESTER Height Measure, the four sections of the measuring rod are marked with unique symbols at each end to show which section inserts into which. Slot the assembled rod into the base.

Slide the first white 'spacing stabiliser' over the rod facing in the opposite direction from the base. Add the measuring arm pointing in the same direction as the base and, finally, the second 'spacing stabiliser' pointing in the opposite direction from the base.

Check that the height measures read correctly in order and that the base plate is steady on the floor with no movement. Place the entire apparatus close to a door or wall so that the two white 'spacing stabilisers' brace it in a rigid vertical position.



Exclusion Criteria

You should be able to measure the height of most participants. In some cases, however, it may not be possible or appropriate to do so. For example, participants who are chair-bound should not have their height taken.

Procedure

- 1) Ask participant to remove their shoes so that you can obtain a measurement that is as accurate as possible.
- 2) Raise the head-plate to allow sufficient room for the participant to stand underneath it.

- 3) The participant should stand with their feet flat on the centre of the base plate, feet together, with weight evenly distributed on both feet. Their arms should hang freely by their sides and the head, back, buttocks and heels should be against the vertical rod but not leaning on it. They should be facing forwards. Make sure that the participant does not lift their heels off of the base plate.
- 4) If the participant cannot stand upright with their back against the SECA LEICESTER Height Measure and have their heels against the rod (e.g. those with protruding bottoms) then give priority to standing upright.
- 5) Move the participant's head so that the Frankfort Plane is in a horizontal position (i.e. parallel to the floor) and the line of vision is therefore perpendicular to the body. The Frankfort Plane is an imaginary line passing through the external ear canal and across the top of the lower bone of the eye socket, immediately under the eye. This position is important if an accurate reading is to be obtained. An additional check is to ensure that the measuring arm rests on the crown of the head, i.e. the top back half.
- 6) If the participant is tall, it can be difficult to line up the Frankfort Plane in the way described. When you think that the plane is horizontal, take one step back to check from a short distance that this is the case.
- 7) Instruct the participant to keep their eyes focused on a point straight ahead and take the measurement.
- 8) If the participant has a hairstyle that stands well above the top of their head or wears a turban, bring the head-plate down until it touches the hair/turban. With some hairstyles you can compress the hair to touch the head. If you cannot lower the head-plate to touch the head, and think that this will lead to an unreliable measure, record this in the comments section. If it is a hairstyle that can be altered, e.g. a bun, ask the participant to change/undo it. If s/he cannot do so (as will be the case with turbans), use a tape measure to measure the height of the bun/turban and enter this into CAPI when asked.
- 9) Record height in cm and mm e.g. 176.5 cms. If a measurement falls between two millimetres, it should be recorded to the nearest even millimetre. For example, if a participant's height is between 176.4 and 176.5 cm, you should round it down to 176.4. Likewise, if the participant's height is between 176.5 and 176.6 cm, you should round it up to 176.6 cm, 6 mm.



- 10) CAPI will prompt you if the measure you have input is not within reasonable limits. Should this occur, check first that you have typed the data in correctly. If you have, check you have assembled the SECA LEICESTER Height Measure correctly and measure the participant's height again. Record the second measurement.

Summary of data to be recorded in CAPI

- 1) Enter the inventory number of the

- equipment you are using.
- 2) Enter the participant's height in cm and mm.
 - 3) If the participant is wearing any special headdresses or hairstyles, enter the height of these when prompted to do so by CAPI. CAPI will subtract this value from the total height.
 - 4) If height is not measured, select an appropriate missing code and give reason when prompted to do so by CAPI at the end of the measure.
 - 5) If there are any problems with height measure, e.g. balance/standing problems, problems with posture, spinal curvature, record these in the notes section in CAPI (this will be a question which comes at the end of all the height measures i.e. after you have recorded sitting height).

Feedback to participants

Record height values, in cm and in feet and inches, on measurement card.

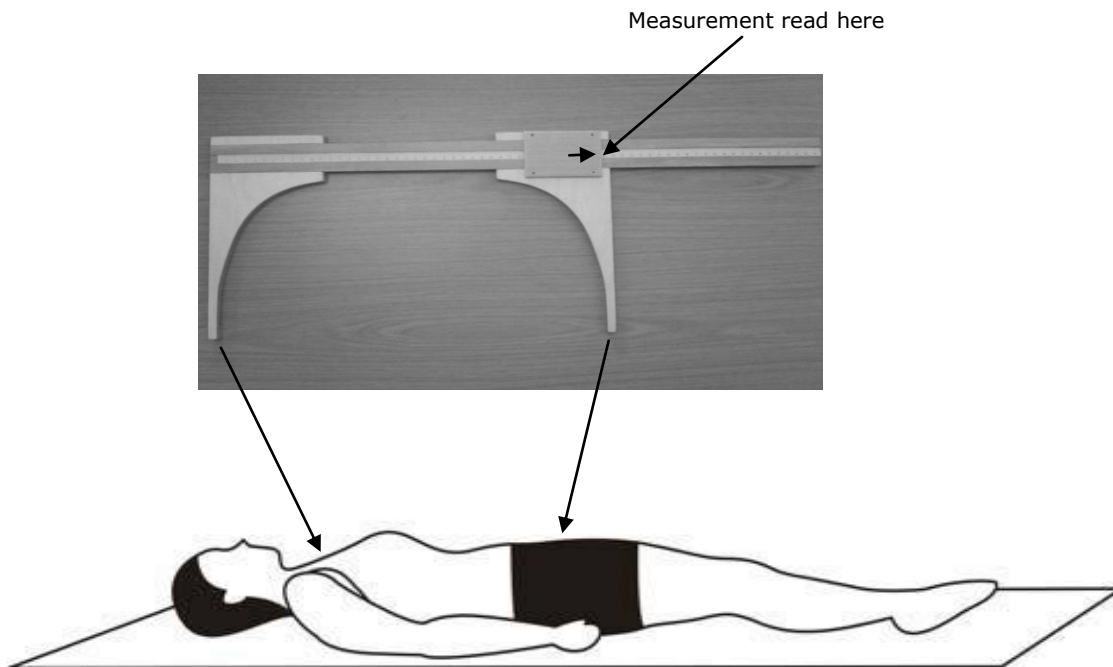
Jugulum-symphysis (JUG-SY) distance

The Jugulum-symphysis (JUG-SY) distance is a measure needed for the Arteriograph machine which you will be administering later in the interview.

The Jugulum-symphysis (JUG-SY) distance is the distance from the sternal notch to pubic bone, measured in a straight line (see diagram below). **You should ideally use the calliper to measure this distance whilst the person is still standing up against the Portable SECA LEICESTER Height Measure.**

Equipment

Portable SECA LEICESTER Height Measure (Stadiometer)
Wooden Calliper



Procedure

The JUG-SY distance should be measured with the wooden calliper provided, in **standing position** with a straight body.

1. Ask the participant to find and point to their own pubic symphysis (the point where the pelvic bones meet at the front – see diagram).
2. The end of the wooden measure should be placed lightly against the sternal notch (dip at the top of the breast bone).
3. Slide the moveable end along to the pubic symphysis. You are evaluating the distance between the two jaws of the calliper. The reading should be taken at the leading edge, by the black arrow and entered into CAPI.

Summary of data to be recorded in CAPI

- 1) Enter the participant's JUG-SY distance in cm.

Sitting Height

Sitting height is measured to get an idea of body proportions i.e. the length of the legs relative to the body trunk.

Equipment

Portable SECA LEICESTER Height Measure (Stadiometer)
Portable folding stool
Tape measure

Exclusion Criteria

Do not measure sitting height if the participant is in a wheelchair.

Do not measure if the participant's weight is greater than 150kg (23.5 stone).

