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**PATIENT-CENTRED CARE: PATIENTS' EXPERIENCES OF AND
RESPONSES TO THE NATIONAL HEALTH SERVICE (NHS)
HEALTH CHECK PROGRAMME IN GENERAL PRACTICE**

Elizabeth T. J. Strutt

ABSTRACT

This thesis investigates patients' experiences of and responses to NHS Health Checks, towards the goal of improving patient-centred care. The findings are based on analyses of semi-structured interviews with sixteen Darlington-based patients who had recently undergone an NHS Health Check. I analysed patients' satisfaction with the NHS Health Check and their expectations about the models and types of care their GP surgery should provide. This analysis identified five aspects of the design and delivery of NHS Health Checks which did not meet patients' expectations:

1. The NHS Health Check did not meet patients' expectations for a general health check which would provide empathy and support for all of their health priorities and concerns.
2. Patients felt that eligibility to attend an NHS Health Check should be based on patients' opinions about when they need or want to have a health check and that access to NHS Health Checks should not be restricted, through age-based criteria.
3. During the NHS Health Check, health was measured in ways that caused some patients discomfort, stress, or anxiety.
4. Patients did not think that all the measures of health used to define their bodies were relevant to their lives. Patients did not necessarily agree with, support, or believe in these definitions of their health.
5. Reliance on general advice about self-help, specifically with the letter of results, did not effectively support all patients to improve their future health outcomes. Some patients found the general advice did not apply to their individual circumstances.

The current format of an NHS Health Check does not adapt well to patients' needs and preferences as individuals and the particular health measures and health outcomes which they think are most important. Improved patient-centred provision of NHS Health Checks may help to improve patient satisfaction.

**Patient-centred care: Patients' experiences of
and responses to the National Health Service
(NHS) Health Check programme in general
practice**

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2011

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CHAPTER ONE: INTRODUCTION

1.1 Research Overview

This study interrogates patients' experiences of and responses to the NHS Health Check programme in general practice. Participants of this study were recruited from a list of patients who had recently attended an NHS Health Check at two general practices in the North-East of England. Each participant took part in an in-depth, semi-structured, one-to-one, face-to-face interview where we discussed their particular experiences of and responses to their NHS Health Check. These interviews were recorded, transcribed, coded in NVivo, and analysed thematically. The results of this process are here represented.

Specifically, the strategic needs of local general practitioners inform this research, but it also has wider relevance to other health professionals working in health promotion and to manage risk of chronic, complex diseases. The research aims to support health professionals who deliver NHS Health Checks and to represent patients' interests. To achieve this balance, the analysis focuses on patient satisfaction with NHS Health Checks towards the goal of improving patient-centred provision. In theory, patient-centred care should both meet the needs of patients and is, currently, a favoured model of care in general practice. With these goals in mind, I analyse patients' experiences of the extent to which the NHS Health Check engaged with and supported their health beliefs, identities, concerns, attitudes, and preferences.

1.2 Aims and Objectives

The aim of the study is to improve the delivery of the NHS Health Check programme in terms of patient-centred provision.

Two objectives will help pursue this aim:

1. To interrogate patients' experiences of and responses to their NHS Health Check.
2. To provide insight into patient satisfaction with their NHS Health Check.

1.3 A Summary of the NHS Health Check Programme

The National Health Service (NHS) Health Check programme aims to reduce levels of cardiovascular disease (including stroke, coronary heart disease, type 2 diabetes, and chronic kidney disease). The policy asserts the role and the responsibility of the NHS through an organised health promotion programme to assess and manage individuals' risks of developing cardiovascular disease over ten years. The NHS deliver the programme under the branding of 'NHS Health Checks', these checks are routinely offered to people living in England who are between the ages of 40 and 74. General practices are among those responsible for recruiting eligible people to the programme and also for delivering the NHS Health Checks.

The NHS Health Check programme is designed to provide a national, unified and systematic cardiovascular disease risk assessment, risk reduction, and risk management programme (Davies, Khunti et al. March 2008: 26). The policy focuses on providing a cardiovascular disease risk assessment, in addition to health and lifestyle advice and support. It claims to afford the public greater knowledge about their chance of developing cardiovascular disease, type 2 diabetes, and chronic kidney disease and more empowerment to make lifestyle changes to improve their health.

The phrase "Vascular Disease Control Programme" was chosen to summarise one of the founding aims of the policy (Muir Grey May 2006: 1), which, as the name suggests, was introduced partly in response to concerns about the rising levels of cardiovascular disease in England:

"Vascular disease includes coronary heart disease, stroke, diabetes and kidney disease. It currently affects the lives of over 4 million people in England. It causes 36% of deaths (170,000 a year in England) and is

responsible for a fifth of all hospital admissions. It is the largest single cause of long-term ill health and disability, impairing the quality of life for many people.” (UK National Screening Committee 2009).

“... a considerable amount of vascular disease goes undetected and those at risk are not identified. If the status quo is maintained then the rates of non-detection and unassessed risk factors will continue, leading to high levels of disease as the age groups get older.” (Crown Nov 2008: 9).

The NHS Health Check programme was designed to improve both life expectancy and quality of life and be cost-effective compared to projected treatment costs for cardiovascular disease. As such, the initiative was deemed “a very important programme in terms of the nation’s ability to fund healthcare” (Douglas Smallwood, chief executive of Diabetes UK) (House of Commons 25 June 2008).

Under the NHS Health Check programme, ‘NHS Health Checks’ began to be delivered across England from April 2009. The NHS Health Check programme is a primary care intervention delivered across a wide range of targeted community settings, including general practices, pharmacies, and workplaces. Through these settings NHS Health Checks are being offered to people who have not already been diagnosed with stroke, coronary heart disease, type 2 diabetes, or chronic kidney disease and who are between the ages of 40 and 74. An age criteria was felt to be most feasible, compared to identifying patients with other risk factors, because of the information recorded on medical records (Goyder, Carlisle et al. 2008: 15). A handbook designed for cardiovascular risk management service providers gives advice on how to implement the screening process: including explaining who should be invited and giving examples of the format of the letters to send to patients (Davies, Khunti et al. March 2008). The handbook is designed to provide a best-practice example to help unify the programme’s practical implementation at local level.

The programme can be framed as part of the National Health Service’s new focus towards ‘Putting Prevention First’ (Vascular Programme 01 April 2008), reducing health inequalities, and empowerment of NHS service users (Number 10 7th Jan 2008). Provision of NHS Health Checks purports to empower service users,

by giving them an indication of their current health. The check also claims to help individuals prevent cardiovascular diseases and improve their quality of life, by supporting them to make lifestyle changes. At an NHS Health Check, the patient is asked about their current lifestyle habits and family history of cardiovascular disease. A number of physiological assessments are also made: such as, measurement of blood pressure, height, weight, and blood glucose levels. The results of these assessments are used to define cardiovascular risk. Cardiovascular risk is calculated using a validated Framingham Risk Calculator incorporated into GP computer systems, which defines high risk as a >20% risk of a cardiovascular event over the next ten years, and lower risk as <20 % risk of a cardiovascular event over the next ten years (Davies, Khunti et al. March 2008). For some people, usually those categorised at 'high risk', extra assistance will be offered in managing and helping to reduce risk, such as referral to medical treatments and/or support programmes. The programme will be fully implemented across England by 2012 or 2013 (Department of Health 2009).