Procedure

- 1) Erect the stool provided and set it astride the base so that the participant can sit with the measuring rod at their back with the legs of the stool all stable and even on a flat and hard surface of the floor.
- 2) Ensure that the participant is sitting as far back and as upright as possible as there is a slight slope towards the front on the stool. On being instructed to sit back as far as possible, many people will lean against the measuring rod. Encourage them to sit upright so that the rod is vertical.
- 3) Position the head in the "Frankfort Plane" as for standing height. Bring the head plate down until it gently rests on the highest part of the subject's head. Press down to flatten hair.
- 4) Take the height reading indicated by the arrowhead as with standing height i.e. record height in cm and mm e.g. 176.5 cms. If a measurement falls between two millimetres, it should be recorded to the nearest even millimetre. For example, if a participant's height is between 176.4 and 176.5 cm, you should round it down to 176.4. Likewise, if the participant's height is between 176.5 and 176.6 cm, you should round it up to 176.6 cm.
- 5) CAPI will prompt you to measure the height of the stool and enter the measurement.
- 6) You will be prompted by CAPI if the measure you have input is not within reasonable limits. Should this occur, check first that you have typed the data in correctly. If you

have, check you have assembled the SECA LEICESTER Height Measure correctly and measure the participant's height again. Record the second measurement.

Summary of data to be recorded in CAPI

- 1) Enter sitting height in cm and mm
- 2) Enter the height of the stool once the participant is sitting on it.
- 3) If sitting height is not measured, select an appropriate missing code in CAPI and enter the reason in the notes section at the end of the measure.
- 4) Similarly, if there are any problems or issues with this measure, record this in the notes section in CAPI (as above).

Feedback to participants

If participant asks, tell them their sitting height.

4.3 Ambient Air Temperature

An increase of temperature is associated with a decrease in blood pressure (1°C rise is associated with a fall of 1mmHg in BP).

Digital thermometers are provided.

Note the temperature and record it when asked in CAPI before recording the blood pressure.

4.4 Arm Circumference, Arteriograph and Blood Pressure



Arm Circumference

The arm circumference measure needs to be taken before the blood pressure measurement to ensure that the correct cuff is used.

Equipment

Arm circumference tape measure.
Skin marker pen.

Procedure

Ask the participant to remove jacket, jumper or any baggy outer clothing. Explain the importance of the accuracy of the measurement and that thick clothing can substantially affect the reading. Where possible the left arm should always be used. If the left arm cannot be used, e.g. because it is in plaster, then carry out the measurement on the right arm and record that you have done so in the notes section on CAPI. If the sleeve is too tight to roll up, the measurement may be done over one layer of light clothing.

- 1) The participant should hold their left arm across their body and at a right angle at the elbow with their palm facing upwards.
- 2) Note the process of the acromium – this is the bony tip of the shoulder
- 3) Mark the process of the olecranon – this is the bony tip of the elbow.
- 4) Using the tape, measure the distance between the two points. Divide this measurement in half. This will be the mid point of the upper arm. Mark this using the skin marker pen.
- 5) Let the arm hang loosely by the side, just away from the body. Ensure that the zero point of the tape is below the measurement value for ease of reading. The tape should not be loose, but neither should it be puckering the skin.
- 6) Record the measurement in CAPI in centimetres and millimetres e.g. 20.3cm. Should the measurement lie between two millimetres, then round it to the nearest even millimetre. For example if the measurement is half way between 20.3 and 20.4 round up to 20.4. If the measurement is between 20.8 and 20.9 round down to 20.8.
- 7) Repeat all the above procedures (points 1 to 6) to obtain a second measurement. Do not re-measure the circumference using the original marks - remark the positions. Record the measurement in CAPI.

- 8) If the difference between the first and second readings is ≥ 0.5 cm you will be requested by CAPI to take and record a third measurement.

Arteriograph

Artery stiffness is an established marker of cardiovascular (CV) risk beyond other traditional factors such as age or blood pressure. Pulse wave velocity (PWV), the time the pulse takes to travel between two sites in the body, is the recommended measure of arterial stiffness. Arteriograph 24 is a device used to measure pulse wave velocity (PWV), central BP and peripheral BP.

Procedure

Explain to the participant that the device is going to be connected to them by a belt, that they will feel the cuff inflate about 8 times, and that we would like them to wear it for most of the interview so we can get an accurate measure of measure of blood pressure and artery stiffness.

Jugulum-symphysis (JUG-SY) distance

Before you start, you will need to make sure you have the Jugulum-symphysis (JUG-SY) distance. This should have already been measured at an earlier point in the interview when the participant's height was being measured. The process of taking this measurement is explained in the Height section of this protocol.

Starting the Arteriograph's software

- 1) CAPI will prompt you to switch to the TensioWin software.
- 2) Make sure the Bluetooth dongle is plugged into the RIGHT HAND SIDE of the laptop in the TOP USB slot.
- 3) Choose TensioWin from the start menu or double click the TensioWin icon on the desktop.
- 4) When the programme starts, you do not need to alter the details of login name or enter a password.
- 5) Click the Ok button or press the ENTER Key on the keyboard to open the program.

Registering a new participant

- 6) On the Patient details page, click on the 'New' button (in the top left hand side of the screen) and a new pop-up window will appear for entering the new participant details.
- 7) Complete the participant details screen **as follows:**
 - a. In the Family name box enter the participant's family name.
 - b. In the First name box enter the **participant's ID number** e.g. 10004K.
 - c. In the Date of Birth box enter the participant's date of birth.
 - d. Enter the height, weight and JUG-SY distance and arm circumference of the participant in the relevant boxes. These measurements should be entered as whole numbers with no decimal places.
 - e. In the ID number box enter your **Worker Reference Number** e.g. D002

- f. Select the sex of the participant at the bottom left corner of the patient details screen.

You can find these pieces of information, if necessary, by switching back to CAPI using the tabs along the bottom of the laptop screen.

When you have entered the arm circumference the programme automatically determines and displays which cuff (1, 2 or 3) to use. Always use the suggested cuff.

- 8) Click 'Ok' to save participant details.

Starting measurements

- 9) Make sure the Arteriograph 24 device is switched on. The device will switch on automatically when the batteries are inserted. However, the device can be switched on/off by pressing the orange button 4 times.
- 10) Click on the 'Set up protocol and program device' button on the bottom left hand side of the screen.
- 11) In the Pre-set plans section make sure the first (default) pre-set plan called 'Standard 1' is highlighted.
- 12) Make sure Arteriograph 24 is selected as the device type.
- 13) Be sure the participant has removed outer garments, such as jackets. The cuff may be placed over one thin layer of light clothing.
- 14) Place the recommended size cuff on the participant's LEFT arm tightly.
- 15) Connect the cuff to Arteriograph 24 device.
- 16) Fix device on participant with the belt provided.
- 17) Click on the 'Send' button. At this point you should see the word 'CONNECT' displayed on the screen of the Arteriograph 24 device while the measurement protocol is being sent to the device. Please wait until this process has been completed.
- 18) Remind the participant that when the cuff inflates they MUST NOT move. If they are in the middle of having a measure taken, they must stop and remain still until the cuff has deflated. If they are standing, they should stay still and keep their arms by their sides until the cuff has deflated. The first measurement will start automatically after 5 minutes and will then be repeated every 15 minutes. Please note a minimum of 4 readings should be taken during the interview. Participants should expect at least 2 measurements in each cycle.
- 19) Once you have covered all these steps, leave the device on whilst you complete the other physical measures. **The Arteriograph should stay on for the whole course of the interview.**
- 20) You can now minimise the Arteriograph software window and use the tabs along the bottom of the screen to move back into CAPI and continue with the interview.

- 21) For removing the Arteriograph 24 when the measurements are complete, retrieving and exporting the participant's data, see chapter 12 of the protocol - 'Removing the Arteriograph'.

Blood Pressure

Elevated blood pressure or hypertension is well established as significantly increasing the risk of many diseases such as stroke and kidney disease. Hypertension is rare at young ages but high normal blood pressure can track into hypertension in later life.

Equipment

The OMRON M5-1 automated sphygmomanometer will produce a reading for systolic, diastolic blood pressure and pulse. Explain to the participant in general terms what the process involves. Because it is a very important source of health data for us, you are asked to take three measurements, using the OMRON M5-1.

Exclusion Criteria

None

Procedure

Measure BP ideally on the right arm. If the right arm cannot be used, make a note of this in the notes section on CAPI.

- 1) Be sure the participant has removed outer garments, such as jackets. Ask them to roll up the sleeve of shirts, blouses etc. so that the upper arm is bare for the blood pressure cuff. If the sleeve is too tight to roll up, the cuff may be placed over one layer of light clothing.
- 2) Seat the participant with his/her arm on the table, the palm facing upwards.
- 3) The participant's legs must be uncrossed and feet placed flat on the floor throughout the procedure. Their elbow should be adjusted to heart level by changing the position of the body in the chair. The OMRON M5-1 should be kept at heart level.
- 4) Palpate the brachial artery, and place the cuff around the upper arm at approximately heart level.
- 5) The lower edge of the cuff with its tubing connection should be placed about one inch above the natural crease across the inner aspect of the elbow. The cuff is wrapped snugly about the arm with the inflatable inner bladder centred over the area of the brachial artery, with the tubes leading down the arm.
- 6) The connecting tube to the OMRON M5-1 should be away from the body. The wrapped cuff should be secured firmly by pressure on the locking fabric over the area where it is applied to the cuff.
- 7) Be sure the participant is sitting with his/her feet uncrossed and the elbow and forearm resting comfortably on the table with the palm turned upwards. The elbow should be at heart level. Reassure the participant if they are nervous, and try to maintain a calm atmosphere.
- 8) Press the '0/1' button to turn on the OMRON. The display will show a zero and a heart symbol.

- 9) Warn the participant not to move his/her arm while the measurement is being taken. The instrument is sensitive to movement while deflating, and may fail to take a reading.
- 10) To take a reading, press the 'START' button. The cuff will automatically inflate and slowly deflate. When the reading is complete the machine will show the systolic and diastolic BP and pulse.
- 11) Record the results in CAPI. CAPI will ask you first for the systolic reading, then the diastolic, then the pulse.
- 12) Take two more blood pressure measurements (To take another reading press the 'START' button. Record both measurements in CAPI.
- 13) If measures 1-3 are inadequate (e.g. error message or implausible reading), note this in CAPI, complete a fourth measure and enter in CAPI. Potential error messages are shown in the diagram below.

Feedback and results to participant

CAPI will instruct you as to what to say to the participant about their BP. Follow the wording in CAPI exactly. If the mean of the last two BP readings is greater than or equal to 150/90 you should advise the participant that their measure is somewhat high and to seek medical advice. If the mean of the last two BP readings is greater than or equal to 160/95 you should strongly advise the participant to seek medical advice and give the participant the BP advice letter.




Record the values of the mean of the last two BP readings on the immediate feedback card (CAPI will calculate the mean of the last two readings for you) and indicate if the participant has been advised to see their GP and issued with a BP Advice Letter.

Summary of data to be recorded in CAPI

- 1) Record the responses of the participant to the pre-screening questions in CAPI.
- 2) Enter the inventory number and type of your equipment in CAPI.
- 3) Enter the inventory number of the cuff you are using.
- 4) Record measurements: Systolic BP, Diastolic BP, Pulse
- 5) If BP is not measured, select an appropriate missing code in CAPI and record the reason in the notes section at the end of the measure.
- 6) Similarly, if there are any problems or issues with this measure, record this in the notes section in CAPI (as above).

Omron error messages

Failure, causes and rectification

Failure and their possible causes	Rectification
<p>Incorrect measurement is indicated by E</p> <ol style="list-style-type: none"> 1. A correct reading could not be obtained because measurement was disturbed by movement of the body. 2. The cuff is not fitted correctly. 3. Your clothing has constricted your blood flow. 4. There is still air in the cuff when the monitor is switched on. 	<ol style="list-style-type: none"> 1. Repeat the measurement keeping perfectly still. Do not move your arm and do not speak. 2. Check that the cuff is correctly fitted. Then repeat the measurement. 3. Remove the item of clothing which caused the constriction. 4. The unit may be defective. Please have it examined and, if necessary, repaired by OMRON Customer Services.
<p>The start button was pressed before the () symbol was displayed</p>	<p>Wait for the () symbol indicating readiness before you press the start button.</p>
<p>The blood pressure values displayed are extremely low or high, or they are implausible.</p>	<p>Refer to the instructions and then repeat the measurement.</p>
<p>The display does not light up when the () button is pressed.</p> <ol style="list-style-type: none"> 1. The batteries are exhausted. 2. The +/- poles of the batteries have been reversed. 3. The battery contacts are dirty. ✘ The batteries are weak or exhausted. 	<ol style="list-style-type: none"> 1. Check the batteries and, if necessary, fit 4 new batteries. 2. Reinsert the batteries with the +/- poles the right way round. 3. Clean the battery contacts with a dry cloth. <p>Fit new batteries.</p>
<p>The cuff pressure does not rise although the pump motor can be heard.</p> <p>Err problem with mem. function</p>	<p>Check that the air tube is properly connected to the monitor. Push the tube connector firmly into the socket.</p> <p>Contact Omron Customer Service.</p>

4.5 Waist and Hip Measurements

The waist circumference and waist-to hip ratio are markers for the distribution of body fat. Central obesity in particular (i.e. a large waist) is thought to be a better measure of obesity and risk of diseases than weight based measures.

Equipment

Flexible tape measure with buckle

Open rolled tape measure, checking that the imperial measures in feet and inches have been scored through and only the metric measures in metres and centimetres remain clearly visible.

Exclusion Criteria

Any participant in a wheelchair or with a colostomy or ileostomy

If you don't think the tape will be large enough to measure the participant do not embarrass them by attempting to do the measurement. Record the reason if the measurement was not taken.

Procedure for both measures

- Ask the participant to remove heavy outer garments (jackets, heavy or baggy jumpers, cardigans and waistcoats) and empty pockets. If the participant is unwilling to remove bulky or tight garments and you feel it will significantly affect the measurement, record this in CAPI and estimate the thickness of the clothing.
- If the participant is wearing a belt, ask them remove or loosen it for the measurement.
- Ensure they are standing erect in a relaxed manner, breathing normally with arms hanging loosely by sides.
- Weight should be evenly balanced on both feet and feet should be about 25cms – 30cms (or 12ins apart).
- If the participant is large ask them to pass the tape around rather than having to 'hug' them.
- Check that the tape is correctly placed and that the tape is horizontal all the way around.
- For both the waist and the hip measurements ensure the zero point of the tape is below the measurement value for ease of reading.

Waist Circumference

- 1) The waist is defined as the point midway between the iliac crest and inferior margin (or lower edge) of the last rib. Ask permission to locate the last rib and slide your hands down to the midpoint. *The participant may prefer to do this him/herself.* Male waists tend to be above the top of their trousers whereas female waists are often under the waistband of their trousers or skirts.
- 2) If participant has a waistband at the correct level of the waist (midway between the lower rib margin and the iliac crest) measure the waist circumference over the waistband. Do not try to avoid the effects of waistbands by measuring the circumference at a different position or by lifting or lowering clothing items.
- 3) Fit tape snugly but not tightly enough to compress the underlying soft tissue. Ensure tape is horizontal. Ask them to breathe in then breathe out gently and to look straight

ahead (to prevent the participant from contracting their muscles or holding their breath). Take the measurement at the end of a normal expiration. Record measurement to nearest even millimetre. e.g. halfway between 68.3 mms and 68.4 mms round up to 68.4 mms, halfway between 68.8 mms and 68.9 mms round down to 68.8 mms. Enter the measurement into CAPI.

- 4) Repeat the measurement and enter into CAPI.
- 5) If the first two measurements are $\geq 0.5\text{cm}$ different a third measurement must be taken; CAPI will instruct you to do this.

Summary of data to be recorded in CAPI

- Waist measures (either 2 or 3 measures).
- Any concerns which arise during the waist measure (difficulty in finding the correct point to measure, having to measure over bulky clothes etc. should be noted at the end of the measure (after hip circumference) in the notes section in CAPI).

Hip Circumference

- 1) The hip circumference is defined as being the widest circumference over the buttocks and below the iliac crest. To obtain an accurate measurement you should measure the circumference at several positions and record the widest circumference
- 2) Measure the participant around the maximum extension of the buttocks. Check the tape is horizontal and the participant is not contracting the gluteal muscles. Pull the tape, allowing it to maintain its position but without compressing the soft tissue. Record measurement in CAPI.
- 3) Repeat measurement and enter into CAPI.
- 4) As with waist circumference, CAPI will instruct you to take a third measurement if the first two are $\geq 0.5\text{cm}$ different.