CHAPTER TWO: NHS HEALTH CHECK PROGRAMME POLICY ISSUES AND RESEARCH APPROACHES

This section provides a critical discussion of the NHS Health Check programme. I situate the NHS Health Check programme within the debates about screening programme policy, disease prevention, and health promotion. These debates raise questions about the patient-centredness of such policy choices. I then discuss approaches which demonstrate the experiential aspects of participation in health care services. This research follows approaches which focus on patients' perceptions of health care services to provide insight into patient satisfaction with NHS Health Checks.

2.1 NHS Health Check Policy as Governance

The NHS Health Check programme can be approached as a form of governance. It is tasked with controlling population wide levels of cardiovascular disease. At conception it was described as a "Vascular Disease Control Programme" (Muir Grey May 2006). This prevention programme aims to invite everyone between the ages of 40 and 74 to an NHS Health Check, by implication, even those who would describe themselves as in good health and have no symptoms are the subject of medical attention. The risk of cardiovascular disease is seen as spread over the population so all bodies within the population "necessarily becomes-just that [at risk]" (Ewald 1993: 221).

Control is exercised over bodies at an NHS Health Check through measurement and analysis. Similarly, in the nineteenth century, the statistical survey and measurement of calories and protein intake can be seen to have extended political power over labouring men by enabling "discipline and efficiency" to be "measured with precision and certainty" (Turner 1991: 167). Foucault and his followers view medical surveillance as a key element of social control. Foucault believes that medicine and institutions, such as hospitals, schools and prisons, are involved in state control by making the body into "something docile, that could be

surveilled, used, transformed and improved” (Foucault 1984; Foucault 1991; Williams and Calnan 1996: 7; Foucault 2003). The “concept of **normality** is central to medical surveillance”; bodies are assessed against a pre-decided normal (Seale 1994: 120). Viewed from this perspective, the NHS Health Check programme can be seen to harness the body as a complex site of power and social regulation and uses the body in order to try to improve cardiovascular health across the population. The state can be seen to support its efforts to exercise control over population levels of cardiovascular disease by embedding the NHS Health Check programme in the authoritative framework of medicine, which is widely viewed as “unified, scientific, biological and not social, non-judgemental” (Kleinman 1989: vii).

Foucault’s approach also focuses on resistance as an aspect of power. Resistance describes the force which always counteracts power. In the context of the NHS Health Check programme, patients are not the subject of unidirectional medical control but may actively interpret, negotiate, endorse, or contest control over their identities (Bunton and Petersen 1997: 8; Hoy 1999). Individuals can extricate themselves from disciplinary power (Bunton and Petersen 1997: 8). Medical discourses merge into realms of experience so that individuals do not actual become their state endorsed identity (Rapp 1997). This vision sees the NHS Health Check as having restrained power to inscribe health identities onto bodies. Foucault tells us that the NHS Health Check acts as a form of governance, but at the same time people may resist its exertion of control and surveillance.

2.2 Health Inequalities

The NHS Health Check programme aims to reduce health inequalities by guaranteeing a unified level of provision of cardiovascular risk assessment and management across all areas of England (Crown Nov 2008: 1). This policy intervention offers an alternative future for the nation’s health where there can be a more equal spread of good cardiovascular health and quality of life in all localities. Currently, cardiovascular diseases mostly affect those from the poorest backgrounds and certain ethnic minority groups, which can be said to both reflect and bolster the

inequalities in UK society (Sproston and Mindell 2006; Randhawa July 2007).

The influences that link a particular cultural sub-group with cardiovascular health are complex and multi-factorial. Explanations for people of South Asian origin having an elevated risk of cardiovascular disease have explored genetic, social, environmental, and behavioural mechanisms (Pollard, Nunez-de la Mora et al. 2008). Evolutionary perspectives have pointed to the evolutionary advantages of human phenotypic plasticity (Pollard, Nunez-de la Mora et al. 2008). This plasticity, rather than genotypic differences, has been used to explain how familial and intergenerational influences can lead to embodied health outcomes. Developmental, epigenetic, and socio-environmental influences have been found to have a complex relationship with ethnic minority cardiovascular health (Kuzawa and Sweet 2009). For example, socio-environmental factors such as discrimination, more common in ethnic minority groups, has been found to affect maternal stress, which can lead to a low birth weight and birth weight has been found to have an inverse relationship with adult cardiovascular disease (Kuzawa and Sweet 2009). Social support and social networks are also thought to be related to ethnic differences in cardiovascular health (Pollard, Carlin et al. 2003: 274).

Wells (2010) argues that public health interventions need to take a long-term approach in order to tackle minority groups' susceptibility to cardiovascular disease. He suggests interventions need to focus on improving health outcomes over two or more generations (Wells 2010: 13). Other research has pointed to the need to also tackle wider social inequalities, such as reducing income inequality (Wilkinson and Pickett 2009). In contrast, the NHS Health Check programme policy adopts the standpoint that health inequalities may be tackled on a more immediate, person-by-person, disease-by-disease basis with emphasis on health education and individual responsibility to self-regulate behaviour.

The 'Better Health, Fairer Health' slogan summarises the North of England regional strategy on health, which aims to reduce health inequalities and improve well-being so that the people living in the North East are the healthiest in the country within twenty-five years (Singleton Feb 2008; Singleton Oct 2007). The NHS Health Check programme would be of interest to the regional advisory groups on 'alcohol', 'later life', 'mature and working life', 'obesity, diet and physical activity',

'prevention, fair and early treatment' and 'tobacco' all working towards the aims of the regional strategy on health promotion (Singleton Feb 2008). The NHS Health Check programme fits well with the regional aims for health, it can be seen as one of many strategies inputting towards the goals of preventing cardiovascular diseases, improving wellbeing, and reducing health inequalities. The NHS Health Check programme, however, seems ambitious in scope given the need for six regional advisory groups all working towards improving similar areas of health.

Progressive universalism argues that health prevention policies in the UK should be designed to improve the health of all socio-economic groups but allow for "a rate of improvement which increases at each step down the socio-economic ladder" (Graham and Kelly 2004: 10). The former Labour government said, as part of their slogan "Building a Fairer Society", that they had a preference for policies which put "into practice the principle of progressive universalism, with support for all, and more help for those who need it most, when they need it most." (Treasury 2003: 5). This principle is only partially put into practice as part of the NHS Health Check programme. In theory, an NHS Health Check is available universally to everyone within the defined age group. Follow-up targeted interventions are then offered to those who need them. However, those from socially deprived backgrounds, who are most in need of help, are historically, least likely to access and benefit from health promotion programmes in health service settings.