Feedback to participants

Record values on the immediate feedback card.

Summary of data to be recorded in CAPI

- Hip measures (either 2 or 3 measures).
- Any concerns which arise during the hip measure (difficulty in finding the correct point to measure, having to measure over bulky clothes etc. should be noted at the end of the measure in the notes section in CAPI).

Positioning the Tape Buckle

↓ READING TAKEN AT BUCKLE END = 145cm





4.6 Body Composition

Body composition is the amount of lean tissue and fat that makes up total body weight. Body fat can be measured by bioimpedance, which gives a more accurate measurement than BMI. Bioimpedance is about the electrical properties of your body and is a measure of how well the body impedes electric current flow. High levels of body fat can result in health problems including high blood pressure and cholesterol levels, arteriosclerosis, coronary disease, respiratory problems and kidney disorders.

Equipment and Overview

The Bodystat 1500MDD measures bioimpedance. Explain to the participant that to measure bioimpedance, a small electric current is applied via 2 electrodes and the resulting small voltage is picked up with another pair of electrodes. This is entirely safe and will not hurt at all.

Exclusion Criteria

Women in the early stages of pregnancy, subjects with pace-makers or **any** implantable electronic device and individuals who are wheelchair bound should not take this measure. If the participant is unable to lie down and the measure is taken standing up, this should be noted in CAPI.

IMPORTANT POINTS BEFORE PROCEEDING WITH MEASUREMENT

- Participants should be measured on a non-conductive (not metal) surface.
- Once the electrode sites have been selected it may be necessary to apply a solvent to remove excess skin oil. Poor contact will result in higher impedance values resulting in an over-determination of body fat levels.
- The skin should be at normal body temperature and not be sweating.
- Once in place, press down on the electrodes to ensure good contact.
- The electrodes may be repositioned if necessary but should not be used on another subject since they may dry out thereby artificially increasing the Impedance values.
- Keep unused electrodes in the sealed plastic bag to ensure freshness.
- **Electrodes should only be used once.** This is to ensure accuracy of measurement and good reproducibility of tests.

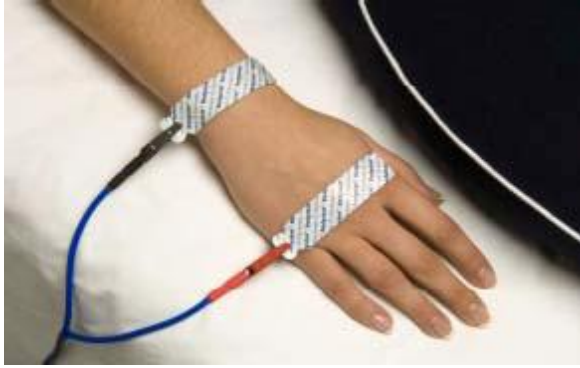
Procedure

- 1) The participant should lie for at least 3 minutes before taking measure.
- 2) Ask participant to remove their right sock or tights and shoes.
- 3) Electrodes are attached to the right hand and right foot as shown below.

4) **RIGHT HAND**

RED LEAD: Behind the knuckle of the middle finger.

BLACK LEAD: On the wrist next to the ulna head.



5) **RIGHT FOOT**

RED LEAD: Behind the 2nd toe next to the big toe.

BLACK LEAD: On the ankle at the level of and between the medial and lateral malleoli (the large protruding bones on the sides of the ankle).



Another easy way to find the correct position of **the black inner electrodes** is to **draw an imaginary straight line** between the protruding bones on the wrist and ankle as described above and illustrated in the diagram. Then place each electrode in the centre of that line with the line also passing through the centre of the electrode tab.

Correct placement of the BLACK INNER electrode on the wrist and the ankle is critical. The electrode placement behind the fingers and toes is not as critical.

As a useful guide, remember BLACK IS BACK, RED AHEAD.

- 6) The participant should lie for 3 to 4 minutes before pressing the ENTER button on the equipment. This is to ensure that the fluid levels have stabilised in the body before a measurement is performed. The machine must be switched on for a minute before taking the measure.

Check the participant to ensure that all the electrodes and leads are firmly connected.

Entering Participant Data

Once the unit has been successfully switched on, the following messages will be displayed on the two line LCD screen:

<p>TEST NUMBER = 001</p>

The BODYSTAT 1500MDD unit automatically allocates the next available number. The test number is used to identify the participant's data back at the SPHSU to calculate their body fat. **It is, therefore, essential the test number is entered correctly into CAPI before moving on to the next step.**

Press the <⇄> key. The screen will then ask you to enter gender, followed by age, height, then weight (you will have recorded this on the measurement card):

GENDER Female

Press either the <↑> or <↓> key to switch between Male and Female.
Press <⇄> to select the displayed gender.

AGE 22 Yrs

Press the <↑> to increase value
Press <↓> to decrease value

HEIGHT 165cm

Use the arrows to increase or decrease the value displayed to the correct height to the nearest cm. Press the <⇄> key to confirm height.

WEIGHT 65.5kg

Use the arrows to increase or decrease the value displayed to the correct weight to the nearest kg. Press the <⇄> key to confirm weight.

Check the subject to ensure that all the electrodes and leads are firmly connected.

Press the <⇄> key.

MEASURING

Wait a few seconds for the results to be displayed on the LCD screen. An audible signal will be heard indicating the completion of the electronic measurement. Ignore the "RESULTS NOT AVAILABLE" shown on the LCD screen and press enter to view the resistance values and phase angle value. The data has now automatically been saved and stored enabling both input and output subject data to be recalled at a later date.

The electrodes and leads may at this stage be removed.

Summary of data to be recorded in CAPI

- 1) Enter the 6 digit inventory number of the equipment you are using.
- 2) Record test number from BODYSTAT machine. This is very important so we can match up more detailed results for the participant in the Unit.
- 3) Record the time the measure was taken.
- 4) Record the lean body mass (in Kgs).
- 5) Record resistance at 50kHz.
- 6) If the measure cannot be taken, select an appropriate missing code in CAPI and record the reason in the notes section at the end of the measure.
- 7) Similarly, if there are any problems or issues with this measure, record this in the notes section in CAPI (as above).

Feedback to Participants

Explain the need to use a special formula to calculate body fat. This will be done when data are returned to MRC and results will be sent to the participant if they wish.

4.7 Spirometry (Lung Function)

Spirometry or lung function tests, which measure the amount of air that can be blown out, assess respiratory impairment and disease as well as being an indicator of general health. Lung function is determined by growth in childhood, and environment and lifestyle during adult life (esp. smoking).

Equipment and overview

The MICRO MEDICAL MICRO PLUS MS03 spirometer is a precision instrument designed to measure:-

Forced Expired Volume in 1 second	FEV₁
Forced Vital Capacity	FVC
Forced Expiratory Ratio	FER
Peak Expiratory Flow	PEF
Maximum Mid-Expiratory Flow,	MMEF

The results are displayed on a clearly legible custom liquid crystal display.

Exclusion Criteria

Ask participants the following:-

	Enter response into CAPI
Have you had abdominal or chest surgery in the last 3 weeks?	YES/NO
Have you been admitted to hospital in the last 6 weeks with heart complaint?	YES/NO
Have you had eye surgery in last 4 weeks?	YES/NO
DO you have a tracheostomy?	YES/NO
[Females] Are you pregnant?	YES/NO

IF THE RESPONSE IS YES TO ANY OF THE ABOVE QUESTIONS THE PARTICIPANT IS **NOT** ELIGIBLE FOR THE LUNG FUNCTION TEST

Enter the responses to the above questions into CAPI.

Enter the inventory number of the equipment you are using into CAPI.

Procedure

Demonstrate blow first yourself. Remember to use a new tube for the participant.

Note: Give the participant a practice go, then three recorded attempts. If the participant is distressed or has breathing difficulties after any of the blows, and does not want to continue, DO NOT INSIST. Enter values for any attempts they did complete and enter the reason for not completing this measure in CAPI in the notes section at the end.

- 1) Ensure that the participant is standing up, if the participant is unable to stand they can remain seated for the measurement, however remember to record this in CAPI in the notes section at the end of the question.

- 2) Switch the unit on by moving the switch to its first position, 'BLOW'. The display will now indicate 'BLOW' and three zeros. Attach a disposable mouthpiece and instruct the participant to "breathe in until your lungs are completely full, now seal your lips around the mouthpiece and blow out as hard and as fast as possible until you cannot push any more air out." Warn the participant that they may feel slightly light-headed doing this. Try to encourage them to improve their performance at each go. The results are strongly affected by how hard and how long the participant blows.
- 3) **Reassure the participant that a degree of 'wheeze' is normal if the test is done properly, with maximum effort.**
- 4) When the participant has completed this manoeuvre, the machine will initially show a value for FEV₁. Record this in CAPI and then move the switch to the 'view' position. The machine will cycle through **five** measurements, **FEV₁, FVC, FER, PEF and MMEF** displaying each in turn. We want you to record all **five** measures.
- 5) **NB.** you can 'freeze' one of the measures by moving the switch back to blow. When you return it to display it will carry on cycling through the measures. However, be careful, if you inadvertently move it to 'off' you will lose any remaining information.
- 6) Once the values have been noted the next test can be carried out by repeating the procedure after switching the unit off and then back on again. Give adequate time in between attempts for the participant to get their breath back. Make sure to record three attempts.
- 7) For each blow, enter into CAPI whether the participant blew correctly or not.

Technically Unsatisfactory Blows

A technically unsatisfactory blow is any of the following:

- An unsatisfactory start, e.g. excessive hesitating or a "false start". If you see * on either side of the *FEV₁* then this tells you that it is an excessively slow start.
- Laughing or coughing especially during the first second of the blow. Many people will cough a little towards the end of their effort but this is acceptable.
- Holding the breath in (i.e. a valsalva manoeuvre).
- A leak in the system or around the mouthpiece. This would include those where the mouthpiece is not firmly held by the lips.
- An obstructed mouthpiece e.g. tongue in front of the mouthpiece or false teeth obstructing the mouthpiece.
- Note that a result of 0.00 on an FEV₁ also means that the test has not been carried out properly.

- 8) Dispose of the mouthpiece - ask the participant to throw it away for you. (The inside of the turbine casing may get clogged up after use with participants who have chest trouble etc. If this happens, ask for a replacement).
- 9) If you are interviewing more than one person per day, ensure that you use a one-way valve on your second visit to prevent the spread of infections from your first to second participant.

Summary of data to be recorded in CAPI

- 1) Enter responses to eligibility questions.

- 2) Enter inventory number of your equipment.
- 3) If an attempt is not measured, select an appropriate missing code in CAPI and record the reason in the notes section at the end of the measure.
- 4) Results for each 3 blows; FEV₁, FVC, FER, PER, MMEF and quality of blows.
- 5) If any of these blows are unsatisfactory, CAPI will prompt you to take a fourth measurement.
- 6) Record any problems taking the measure in the notes section in CAPI at the end of the measure.

Feedback to participants

If asked, give participant their FEV₁ measure but say the measurement varies considerably due to lots of factors. Do not compare their measure to other participants.

4.8 Taking Informed Consent (Stage 2 - Bloods)

At this stage ask the participant for consent to take a blood sample

- 1) Ask the participant if s/he has read and fully understands the information sheet with regard to the blood sample and if they have any questions.
- 2) Once questions are answered, ask them to complete Consent form 2 - Bloods.
- 3) Go through each item on the consent form. There are a number of different components to the blood consent:
 - A sample for initial analysis;
 - Receiving results of the initial analysis;
 - Notification of the results to their GP;
 - Indefinite storage of a portion of the blood sample;
 - Extraction and indefinite storage of DNA from the blood sample.

Ask the participant to initial each box if they agree and enter their responses into CAPI. If they consent to results being sent to their GP, CAPI will prompt you to ask for their GP details. Switch to the 'GP' tab at the top of the screen. Select a GP surgery matching the participant's response from the drop down menu. Sometimes, a participant will not know the name of their GP or the exact address of the practice. If the information they can provide do not match with any in the drop down list, enter the details verbatim. If entered earlier during questionnaire checking, simply check these details are correct (by clicking on the 'GP' tab) and move on to the next question in CAPI.

- 4) You should seek to obtain consent to all parts before you commence blood sampling. However, **it is not a requirement that participants consent to all parts**. However, if a participant does not want to initial a box, please place a large cross in the box to show that the particular section has been covered
- 5) Once the boxes are completed, the participant prints and signs their name. Without a signature the consent form is invalid.

Note - you only need to get the participant to sign a consent form if they have chosen to do at least one of the options on the form.

If the participant **does not want to give a blood sample** but they **do want their GP to receive their height, weight and BMI**, please get them to initial the third box on Consent Form 2 and cross out the parts of the sentence relating to bloods, cross through the other boxes and sign the form. **If they do not want these results to be sent to their GP or to give blood, then they do not need to sign Consent Form 2 at all.**

- 6) Complete your name, the date and your signature.
- 7) Once completed, detach the pink copy and give it to the participant and place the white top copy with the barcode in the Consent Folder
- 8) If the participant has consented to feedback to their GP, the system will prompt you to enter the participant's GP details. To do this, click on the "GP" tab at the top of the screen. Enter the participant's GP details by choosing from the drop-down list. If the person's GP is not listed, you can enter these details manually. Click 'OK' to save your updates.
- 6) You can click on the "Survey" link at the top of the screen at any time to get back to the survey and continue with the interview.

As blood taking is an invasive procedure we need to obtain written consent as well as verbal consent to take it. This has to be obtained from the participant **in all cases**.

If you cannot obtain written consent, the CAPI system will route you accordingly. **On no account** should you ever take blood before you have obtained written consent to do so from the participant.

Note - the consent form explicitly mentions that HIV tests **will not** be performed, so that the participants are not placing themselves at risk of financial disadvantage by taking part in the survey (some insurance companies may disqualify people, or demand higher premiums, if they have ever been **tested** for HIV, regardless of the result of the test).

4.9 Blood Sample

Once the consent procedure has been completed you may then go on to take the Blood sample.

Biomarkers are naturally occurring substances in the blood that can signal disease when found at levels that are significantly different to levels found in healthy individuals. The blood samples will be tested for the following:

Total cholesterol – Cholesterol is a type of fat present in the blood, related to diet. Too much cholesterol in the blood increases the risk of heart disease.

HDL cholesterol – This is 'good' cholesterol which is protective for heart disease.

Glycated haemoglobin (HbA1c) – Indicates the presence or risk of type 2 diabetes, which is associated with an increased risk of heart disease.

Fibrinogen – A protein necessary for blood clotting. High levels are also associated with a higher risk of heart disease.

Adiponectin – is A protein hormone that modulates a number of metabolic processes including glucose regulation. Levels of the hormone are inversely correlated with body fat percentage in adults.

C-reactive protein – The level of this protein in the blood gives information on inflammatory activity in the body, and it is also associated with risk of heart disease.

DNA – Genetic factors are associated with some common diseases, such as diabetes and heart disease, and relate to general biological aspects of the ageing process.

In addition blood samples will be tested for:

- 1) Liver Function
- 2) Kidney Function
- 3) Full Blood Count (FBC)

A sample of blood will also be stored for later analysis of hormone systems (e.g. vitamin D, nitrates and nitrites, gut hormones) and blood constituents detected by metabolomics proteomic methods.

Exclusion Criteria

All participants, with the following exceptions, are eligible to give blood.

a. People with clotting or bleeding disorder By clotting or bleeding disorders we mean conditions such as haemophilia and low platelets, i.e. thrombocytopenia. There are many different types of bleeding/clotting disorders but they are all rare. With these problems, do not attempt to take blood, even if the disorder is controlled. (People who have a past history of thrombophlebitis, a deep venous thrombosis, a stroke caused by a clot, a myocardial infarction or an embolus are NOT considered to have clotting disorders and should not be excluded).

b. People who are not willing to give their consent in writing.

- c. **Woman with recent mastectomy:** you should not take blood from someone who has arm swelling post mastectomy but it is OK to take blood if there is no swelling.
- d. **Participant on renal dialysis:** blood should not be taken from an arm with a shunt in place for renal dialysis.