A number of studies support the claim that attendance at health promotion programmes is related to a person's other behaviours, their daily schedule, social background, and health attitudes. A study comparing attendees and non-attendees to a health check in a general practice setting found that "those accepting an invitation to a health check are likely to be people already known to the doctor, who are well motivated, and not necessarily the people who are at high risk for diseases which merit screening or which are associated with inappropriate lifestyle choices." (Pill, French et al. 1988: 56). Another study finds that a "larger number of people with lower risk factors" attended screening and participated in an intervention programme over one year (Wood, Kinmonth et al. 1994). Goyder et al. (2008) finds that people who attended their medical practice infrequently were the least likely to answer an invitation to screening (Goyder, Carlisle et al. 2008: 9). These findings raise

concerns that the NHS Health Check programme actually has the potential to widen health inequalities.

Concerns have been raised about how well this policy will manage to recruit, monitor, and improve the health of those at high risk of cardiovascular disease (House of Commons 25 June 2008). Solutions to address health inequalities through health prevention programmes have focused on the setting. Community-based health promotion is recommended as a way to make health services more accessible (Beishon and Nazroo 1997: 52; Goyder, Carlisle et al. 2008: 70). Some work is being done to provide NHS Health Checks “in settings other than health service settings to ensure access for those groups and communities with low uptake” (Healicon and Watkins 2008: 4; Healicon and Watkins 2009: 4). In Durham and Darlington, alternative settings such as the workplace (Pollard, Joyce et al. 2010) and local pharmacies (Healicon and Emery 2009) have been explored to date. Widening access to NHS Health Checks in community settings is a strategy for the reduction of health inequalities which more “proportionately” targets health interventions “across the social gradient” (Marmot 2010: 141). Diversifying routes of access to NHS Health Checks is just one strategy for improving health outcomes. The Department of Health have encouraged health inequalities to be addressed in ways that patients find most appropriate (Vascular Programme 13 November 2008). This study focuses on how a general practice setting in County Durham can improve health outcomes by taking a more patient-centred approach.

2.3 Disease Prevention

Case studies establish that patient outcomes are affected by the design and implementation of the screening programme (Eborall, Davies et al. 2007: 2; Paddison, Eborall et al. 2009: 1). Research on health screening programmes has argued that screening can be beneficial for patients because of the opportunity for disease prevention or early diagnosis, but screening can also have negative psychosocial impacts on patients and healthcare organisations (Goyder and Irwig 2000; Adriaanse, Snoek et al. 2002; Eborall, Davies et al. 2007). General questions

have been raised about health screening programmes in terms of take-up, affordability, the reliance on behaviour change, the health impacts of ignoring some signs and symptoms and focusing on others, and the psychosocial impacts caused by patient interpretations of tests results and the production of false positives (Griffin, Little et al. 2000; Marteau, Senior et al. 2001; Doust, Mannes et al. 2007). The NHS Health Check programme can be viewed as one of many possible policy options and so offers just one of many possible balances of the advantages and disadvantages of screening.

Alternative solutions have been put forward more recently, such as age screening for cardiovascular disease risk in the over 55 age group, which is simpler than Framingham screening, as it does not require a blood test or medical examination, but generates a similar screening performance (Wald, Simmonds et al. 2011). The five yearly Framingham screening gives a false-positive rate of 21% and has an 86% detection rate (Wald, Simmonds et al. 2011: 3). Another study finds that cheaper solutions, such as screening everyone aged 50 to 74 for cardiovascular disease or using a stepwise approach to screening, would prevent a similar number of new cardiovascular events annually to those prevented by NHS Health Checks (Chamnan, Simmons et al. 2010).

A key aim of the NHS Health Check programme is to help prevent cardiovascular disease; it follows the current recommended stance of “Shifting progressively the balance of spend from acute care into primary and preventive care and upstream interventions.” (Marmot 2010: 154). Policy options which ground the design of the NHS Health Check programme were modelled on how effectively different scenarios could improve quality of life years. The benefits were measured as “quality adjusted life years to patients and monetised on the basis of an estimate of social value of a QALY of £50,000.” (Crown Nov 2008: 2). The option with the highest cost but resulting in making improvements to the most quality of life years was chosen: to offer everyone aged 40 to 74 an NHS Health Check once every five years.

The use of quality of life measures at the stage of healthcare resource allocation has been criticised for ignoring perceptions of quality of life among some age, disabled, and cultural groups (Edgar, Salek et al. 1998: 90). Pursuing the goal of

improving quality of life for those who are 40 to 74 can be viewed in the context of wider cultural preferences, which view death and ageing negatively, whilst look positively upon life, health, youth, and fitness (Featherstone 1991: 186). These criticisms raise concerns that patients' various ideas about ageing, quality of life and priorities for health might not be well supported by the NHS Health Check programme.

The governmental reports that contextualise the NHS Health Check programme emphasise the goal of preventing cardiovascular disease as both an individual and government responsibility. The purpose of the NHS Health Check programme is not to provide "the all or nothing concept of a positive or negative result", but to provide "individualised advice about what they can do to reduce their own individual risk" (Davies, Khunti et al. March 2008: 014). Of course, patients will not necessarily agree that efforts to provide individualised advice have been successful. For example, previous research advises that the family are an important source of influence in our society, and suggests that an individualised approach which does not involve the family may not engage patients (Beishon and Nazroo 1997: 42, 52; Farooqi, Nagra et al. 2000: 295).

The NHS Health Check programme's individualised approach can be seen within the context of the 'New Public Health', which focuses on the holistic person, both social and physical, and as a consequence puts individual behaviour as well as the physiological body under surveillance (Green and Thorogood 1998: 31). The NHS Health Check programme is based around the biopsychosocial model of health which emphasises wellness, quality of life, and the holistic person. This model of health "allows recognition of the complexity of the individual's perception of their own health and well-being and their ability to make sense of, and give value to, their physical condition." (Edgar, Salek et al. 1998: 93). Objective measures of health and life history information are both valued towards the aim of promoting health and wellbeing. At an NHS Health Check questions are asked about levels of exercise, diet, other lifestyle choices, and stresses, which can be seen to reflect the influence of arguments from complementary therapy practices which aim to "treat the person rather than the disease" (Smith and Goldblatt 2004: 60). The patient is then provided with lifestyle education and advice, which can be seen to function as a form of

disciplinary education, aimed at encouraging individuals to “conserve their bodies through dietary care and exercise” (Featherstone 1991: 183). Featherstone’s (1991) comment focuses on health prevention as a form of governance but does not explore how individuals make their own decisions about the risks, and negotiate, contest and adopt the lifestyle education and advice they are given.

2.4 Risk and Anticipatory Action: Foreseeing the Possibility of Developing Cardiovascular Disease

The concept of risk is central to the NHS Health Check programme. The term ‘risk’ describes the probability of an outcome occurring (Knight 2006). Risk has become a topical concept in expert discourse and news stories during the late twentieth century (Lupton 1999: 9-10) because society believes in its power to manage and control risk (Luhmann 1993). During NHS Health Checks, risk is used to explain to patients the possible future consequences of their behavioural choices. Smoking, alcohol consumption, lack of exercise, and unhealthy diets are deemed risky behaviours. Individuals who participate in these behaviours are more likely to be at higher risk of developing cardiovascular disease in the next ten years. As Giddens’ (1999) tells us, our society is a ‘risk society’, where societal concepts of and preoccupation with the *future* have a fundamental role in producing the notion of risk (Giddens 1999: 3). A risk society is said to be defined by uncertainty, even “Food became a foretaste of heart disease.” (Massumi 1993: 10). A risk society is both characterised by a growth in public dependency on experts and institutions that control the risks and a reduction in levels of public trust in expertise and institutions to effectively manage those risks (Beck 2000). Whilst the public want to use NHS Health Checks to inform and manage their uncertainties about the future they do not trust everything that they are told about their risks.