Equipment

Tourniquet

Alcohol swabs

Vinyl gloves

Adhesive dressing

Micropore tape

Set of labels for blood sample tubes

Royal mail 'safebox' X 1

"To" labels

"From" MRC Labels

Vacutainer holder

Cotton gauze

Butterfly needles 23G – (yes)

Needle disposal box

Vacutainer EDTA purple tubes

Vacutainer citrate blue tubes

Vacutainer plain gold tubes

Haz Tabs or Presept tablets

The Blood Tubes

Blood collection should be taken in the following order:

No of tubes	Amount of blood and tube type	Top colour	Test
1	3.5ml citrate tube	blue	Fibrinogen
1	5ml serum separator tube	gold	Lipids, adiponectin, vit D, CRP, kidney and liver function, & storage
1	3ml in 4ml EDTA tube	purple	FBC
1	3ml in 4ml EDTA tube	purple	HbA1c, DNA and storage
1	8ml in 9ml EDTA tube	purple	Gut hormones

Taking the Sample

You will be taking a maximum of five tubes (one blue topped tube, one gold and three purple), three for initial analysis and storage, one for DNA extraction, and one for Fibrinogen. CAPI will instruct you about which tubes to use, according to the information input regarding consent.

Procedure

- 1) Collect and prepare relevant equipment and specimen bottles.
- 2) Approach participant in a confident manner, explain procedure.
- 3) The participant should be seated comfortably in a chair, or if they wish, lying down on a bed or sofa.
- 4) Wash hands and put on gloves.
- 5) Ask the participant to roll up their sleeve on their chosen limb and rest their arm on a suitable surface. Ask them to remove their jacket or any thick clothing, if it is difficult to roll up their sleeve.

- 6) The antecubital fossae (triangular area on the front side of the elbow joint of the arm) may then be inspected. It may be necessary to inspect both arms for a suitable choice to be made, and the participant may have to be repositioned accordingly.
- 7) Do **not** ask the participant to clench his/her fist.
- 8) Support chosen limb and apply the tourniquet around the participant's arm, if necessary the vein may be tapped gently to aid filling. Please note, it is desirable to use the tourniquet applying minimal pressure and for the shortest duration of time. Do not leave the tourniquet in place for longer than 2 minutes.
- 9) Ask the participant to keep his/her arm as still as possible during the procedure.
- 10) Clean participant's skin with appropriate preparation for 30 seconds and allow to dry. Do not touch the site after cleansing.
- 11) Grasp the participant's arm firmly at the elbow to control the natural tendency for the participant to pull the arm away when the skin is punctured. Place your thumb an inch or two below the vein and pull gently to make the skin a little taut. This will anchor the vein and make it more visible.
- 12) (a) Insert needle smoothly at approx a 30° angle
- 13) (b) When winged tipped devices used - obtain a flashback then insert needle approximately 1mm further.
- 14) Withdraw required specimens via Vacutainer System with the participant's arm in the downward position.
- 15) Release the tourniquet before withdrawing needle.
- 16) Ensure the wings of the butterfly are firmly held or secured against the skin. Using one hand, cover the puncture site and sliding shield with cotton wool, with the forefinger and thumb of the other hand press in both sides of the safety hub.
- 17) Slide the safety hub backwards.
- 18) An audible click confirms the shield is completely locked. The cannula should be fully enclosed in the protective shield.
- 19) Apply digital pressure over puncture site. Ask the participant to hold the pad firmly for three minutes to prevent haematoma formation.
- 20) Following haemostasis apply adhesive dressing to puncture site. (Check participant is not allergic before applying! - If they are allergic, use cotton gauze secured with micropore)
- 21) Ensure participant is comfortable.
- 22) Label bottles with relevant details.
- 23) Discard all waste and sharps.

- 24) Discard gloves and wash hands
- 25) Follow procedures for completing forms and transferring specimens to labs.
- 26) **When venepuncture is unsuccessful after 2 attempts, no further attempts should be made.**
- 27) If unsuccessful, record the number of attempts in CAPI in the notes section.
- 28) Record which arm the sample was drawn from.

If there is a problem and the participant decides they don't want all the tubes for collection filled, or the blood is not running freely stop collecting blood at the end of the tube you are taking and note this in CAPI by clicking on the flag symbol and entering details.

IMPORTANT WARNING

Never re-sheath the needle after use.

Do not allow the disposal box to become overfull as this can present a potential hazard

Possible Problems

Please Note – If an adverse reaction occurs, please record in CAPI and complete an incident report form and ask the participant to sign it.

PROBLEM	CAUSE	SUGGESTED ACTION
Fainting Participant	1. Participant looks or feels faint during the procedure	Discontinue procedure Ask participant to lie down with their feet elevated Ask if they are happy to continue after a suitable length of time, the participant should be supine, and the circumstances recorded.
Excessive pain	1. Anxiety, fear, low pain threshold 2. Frequently used veins 3. Nerve touched 4. Poor technique by operator	Confident unhurried approach. Make sure participant is in a comfortable position.
Very anxious participant	1. Previous bad experience 2. Needle phobia	Confident unhurried approach. Make sure participant is in a comfortable position.

		Use all methods to dilate vein including applying local heat Consider using winged device
Limited access	1.Repeated use 2.Bruising due to fragility or medication 3.Peripheral shutdown	Confident approach. Only proceed if sure of successful first attempt, otherwise seek help. As above and ensure vein anchored. Ensure adequate pressure to puncture site Use all methods to try and dilate veins. Consider using BP cuff. Consider massaging above venepuncture site to assist venous filling/return
Infection	1.Poor aseptic technique	Practice good hand washing techniques as per Infection Control Manual.
Missed vein	1.Inadequate anchoring 2.Wrong positioning 3.Less than 100% concentration	Withdraw needle almost to bevel and manoeuvre to realign needle with vein. Remove and try again if too uncomfortable for participant
Blood flow stops	1.Over shooting vein or advancing needle while withdrawing blood. 2.Vein collapses due to contact between needle and valve or vein wall. 3. Poor blood flow	Gently ease needle back and continue Release and re-tighten tourniquet and continue. As before and gently massage above needle tip to pull blood into vein.
Haematoma	1.Perforation of posterior wall of vein. 2.Removing tourniquet before removing needle. 3. Inadequate pressure over puncture site	Insert needle at correct angle and stop when you have flashback. Do not advance needle during sampling Remember to release tourniquet. Apply pressure and dressing to area or supervise participant doing so.
Transmittable diseases	1.Viruses	All blood should be handled with care. Universal precautions apply Wear gloves for sampling

Needle inoculation	1.Lack of caution	Safe disposal of equipment
	2.Overfilling of sharps containers	Follow MRC policy for needle stick injuries

Blood Sample Transfer to Laboratory

All blood samples will be sent to St Thomas's Hospital, London. They will be collected by a City Sprint courier. If it is a home visit, City Sprint will be contacted when the nurse / researcher is 10 minutes away from their base (KCL/ Denmark Hill). The courier will then come to this location to pick up the bloods. If the pick-up is from a GP surgery, the nurse will contact the courier at the end of the participant visit. The procedure to contact the courier is as follows:

- Call City Sprint on **0845 020 3000** and provide the following information.
- It is the **DASH Study**
- Account Number **M70132**
- Purchase Order **4050149366**
- Details of the booking i.e. your surgery details and St Thomas's address i.e.
- The Special Processing Unit, 5th floor North Wing, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH.

WARNING: Do not close MailSafe box lid until all the contents are inside the package.

Procedure

- 1) Label the tubes as you take the blood.
- 2) Use the set of ID number labels to label the vacutainer tubes.
- 3) You have one sheet of labels per participant - check the serial number, person number, full name and date of birth printed in the top left of each one.
- 4) Attach one serial number label to every tube that you send to the lab.
- 5) Do **not** write any information (such as date of birth) on the labels.
- 6) All tubes from one person should be packed into one dispatch container (Mail Safe box) with a GRI Dispatch Form and 2 spare labels.

You will be given Royal Mail Safeboxes which contain:

- An absorbent insert
- A transparent bag
- A single tube absorbent insert

- 7) Remove absorbent material and plastic bag from Royal Mail Safe Box.
- 8) Place labeled tubes in fingers of absorbent material.

(1 tube per finger and a maximum of 5 tubes per safe box.)

- 9) Place in plastic bag and seal.
- 10) Place bag and contents in clear plastic container within Safe Box.
- 11) Please ensure dispatch document has been completed:

Completing Blood Dispatch Note

- a) Affix the participant's ID number label to each of the 2 copies of the dispatch note. These must correspond to the barcoded labels you have placed on the tubes.
- b) Complete the dispatch note, pressing firmly with your pen so that both copies are clear
 - remember to fill in the participant ID, the time and date of blood collection and your Worker Reference Number.

If you have only achieved an incomplete blood sample (e.g. have only filled one tube), please state this clearly on the dispatch note and give the reason in CAPI.

- 12) Place the yellow copy of the dispatch document in the compartment next to the sample in the Royal Mail Safebox along with 2 spare copies of the ID label. Please ensure all contents are inside at this point as *once the package has been closed it cannot be opened without destroying it.*
- 13) *Remove the cardboard separator from the lid. Place the lid over the bottom of the container and firmly press shut. Peel the outer backing from the label and wrap around the Safe box.*
- 14) Ensure the package is addressed correctly (prepared labels) and the return address has been completed (prepared labels).

The hospital ID number will be added to the tubes as they are put in the rack for analysis. The hospital number will be used on storage samples and our ID number will also be added. The DNA and serum samples will have the spare ID labels added to them and then will be stored in a -72 freezer at Kings College, 150 Stamford Road, London

Important

Ensuring that you label each tube with the correct ID number for the person from whom the blood was obtained is critical. Apart from the risk of matching up the blood analyses to the wrong person's data, we will be sending the GP the wrong results – for example the wrong person could be informed that an abnormality has been detected.

Sharps

Sharps disposal containers conforming to British Standard CE marking or BS7320 : 1990 will be provided for non-GP surgery interviews. The containers should be assembled and labelled as instructed i.e. Nurse ID (Worker Reference Number), Date assembled and Date closed. Ensure that the base and lid of the container are securely fitted together. The sharps disposal container should be carried to and from the interview in the backpack provided. Always carry the disposal container using the handle attached to the container when moving the disposal container at interview, holding away from the body.

Use the recommended butterfly needle and vacutainer to take blood from the participant. Once the relevant bloods are drawn and the tubes **are closed**, follow the procedure below to dispose of the needle and vacutainer holder.

It is the responsibility of the person using the sharp to ensure its safe disposal.

In GP surgeries use the Sharps disposal procedure in existence in the practice.

In non-GP surgery visits follow the procedure below:-

- Sheath the needle before withdrawing from the participant's vein.
- Ensure that the lid of the disposal container is fully open so that the needle and vacutainer will not catch as they are lowered in to the opening.
- Dispose of Safety Blood Collection Set and Vacutainer holder as a single unit.

- Place sharps into container aperture ensuring that fingers are never less than approximately 2 inches above the opening
- (In homes/ other non-GP venues) Ensure sharps containers are placed off the floor, out of reach of children, and as near as practicable to sites of use, and make certain that unauthorised people cannot gain access to them.
- **Do not** dispose of sharps with other clinical waste.
- **Do not** expose sharps containers to extreme temperatures unless this is part of the disposal process.
- **Do not** resheath needles.
- **Do not** throw sharps into disposal containers, or drop them from a great distance.
- **Do not** overfill sharps containers (fill line is clearly marked) - provide adequate numbers of containers.
- **Do not** attempt to retrieve items from sharps containers or press down on contents to make more room.
- If you take too many bottles by mistake, place the extra bottles in the sharps disposal container as well as the needle and vacutainer and press final closure
- Sharps disposal container should be finally sealed either when three-quarters full, when it contains a vacutainer bottle containing blood, when there has been a substantial spillage or at maximum intervals not exceeding two weeks.
- Closed Sharps disposal container should be disposed of in the surgery or hospital in which you are located
- Disposal of sharps disposal containers can be carried out at monthly meetings or at any time deemed necessary by the Research Nurse.
- Do not allow used sharps containers to accumulate. Store in a safe, secure area while awaiting final disposal in your surgery or hospital
- It will be the responsibility of the Nurse/ RAs doing nurse interviews to keep any closed sharps disposal containers in a safe, secure storage area whilst waiting disposal.

Use of Sharps

- **Never** leave sharps lying around.
- **Never** walk about with unguarded sharps.
- **Never** keep sharps in your pocket.
- **Always** take a sharps container to the point you use the sharp.

Accidental Spillage

i) Blood spillage in GP surgery

Please follow the blood spillage procedure of the surgery

ii) Blood spillage at Participants Home/ Other non-GP venue

Should there be a situation where blood is spilled in the participants' home then, as soon as possible and wearing gloves, simply clean with soap and water and dispose of paper towels into the participant's domestic waste. **Always** take a spare sharps disposal container with you in case you need to finally seal the one currently in use.

If there is the possibility of any spillage because of leakage of liquid in a sharps disposal container, the container should be finally sealed in the participant's home and a replacement container used for the next participant. In the unlikely event that a spillage occurs anywhere other than the location of the interview, the following steps should be taken

- Clean up all blood spillage as soon as possible. Use chlorine releasing agent e.g. Haz Tabs or Presept tablets added to tap water or Milton (undiluted). Disposable gloves should be worn (with aprons and eye protection if splashing is likely).

- Discard disposable gloves (and apron, eye protection if applicable) as 'Clinical Waste' in a yellow disposal bag and wash hands thoroughly
- Seek help to guard the area while dealing with spillage
- Prepare a new, correctly assembled sharps disposal container
- Consider a plastic dustpan to carefully collect spilled items and transfer to new sharps disposal container which you should finally seal
- Do not rush this procedure
- Store in a safe area while awaiting final disposal at the surgery or hospital.

Needle-stick Injury

Should you incur a needle-stick injury please refer to the Health and Safety section of the manual for what to do next.

4.10 Checking the Questionnaire and Self-complete 24 Hour Dietary Recall

Main Questionnaire

Ask the participant if they have completed and brought along their Main Questionnaire.

Enter their response into CAPI. CAPI will then prompt you to do one of the following:

1) YES – questionnaire completed and brought along

Follow the procedure for completed questionnaires (step 4)

2) YES – questionnaire completed BUT NOT BROUGHT ALONG

Ask the participant if they would be prepared to complete the questionnaire again. Enter their response into CAPI

If yes – attach the relevant barcode ID label to the questionnaire and give to participant

Follow the procedure for completed questionnaires (step 4)

If no – give them a reply envelope (and ask them if they would post their questionnaire as soon as possible)

3) NO – questionnaire not completed

Ask the participant if they would be prepared to complete the questionnaire now.

If yes – attach the relevant barcode ID label to the questionnaire and give to participant

If no – enter their response on CAPI. Ask them if they have a reason for not completing the questionnaire and enter the response on CAPI.

4) Procedure for completed questionnaires

Check through the completed questionnaire. Ask the participant about any questions or question items they have left out. Reassure participants that they can omit any question they do not wish to complete, but that you are just checking there are none accidentally left out.

5) GP contact details

If they provide their GP details, select the "GP" tab at the top of the screen and enter their GP details here. In most cases, you will be able to find the GP surgery name in the drop-down list. Sometimes, a participant will not know the name of their GP or the exact address of the practice. If the details they can provide do not match with any in the dropdown list, enter them verbatim.

24 Hour Dietary Recall

Ask the participant if they have completed and brought along their 24 hour recall. Enter their response in CAPI.

- 1) If the participant has brought along their recall collect the back two pages from the questionnaire and place in the recall folder. Return the photo-pages to the participant for the telephone interview.
- 2) If the participant has completed their recall or has not got their recall with them, ask them if they would be willing to complete another copy and fill it in before leaving the surgery or post it back to us from home. Attach the relevant barcode ID label to each of

the data pages at the back of the 24 hour recall questionnaire and give to the participant, telling them to detach the back pages once completed and place in the pre-addressed envelope. The participant should keep the photo-pages for the telephone interview.