The health strategy represented by the NHS Health Check programme can be called pre-emptive biopolitics. Pre-emptive biopolitics describes strategy which acts on the body in the present as a way of controlling potential futures: “a future is made present and becomes a cause for action.” (Anderson 2010: 17). The use of the NHS Health Check programme as a way to prevent unwanted futures relies on patients

feeling motivated to take anticipatory action. It is important that patients can believe in their risk categorisation and are able to visualise the health futures available to them and how their future health possibilities relate to their behaviours past and future.

Individuals might not take anticipatory action if they do not trust in their risk categorisation. The public have reason to question their trust in expertise about risk when they are told information which contradicts their established worldview. Trust is integral to human relationships with their social environments (Luhmann 1979: 3). NHS Health Checks try to persuade people who are at higher risk that they should not continue to trust in all their existing relationships, such as their relationships with food or with the body. Individuals might find it difficult to engage with NHS Health Checks when the experts contradict these pre-existing perceptions of trust.

Psychometric theory and cultural theory also contribute to understandings of how individuals act on their knowledge of risk. They emphasise the influence of individual attitudes towards risk and their perceptions of risk. Rational action theory shows us that individual interactions are a site of risk negotiation, but other theorists have rejected the assumption that there is rational response to various everyday risks (Starr 1969). Psychometric theory highlights the importance of subjective knowledge and individual choices and asserts four ways in which individual risk-taking varies from the rational-action model (Jaeger and Renn 2001: 101). These are:

1. Individual preferences: in making decisions people have choices about how they balance risks with rewards (Adams 1995).
2. Individual tendencies, leanings and foibles, for example personal experiences or previous involvement with the risk, may affect decision-making (Slovic, Layman et al. 2001).
3. The dread factor of nightmare quality, but extremely unlikely risks, for example radiation or serial killing.
4. The multiple meanings that may lie behind an individual's perception of risk and which account for their making of 'irrational' decisions.

In terms of the NHS Health Check, the psychometric model shows that different risks evoke different responses depending on individual subjective experiences and knowledge of the risk. Individual preferences can determine the virility of the risk as

a cause to take anticipatory action.

Cultural theorists provide insight into how cultural and political frameworks can explain why individuals take a particular attitude towards or perception of risk (Douglas 1992; Douglas 1999: 220-222). Perceptions of risk are viewed as contextually constructed and enacted, shared with the community, and changeable (Douglas and Wildavsky 1982: 192). The cultural theorists are interested in how shared moral values, unspoken assumptions, and communal practices determine or interact with people's responses to risk (Lash 1993; Lash 2000). Tulloch and Lupton (2003) identify the communal elements of risk by discussing consensus about risk within different cultural sub-groups (Tulloch and Lupton 2003). Patients' socio-cultural knowledges and their communities are likely to influence how they respond to the risks presented to them by the NHS Health Check.

The meaning of risk is context dependant. Cultural research also highlights the fluidity of the term 'risk' within one culture. Lupton's (1999) analysis of the usages of the term 'risk', finds that risk is "a very loose term in everyday parlance" (Lupton 1999: 9). In everyday speech risk can be used to relay the possibility of anything from catastrophic events to minor annoyances. In political spheres, particularly when debating policy, risk is aligned with danger: "*risk* now means danger; *high risk* means a lot of danger" (Douglas 1992: 24, original emphases). Lupton's (1999) and Douglas' (1992) approaches both look at the cultural and political dynamics of risk communication. In some contexts risk is employed for emotive affect, whilst at other times it is used casually. The use of risk can have socio-political motives and it can elicit such contrasting responses that patients might view the risk terminology used at an NHS Health Check as emotionally affecting or meaningless.

The literature about risk communication as the cause of misunderstanding between patients and health professionals is a well-established reason why patients do not take anticipatory action to a risk diagnosis. One such study finds that patients who were given a 'low risk' categorisation became complacent about their health, believing that they were 'in the clear' (Eborall, Davies et al. 2007). Another found that participants who were classed as 'at risk' were reassured that they had not developed a cardiovascular disease and so reasoned they did not need to modify their

behaviour (Marteau, Kinmonth et al. 1996; Adriaanse, Snoek et al. 2002: 410). These results show that the communication of risk can be a barrier to patient understanding of the significance of their risk categorisation, and the importance of behaviour change.

There have been many associated studies about the role of risk communication in determining people's responses to health screening programmes. Research has particularly looked at how the choice of words used by health professionals influences patients' interpretations of their risk. One study found that using the term 'normal smear result' lead to false reassurance as it did not explain that there is a residual risk inherent in the result (Marteau, Senior et al. 2001). They concluded that risk terminology needs to be incorporated into screening feedback to improve understandings of the diagnosis, which would be achieved by explaining the risk through the use of numerical, verbal, and/or pictorial representations of probabilities (Marteau, Senior et al. 2001: 528). These findings make the claim "that the way that risks are framed can make a difference to how we respond to them." (Boyne 2003: 80). This body of work tells health professionals who use the term risk during the NHS Health Check programme to confront the complex issue of explaining their meaning of risk to the public.

Research shows that an approach to health promotion based on self-help and focused on behavioural change has limited scope for improved health outcomes. Individuals make decisions about risk in a socio-cultural environment. Patients do not all have the same perceptions of the risks and so do not always agree with the health advice about behaviour change. Health advice can be contrary to cultural beliefs about the causes and consequences of disease (Lewin, Robertson et al. 1992). For example, research among people of South Asian origin found that their beliefs, including their views on the hereditary nature of heart disease and 'fate', acted as barriers to them adopting healthier lifestyles (Farooqi, Nagra et al. 2000; Netto, McCloughan et al. 2007: 183).

As well as considering their views about the risks, individuals must feel comfortable with and able to change their behaviour. Religious and other cultural reasons, such as family responsibilities and modesty, can affect participation or non-participation in health-related behaviour (Beishon and Nazroo 1997: 50).

Cardiovascular risk factors can include barriers to lifestyle change, which are not physiological or quantitatively measurable factors. Solutions to these issues have been focused on encouraging the desired behaviour change through health education (Goyder, Carlisle et al. 2008: 9; Healicon and Emery 2009), and adapting health behaviour messages to cultural sub-groups, such as those of South Asian origin (Kelly 2005). Strategies to encourage patients to adopt healthy behaviour have focused on adapting health promotion messages to the social aspects of people's lives. Socio-cultural influences have been viewed as barriers to achieving positive health outcomes.

Perspectives focused on trust in the risk categorisation, attitudes towards risk, perceptions of risk, the communication of risk, and socio-cultural influences on behaviour each provide a different perspective contributing to our understanding about why individuals might not take anticipatory action when they are told they are 'at risk'. Studies into the miscommunication of risk imply that the medical definition of risk should be shared by the wider public, if only risk was communicated effectively. Whereas, the psychometric and cultural theorists do not assume that individuals should innately take anticipatory action to a cardiovascular risk diagnosis. These theorists argue that patients' subjective preferences and cultural values will determine how they respond to risk.

2.5 Health Promotion Strategy: its Assumptions and Moralities

Health promotion strategy which include policies like the NHS Health Check programme have been criticised because they "work on the assumption that expert knowledge, if effectively imparted to lay people, will change their attitudes...and thus...people will alter their behaviour accordingly." (Green and Thorogood 1998: 40). Health promotion strategy can be said to uphold imperialist imageries. Health promotion aims to spread its worldview and assumes that ignorant individuals need re-educating by health care experts (Nettleton 1991).

The NHS Health Check programme focuses on assessing risk of cardiovascular disease in order to construct a cause for anticipatory action. Communicating risk involves "serving some interests and not others, emphasizes

some 'risks' while erasing others" (Boyne 2003: 46). Those delivering NHS Health Checks aim to communicate risk so that patients want to take the recommended anticipatory actions, such as making 'healthy' behaviour choices. "The healthy choice of public health thereby conceals its own morality by harnessing 'healthy' to rational, and this becomes synonymous with the sensible, better, correct, choice." (Green and Thorogood 1998: 49). Individuals who have different priorities for health or take a different attitude towards risk, and so do not follow the advice provided at the NHS Health Check, may be viewed as 'irresponsible', lacking in self-discipline, and 'weak' (Nettleton 1991). The cause for anticipatory action presented by the NHS Health Check programme relates cardiovascular health to a moral framework and enables blame and responsibility to be emplaced onto individuals.

Health promotion strategy has been criticised for prioritising state and medical preferences and priorities for health. This approach to public health can assume that the 'healthy' choice is a universal concept and asks individuals to self-discipline their behaviour. Individuals deemed irresponsible are blamed for not following advice or 'barriers' are found in the social structure. Despite these criticisms it has been argued that health promotion can be empowering if patients and their communities have the freedom to make their own choices about whether or not to agree with the experts (Tones 1986: 11). Foucault (1984) would argue that patients already have some degree of freedom, he sees individuals as autonomous and conceptualises resistance as the counteracting force, present where power is exerted. Resistance here is seen as integral to health promotion strategy, so does the State need to actually facilitate patient empowerment?

2.6 A Patient-Centred Approach

Patient-centred care argues for patient empowerment in their health care. The Secretary of State for Health, Andrew Lansley, wants to focus on establishing a patient-centred health service. He wants "measures of quality which prioritise what matters to patients – not boxes ticked and processes followed – but their actual health outcomes." (Lansley 2 July 2010). Patient-centred care is a strategy of control in the sense that it can be used as a tool to serve the interests of government, to win

votes or to exert more effective influence on population health. This model of care, if used as a tool for power, will not stop the action of the Foucauldian force of resistance.

Patient-centred care involves numerous components, which are subject to debate and redefinition. The Institute of Medicine coined a widely accepted definition: patient-centred care means “providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.” (Institute of Medicine March 2001: 3).

“Picker Institute Europe's empirical research has identified eight aspects of healthcare that are most important to patients. Healthcare is truly patient-centred - and most likely to engage - when all these things are working well.

Three concern **the relationship between individual patients and professionals:**

- involvement in decisions and respect for preferences
- clear, comprehensible information and support for self-care
- emotional support, empathy and respect.

Five relate to **the way that services and systems work:**

- fast access to reliable health advice
- effective treatment delivered by trusted professionals
- attention to physical and environmental needs
- involvement of, and support for, family and carers
- continuity of care and smooth transitions.” (Picker Institute Europe 23rd December 2009)

The principles of patient-centred care are widely accepted in the NHS and in general practice, but are not always implemented (Crown 30 June 2008; Royal College of General Practitioners 2007). Health care providers can be pressurised to work for the health needs of the overall population, but individual patients do not necessarily feel that they share these needs. The NHS Health Check was borne out of the interests of public health and concerns about the financial viability of the NHS,

but this raises questions about the patient-centredness of this policy solution. Patients' experiences of the delivery of health care services can be used by service providers and policy makers to improve patient-centred care (Gerteis, Edgman-Levitan et al. 1993). This study explores patients' experiences of the NHS Health Check programme. I am interested in the extent to which patients find the concept and practices of the NHS Health Check relevant and important to their lives, particularly looking at how the check connects with patients' health concerns, priorities, and health care preferences. This knowledge may help those delivering NHS Health Checks better understand and meet the needs of their patients. This research may help to achieve a more patient-led approach to preventative care and health education in general practice.

2.7 An Embodied Encounter with Medicine

Many social theorists caution against the privileged status of medicine as factual (Lock and Kaufert 1998: 6) and instead locate medicine, both its knowledges and practices, within cultural, historical, and political frameworks (Mishler, Amarasingham et al. 1981). "There is, of course, a biological reality, but the moment that efforts are made to explain, order, and manipulate that reality, then a process of contextualization takes place in which the dynamic relationship of biology with cultural values and the social order has to be considered." (Lock 1988: 7). Much work in this field has analysed the assumptions medicine makes and the values it imparts, its power and authority, how medicine inscribes or constructs disease categories onto the body, and its interactions with individuals and society more broadly (Kleinman 1980; Lock 1988; Kuipers 1989: 100; Laqueur 1990; Sandelowski 1990; Hayden 1995; Kitzinger and Wilkinson 1996; Newman 1996; Martin 1997; Rapp 1997; Abel and Browner 1998; Scheper-Hughes and Lock 1998; Jordanova 1999; Weiss 1999; Archimedes 2005). This body of literature has improved transparency about medicine's culturally constructed imageries and socio-political contexts (Harding 1991: 308; Harcourt 1997: 26). These theories and insights into medicine's knowledges and practices can be applied to the NHS Health

Check programme. My research interests, towards patients' experiences of the practices of the NHS Health Check and patients' responses to the empirically measured health identities applied to their bodies by the check, have been inspired by this body of literature.

This research focuses on providing information about how people bring an NHS Health Check into their private realms of knowledge, experience, and perception of the world (Abel and Browner 1998). Previous researchers have emphasised the importance of viewing health care services from the perspective of patients. Programmes designed to measure health, such as the Body Mass Index (BMI) monitoring programme, have been analysed in terms of the "fleshy, material, and experiential bodies of those individuals involved in the process of measurement." (Evans and Colls 2009: 1053). Decisions about risk and medical intervention were made by looking at health evidence in light of individual theories of the world, experiences of life and wider sources of information (Poltorak, Leach et al. 2005). Patients' knowledge about disease and risk represents an assemblage of diverse information from a variety of sources (Mosavel and El-Shaarawi 2007). Individuals source their knowledge about their risk of coronary heart disease from their family and friends, work colleagues, the media, and health-care workers (Beishon and Nazroo 1997). Constructions of risk for people with dementia, and their carers and practitioners were embedded in everyday events and social situations (Clarke 2010). These approaches highlight the complexity of realms of knowledge and the risk decision-making process. They approach health choices and behaviours as embodied: personal, complex, socio-cultural and fleshy.