- 3) In all cases CAPI will prompt you to alert the participant that a member from the study team will be in touch in about three weeks to conduct another recall over the telephone. Explain to the participant that together the self complete and administered dietary recalls will give a better picture of dietary habits than just a single one. You do not need to request an immediate response but if one is made (i.e. if they do not want to be contacted), note it in CAPI in the notes section.

4.11 ActivPAL

An ActivPAL is a small electronic monitor developed specifically for the purpose of quantifying physical activity. The device is attached to the centre of the right thigh and measures time spent; standing, stepping, sitting or lying down. The ActivPAL monitor houses a microprocessor which controls the processing and recording of the sensor signal and communication with a host Personal Computer (PC).

Equipment

ActivPAL3 physical activity logger

Nitrile Sleeve

7 10cm x 13cm strips of waterproof hypafix transparent dressing (2 to prepare and attach device and at least 5 spares to give to participant to take away with them)

Scissors

Black permanent marker pen

7 10cm x 13cm strips of waterproof *flexifix* transparent dressing (as an *alternative* dressing for those who have sensitive skin or are allergic to medical dressings)

Exclusion Criteria

Participants in a wheelchair cannot be measured.

Set up of Equipment

All of the ActivPAL monitors must be set up and **fully charged** prior to nurse interview commencing.

For full procedure on how to set up, programme and prepare the ActivPAL device, see the 'Preparation for Nurse Interview' chapter of this manual.

Procedure

- 1) Ask the participant if they would be willing to wear an ActivPAL monitor for 5 days. Record their response in CAPI.
- 2) Ask the participant if they have sensitive skin or have any known allergies to medical dressings (e.g. plasters, latex). If the answer is yes, use the flexifix dressing to attach the ActivPAL to the participant and give the participant spares of flexifix. If the answer is no, use the hypafix dressing. Hypafix is the standard dressing and should be used unless the participant specifically states that they have sensitive skin/allergies.
- 3) If the participant is happy to wear the ActivPal, ask them to change into their shorts if they have brought these with them. Give them adequate space and privacy to do this. If they do not have shorts with them, ask them (if they are comfortable to do so) to remove their trousers or outer garments on their bottom half and sit in the chair with their upper thigh visible.
- 4) Record in CAPI the Inventory Number of the monitor given to the participant.
- 5) The device must be attached to the front of the participant's right thigh, half way between the knee and the hip. To do this, use one strip of waterproof transparent

dressing, 10cm X 13cm in length. This strip of dressing should be applied over the ActivPAL to fasten the monitor to the participant's right thigh (see next step).

- 6) The participant should secure the monitor themselves under the supervision of the researcher / nurse. The participant should be given an opportunity to change into a pair of shorts so that they can do this without embarrassment and the researcher should try to ensure that they have sufficient privacy (e.g. using screens) wherever possible. Firstly, the front backing of the tape should be removed by peeling from the middle. The adhesive side of the tape should be placed down onto the participant's right thigh, about half way down, with the middle part aligned with the centre part of the ActivPAL. Finally, the back piece of the backing should be removed and pressed upon firmly to secure the dressing (see figure 1).



Figure 1. Image of ActivPAL securely attached in the correct position.

- 7) This arrangement should enable the participant to wear the device for a period of 5 days without having to remove it. Each participant should be asked whether or not they partake in regular activities where they are fully submersed under water (such as swimming or regular baths) and provided with spare pieces of dressing to re-apply the device if it is removed. Every participant must be provided with at least five spare pieces of dressing to enable them to re-attach the device if it comes loose or falls off during the period of wear.
- 8) Each participant should be briefed according to the information outlined above on how to attach and re-attach the monitor.
- 9) Let the participant know that a researcher from the DASH team will send them a text to remind them to return their ActivPAL monitor at the end of the 5 day monitoring period.

Notes

It should be made completely clear to all participants they are able to wear the monitor whilst showering, however if they plan to take a bath or go swimming the **ActivPAL monitor must be removed** and subsequently re-affixed.

Each participant should be instructed to review their dressing on a daily basis to ensure there is no irritation or discomfort as a result of wearing the ActivPAL monitor. If

participants experience any problems such as itchy, sore skin, they are told to remove the device without delay.

When the ActivPAL monitor has been attached in the correct manner and configured appropriately, the device will automatically record participants sitting/lying, standing and stepping time.

Summary of data to be recorded in CAPI

- 1) Record the participant's response to wearing an ActivPAL monitor for 5 days.
- 2) Enter the inventory number of the ActivPAL device.

4.12 Removing the Arteriograph

Please note a minimum of 4 readings should be taken during the interview. Once the interview has been completed and at least 4 arteriograph readings have been taken follow these steps to remove the arteriograph device and retrieve the data.

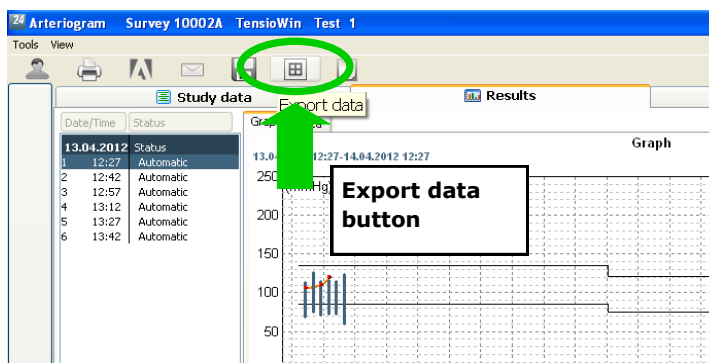
- 1) Remove the cuff from the participant's arm, disconnect the cuff from the Arteriograph and unfasten the belt fixing the device to the participant.
- 2) Switch back into the Arteriograph software by selecting the TensioWin tab at the bottom of the screen.

Retrieving the participant's data

- 3) In the Arteriograph software, click on 'Retrieve data from device' (the big button at the bottom of the screen in the middle).
- 4) Make sure Arteriograph 24 is chosen as device type.
- 5) Click 'Ok' to download data from the device to the software.
- 6) At this point you should see the word 'CONNECT' displayed on the screen of the Arteriograph 24 device. Please wait while the process reaches 100%.

Exporting the participant's data

- 7) To export the data, click 'Export' button at the top of the participant's results screen.



- 8) A pop-up window will appear on the screen asking you how the export file should be named and where it should be saved.

The exported data file should be saved in:

'My Documents\Arteriograph data export'.

The name of the exported data file should be the participant ID number followed by the date of the interview.

E.g. 1004K-12Apr2012

Exiting the TensioWin programme

9) To exit participant data, click the left vertical button with the left arrow.

10) To exit the TensioWin software, click the left vertical button.

4.13 End of Session – Checking and Feedback

Check the following:

- 1) The immediate feedback card has been completed and issued. You can scroll through a sidebar in CAPI and click on individual questions if you need to review the measures to record on the feedback card.
- 2) A Blood Pressure letter with advice to visit their GP has been issued if the participant's blood pressure was above stated thresholds.
- 3) The consent forms are in the consent form file.
- 4) The completed questionnaire is in the questionnaire file.
- 5) The dietary recall questionnaire is in the dietary recall file
- 6) The Arteriograph data are saved on the laptop (see above).

Inform the participant of/ note the following:

- 1) Remind the participant that we will post their blood results to them in about 8 weeks, by which time we should receive them from the lab.
- 2) Remind the participant that a researcher will be in touch to conduct a telephone evaluation after they have received their blood results – in particular to get their feedback on what worked well and what did not. Explain to participant that their feedback is very important for the best design of the follow-up of all study members.
- 3) A £25 Love to Shop voucher will be sent to the participant within 2 weeks of the Survey Office receiving confirmation that the interview has been conducted.
- 4) Tell them about the focus groups and give them Information Sheet 2 which is about the focus group sessions. Inform them that there is an additional £10 voucher for taking part in a focus group.
- 5) Note in CAPI their initial response to the idea of participating in the focus groups, and let them know that a researcher will be in touch.
- 6) Close by thanking the participant for their time and letting them know that they can contact the study office on 0800 389 2129 or by email at dash@sphsu.mrc.ac.uk if they wish to discuss anything related to the study.
- 7) Finally, note any unusual occurrence or circumstances during the interview. CAPI will give you a question with space to write any notes.