The notion of embodiment discusses: the lived body: mindful, active and emotional, because the body forms the basis for our being in the world and our similarity with other actors (Csordas 1990). Embodiment focuses on analysis of "a way of living or inhabiting the world through one's acculturated body." (Weiss and Haber 1999: xiv). It views "the body both as a lived presence and as a cultural and social force" (Casey 1996: 37). This conceptual framework is used to explore the complexity and richness of our corporeal life:

"Human beings are creatures of the flesh. What we can experience and how we make sense of what we experience depend on the kinds of bodies we have

and on the ways we interact with the various environments we inhabit. It is through our embodied interactions that we inhabit a world, and it is through our bodies that we are able to understand and act within this world with varying degrees of success.” (Johnson 1999: 81).

Embodiment centralizes the experience of bodily being-in-the-world, a perspective which is seen to intersect the nature/culture divides in other theories. For example, it addresses the criticisms of social-constructivism, particularly the argument that the constructivists exaggerate “the degree to which these [cultural factors], rather than the reality of the natural world, determine the shape of medical knowledge” (Seale 1994: 104). Embodiment has instead helped to “rethink relations between the biological and the social, nature and culture” (Williams 2003: 69) and has helped us to better understand the entanglement of biology and culture (Csordas 1990; Casey 1996). Analysis of the materiality of bodies, human embodied perceptions and lived experiences has been seen to unite social and physiological perspectives (Williams and Calnan 1996; Johnson 1999).

An embodied framework sees experiences and subjectivities as part of lived, fleshy and material bodies enacting in complex lifeworlds. “Forms of embodiment point us to the stubborn enfleshment of humans, they cannot be dissolved into thought, nor can they be reduced to a Foucauldian notion of ‘discourse’.” (Mellor and Shilling 1997: 5). It makes the assumption that “we come to know our world through the activity of being in the world” (O’Donovan-Anderson 1996: 156), thus asserting that the body is the “existential ground of culture” (Csordas 1999: 149). Theories of embodiment frame the body as the central pillar of human action. Embodiment theorists assert that humans “acquire information *through* their bodies” (Mellor and Shilling 1997: 5). The research frames patients as “lived, bodily” participants of the NHS Health Check programme (Weiss 1999: 55).

My approach focuses on analysing the lived, experiential aspects of encounters with the NHS Health Check programme. This study looks at how participants take the NHS Health Check programme into their lives. I examine how patients’ responses to and experiences of an NHS Health Check interrelate with their wider attitudes and viewpoints. I investigate how individuals relate to their NHS Health Check in the context of their embodied attitudes and thoughts about health

priorities, health identities, lifestyle preferences, risk, prevention, trust, aging, fatalism, heredity, future, and health securities.

Health interventions need to be sensitive to the ways that individuals merge official information about health with wider opinions and personal and communal stories (Poltorak, Leach et al. 2005). It has been suggested that policy makers and health care professionals could use understandings of the “formal, embodied and familiar dimensions of popular knowledge” to “potentially mimic this knowledge system, making their interventions a sustainable part of everyday family life.” (Craig 2000: 703). Implementers of NHS Health Checks will be interested to discuss the options and opportunities to sensitively adapt their health intervention based on the insights into their patients' experiences voiced in this thesis.

CHAPTER THREE: METHODS

3.1 Research Design

The roots of this study came out of discussions between me, my supervisors, and a GP in Darlington. We identified a need for research into how people of South Asian origin experience NHS Health Checks and the GP felt that his practice could provide access to the patients needed. Subsequently another surgery in Darlington also came forward to collaborate on this study. However, once I began the task of recruiting people of South Asian ethnicity from these two surgeries, I found that the actual number of potential participants was vanishingly small. The population of 'Asian or Asian British' in Darlington amounts to only 0.9%, whereas across the whole of England, Wales, and Northern Ireland they amount to 4.6% of the population (Neighbourhood Statistics and Census Output 2001). About six people of South Asian ethnicity had attended an NHS Health Check at the two surgeries. By the time I was privy to this information, much of the groundwork for the study had been done: I had NHS ethical approval, and through my meetings with practice staff, had established valuable relationships. Additionally, I felt that I had made a commitment to the surgeries and the staff to do research into their delivery of NHS Health Checks. All was far from lost however. In my discussions with staff there seemed to be recognition that delivery was at times, and despite their best efforts, sub-optimal. Staff identified problems which, in my view, related at least in part to patients' expectations of NHS Health Checks - both the consultation itself and their health outcomes. It was clear that there existed a genuine interest in how staff might improve the preventative care and health education they provide, and I was enthusiastic about researching this. I set about looking at patients' satisfaction with NHS Health Checks and how general practice staff could improve their patient-centred care.

This research design is focused on facilitating the capturing of patients' experiences of NHS Health Checks. I use interview methodology to collect data directly from patients about their experiences of and responses to NHS Health

Checks. The research methodology is not designed to map shared interpretations or engagements with the NHS Health Check based around social variables such as gender, ethnic, age, or class. I focus on the ways patients as individuals engage with the NHS Health Check. I decided to conduct interviews with just sixteen people who had recently attended an NHS Health Check to facilitate the collection and documentation of in-depth individualised information, to find out the meanings and viewpoints participants attribute to their behaviours and experiences. Patients were recruited from the practice databases of the two surgeries in Darlington who had volunteered to host the study. I wanted to speak only to those who had recently had an NHS Health Check so they would be able to remember the consultation and their immediate impressions of the outcome of the check. I conducted one interview per participant in order to minimise the time commitment they had to make.

Interview questions sought to ascertain patient satisfaction with different aspects of NHS Health Checks. I focus on finding out from patients - the extent to which NHS Health Checks addressed their health needs, expectations, concerns and priorities. I conceive of the thoughts and viewpoints imparted to me at interview as a way for my participants to express and conceptualise their embodied experiences. The qualitative data I collected was analysed with the purpose of providing information about the perceived understandings, experiences, and needs of primary care patients. These findings can be utilised by health professionals towards the goal of improving the delivery of the NHS Health Check programme in terms of patient-centred provision.

One-to-one interviews were deemed to be the best way to enable all participants, including those who were more introverted, to feel free to talk openly about their personal experiences and opinions (Agar 1996). Interview topics were prepared before the interview, but questions were semi-structured, open-ended and non-directive (Saville-Troike 1999), so that participants could talk freely and in-depth about what they felt were the noteworthy points and raise new areas for discussion (Paul 1953). Participants may not have been able to impact on the research interests using more structured and prescriptive methods such as questionnaires. My informal approach also offered the chance to better understand individual life histories and circumstances.

Focus groups could have been used as a productive way of identifying areas to research at the beginning of the process and to find out patients' opinions of the conclusions of this study at the end of the process. However, the time constraints of this study meant I felt that I should focus on the main aims of the study. Focus groups would not have contributed efficiently to the aims of the study because I could not have used them to develop any depth of understanding about the individuals in the group and some people may not have felt able to speak freely in the group. Statistics on cardiovascular disease risk categorisations and the size and significance of patient behaviour changes were not collected because they would contribute little to my research goal of understanding the lived, experiential perspectives of NHS Health Check attendees.

Participant observation was largely beyond the scope and resources of the project. I was able to conduct observations of NHS Health Checks, but due to the practicalities of informed consent whereby patients must have at least twenty-four hours to consider if they would be willing to participate, these observations had to be for educational purposes. This meant that I was not able to document specific patient-health professional interactions. Participant observation of patients' daily lives would have provided me with knowledge about how participants physically behave and interact, but would have been very intrusive and somewhat impractical. If I were to have included some participant observation, combined with interviews, the two would have complemented one another, giving me insight into the dichotomies and relationships between what people say and what people actually do (Agar 1996).

3.2 Fieldwork Location

The fieldwork was conducted in Darlington, which is situated in County Durham, North-East England, with two of NHS Darlington's medical practices, Carmel Medical Practice and Orchard Court Surgery. One reason Darlington was chosen as the location of the fieldwork was due to the willingness of the two General Practitioner Leads at the study sites to give access to their patients. The 2001 census

reveals a large proportion, 98%, of the population of Darlington is 'White'. Within the local authority (LA) area of Darlington there is a population of 97,838, according to the 2001 Census statistics, 95,741 of these class their ethnicity as 'White' (Neighbourhood Statistics and Census Output 2001). Tens of thousands of people living in Darlington are eligible for an NHS Health Check, approximately 41% of the total Darlington LA population. This percentage was calculated from 2001 census data which recorded 40,108 people aged 40 to 74 living in Darlington (Neighbourhood Statistics and Census Output 2001).

Darlington is noteworthy for its inequalities in terms of levels of deprivation and health. When the Darlington results from the 2004 Index of Multiple Deprivation were converted to percentages, with the most deprived nationally being 1%, an estimate shows that Central Darlington ward was 3%, whilst, still in Darlington, Hummersknott Ward was 93% (Darlington Borough Council 2007: 6). The two practices taking part in the study take patients from across Darlington. Carmel Medical Practice is, however, located in one of the least deprived of all Darlington wards, Hummersknott, and Orchard Court Surgery is in Pierremont Ward, which is more deprived at an estimated 31% (Darlington Borough Council 2007: 6).

In Darlington, male and female life expectancy at birth is poor compared to the rest of England. "Darlington males live on average 1.7 years less than English males and Darlington females live on average 1.1 years less than English females." (North East Public Health Observatory January 2007: 1). There is large variation between male life expectancy in the two wards in Darlington where the surgeries are located: males in Hummersknott Ward live 5.3 years longer than those in Pierremont Ward (North East Public Health Observatory January 2007: 4). There is less of a difference for females: they live 1.2 years longer in Pierremont Ward than in Hummersknott (North East Public Health Observatory January 2007: 4). "Circulatory diseases are a key contributory cause of the poor life expectancy" for men and for women in Darlington (North East Public Health Observatory January 2007: 1). NHS County Durham and Darlington is committed to reducing the gap in life expectancy between County Durham and the rest of England. NHS Health Checks are a vital part on their strategy (NHS County Durham Sept 2009: 8). The

NHS Health Check targets the high rates of cardiovascular disease and the lifestyles which are attributed as causes of the difference in life expectancy. The PCTs would hope to use information about patient satisfaction to enhance patient engagement with NHS Health Checks and more effectively use the checks as a tool to achieve positive health outcomes for people in County Durham.

3.3 Sample

Fieldwork was completed between July 2010 and November 2010 and involved:

1) Observations -

People aged 40 to 74 were invited to their practice routinely to have an NHS Health Check. Approximately fifteen of these routine appointments were observed. These observations were conducted for educational purposes. This aspect of the study helped me to better empathise with the experiences of NHS Health Check attendees, it helped to inform interview questions, and to understand interview responses. While I was at the practices to conduct these observations I took the opportunity to speak informally to some administrative and healthcare practice staff to find out their perspectives about the NHS Health Checks. I also gathered information from these practice staff about their methods of recruitment to the NHS Health Check.

2) Interviews –

One-to-one informal interviews, each lasting between fifteen minutes and one hour, were carried out with sixteen participants, recruited from the registers of patients at the two practices. All of whom had attended an NHS Health Check and had been given their results. One additional interview was carried out with a patient who was classed as a non-attendee, but who was actually ineligible for an NHS Health Check. All participants invited to join the study could read, write, and converse in English, so there were no obvious issues with their understanding of the letter of invitation, information sheet, and interview questions. Patients were excluded from invitation to the study if they had a mental health issue which could put me at risk. In practice none of the patients who had recently had an NHS Health Check fell into this

category. Interviews took place in the participants' homes to facilitate openness, and I took appropriate measures to ensure that I was safe, including completing a risk assessment form and strictly adhering to the University Lone Worker policy. Participants were given the option to receive feedback about the research.

Table A. Patients who attended a cardiovascular risk assessment first appointment and were invited to participate in the research

	Carmel Medical Practice		Orchard Court Surgery	
	Male	Female	Male	Female
Number of patients who were invited to take part in the research	19	21	23	4
	Total = 40		Total = 27	
Patients who replied to the letter of invitation and were interviewed	6	6	3	1
	Total = 12		Total = 4	
Response rate	30%		15%	

At Carmel Medical Practice I sent letters of invitation to all patients on the database who had attended an NHS Health Check between 14th April 2010 and the 21st July 2010. This sample was chosen mainly because the study was looking to speak to those who had most recently had an NHS Health Check, so participants would find it easier to recall what happened at their check and their short-term responses to the programme. The majority of those who came forward for interview were White British; however I did interview three people of Asian ethnicity: one man and one woman of South Asian ethnicity and a man of Middle Eastern origin. The ethnic minority patients (CM11, male; CM12, male; and CM13, female) who I interviewed were all recruited by the practice GP with a follow-up telephone call. This GP was keen to hear from some ethnic minority patients. All my other

participants, at both practices, answered the first letter of invitation by posting back a reply slip in the stamped-addressed return envelope I had provided. I tried to make it quick, simple, and free to respond to the letter of invitation, but still the response rates seemed quite low.

At Orchard Court Surgery I also invited patients to participate in this study who had recently attended an NHS Health Check. The sample was also chosen to be representative of the body of recent NHS Health Check attendees at the practice, so, rather than selecting equal numbers of men and women, participants were selected by inviting everyone who had attended an NHS Health Check between 14th April 2010 and 21st July 2010. All those in this sample were of White British origin. This sample consisted of an unbalanced ratio of male to female invitees because of the surgery's methods of recruitment to the NHS Health Check programme, as will be further explained in chapter four of this thesis.

At Carmel Medical Practice seven people, two women and five men, of South Asian ethnicity who had not attended an NHS Health Check were invited to the study. Of the thirteen remaining non-attendees invited to take part in the study all were of White British origin and they were selected because they had most recently been placed into the 'declined' category. At Orchard Court Surgery two patients of South Asian origin, both men, were invited to have an NHS Health Check and both had declined, did not respond, or failed to attend. Both were selected to participate in the research to establish a voice for this minority group. The other sixteen patients who were invited from the non-attendee group were selected because they had most recently been put in the category of patients who 'declined' an NHS Health Check.

Including those patients who were invited but who did not attend an NHS Health Check was beyond the scope and resources of this study. Despite inviting non-attendees (see Table B, below), I only managed to recruit one 'non-attendee', a White British male (CM6). The person I recruited did not remember getting a letter of invitation to the NHS Health Check programme and perhaps he did not, because he already had been diagnosed with diabetes, which officially exempted him from invitation. I found it difficult to recruit people who did not engage with the NHS Health Check programme to participate in research about it.

Table B. Patients who declined, did not respond, or failed to attend a cardiovascular risk assessment and were invited to participate in the research

	Carmel Medical Practice		Orchard Court Surgery	
	Male	Female	Male	Female
Number of patients who were invited to take part in the research	12	8	15	3
	Total = 20		Total = 18	
Patients who replied to the letter of invitation and were interviewed	1	0	0	0
	Total = 1		Total = 0	
Response rate	5%		0%	

Although I got ethical approval for practice staff to follow-up the unanswered letters of invitation with a telephone call, recruitment of non-attendees may have been limited by the lack of time practice staff had available to undertake this task. I was not able to phone patients myself due to the limitations of NHS Ethics, whereby I was not allowed to have access to patient contact details without each patient's prior consent.

3.4 Ethics

Ethical safeguards concerning the anonymity of participants and the confidentiality of information divulged were approved by the Department of Geography at Durham University in accordance with the British Sociological Association guidelines. Permission for the study to go ahead was also sought via the NHS Research Ethics Service. Full NHS Research Ethics Service permissions were

given before any contact was made with patients.

3.4.1 Ethical Practices

The ethical issues and safeguards considered and implemented as part of this study followed the contemporary guidelines produced by the NHS Research Ethics Service. Letters inviting participation in the study were provided to potential participants in the post by general practice staff. They used their patient records and databases to identify participants meeting the criteria described in the 'Sample' section of this chapter. I drafted the letters of invitation, but it was a requirement of the NHS Research Ethics committee to address these letters from the appointed practice GP Lead (see appendices A and B). A limitation of this approach was that some potential participants may have felt uncomfortable or unable to come forward to participate in the study if they were not fond of the personality of the GP Lead or felt negativity towards their GP practice. I only had access to patient contact details after the potential participant had agreed to be contacted by returning a reply slip and I did not have any access to medical records. Each participant was given as long as they needed to decide if they would like to be included in the study, within the July 2010 to January 2011 time frame of the fieldwork.

At the interview, I took informed consent from all my participants, which involved referring to the information sheet while discussing "a broad outline of what the research is about, the sorts of issues you will be exploring, and what you expect of them [the participants]", before he or she was asked to complete a consent form (see appendices E and F) (Dowling 2000: 26). This form covered consent for all aspects of the study including giving their consent for the interview to be digitally recorded. In writing up the study, participants were given code identifiers and I did not reveal the true identities of participants to anyone else, including the supervisory team. All participants of this study gave their specific consent for direct quotations to be published. These quotations were anonymised and care was taken to ensure that no other information published allowed participants to be identified, such as the combination of gender, age, ethnicity, and location.

The chief investigator was the only person with access to the audio recordings and other personal data generated as part of the research. I ensured that the full transcripts I made of each interview were only available for viewing by the supervisory team and the relevant interviewees, in order to protect the anonymity of interviewees. The audio recordings of interviews were stored on a secure research drive within Durham University to ensure confidentiality of data. Anonymised transcriptions of audio-recordings will be kept once the study is over and will continue to be stored on a secure research drive held within Durham University. The identifiable voice recordings will be destroyed as soon as the research degree has been awarded.

Patients were asked for their consent before the student observed any consultations, using a red/green card system regularly employed at the practices. No quotations or personal information was used for the research from these observations and they were not recorded. The purpose of observing appointments was so that I could familiarise myself with how the two medical practices involved in the study deliver an NHS Health Check and assess cardiovascular disease risk.

3.4.2 Reflections on the Process of Gaining Ethical Approval

Before the start of fieldwork a Research Ethics and Data Protection Monitoring form and a Site-Specific Risk Assessment form were completed and approved by the Department of Geography, Durham University (see appendices J and K). Here my study met the definition of 'ethical practice' quite painlessly. However, this study also required NHS Research Ethics approval, which involved fulfilling more complex procedures and completing a substantial quantity of forms. Appendix L shows the NHS Research Ethics Committee form (NHS REC), NHS Research and Development form (NHS R&D), and the two NHS Site Specific forms (NHS SSI) that I completed. A Research Passport form was also requested. The Passport asked for evidence of Criminal Records Bureau checks and Occupational Health checks - such as my vaccination history and fitness for work checks. The process of gaining NHS ethical approval required a lot of background reading and

still, at times, caused me some confusion. For example, in one of the forms I was signposted to complete the two site specific forms, whilst another section of guidance said they were not required. I did complete the NHS SSIs, although I did not definitively find out if they were required for this type of study.

I feel it appropriate to comment on my experience of working with the local NHS Ethics Committee. Even now I find it hard to comprehend, but their requirements took me the best part of three months' full time work to satisfy. As detailed above, the work involved completing literally dozens of forms, enclosures, clarifications, and revisions, and the full process took a total of seven months to complete – certainly not insignificant for a study of this size. Perhaps most frustrating was that, as a result, I was unable to work on recruitment with the GP surgeries or collect any data for the first nine months of the project, including the preliminary literature reviews conducted in the first two months after enrolment.

I remember in particular the day of the Ethical Review Meeting in which I was required to present details of my study to a panel of eighteen health professionals and administrators, and to clarify many points about the study in person. Regrettably, I found some of the questioning to be adversarial in nature, and I believe the panel's approach only softened when it became evident to some members that I was beginning to break down under the pressure. Nevertheless, I concluded the meeting and I duly received a follow-up request for further information (see appendix M) which required twelve additional points of clarification and updates to twenty of my original enclosures. Of course, the revised versions of documents also had to be sent to the NHS Research Governance Unit to be added to the separate records they were keeping about my study.

I asked a professional who worked for the local NHS Research Governance Unit to help me to answer the questions in the follow-up letter, so I would have more chance of finally meeting the NHS Research Ethics Committee's (REC) requirements. This 'expert' did not agree that all of the questions I was being asked were fair. He argued that the questions on research governance were not in REC's jurisdiction and my Department of Geography Site Specific Risk Assessment approval should have been evidence enough that the appropriate safeguards for

researcher safety had been considered.

Although I have always tried to be outwardly patient and diplomatic in my acceptance of the requirements, I must admit that I often objectively viewed this work as gratuitously burdensome and inefficient to an extent I have never before witnessed. The complex web of forms and enclosures required by the committee and the Research Governance Unit were difficult to navigate, seemed to duplicate unnecessarily, and involved many seemingly irrelevant and intrusive checks. Additionally, at a time when NHS resources are stretched, it occurred to me to wonder whether the eighteen-strong local NHS Ethics Committee might be overstaffed. I remember that I even started on a little mental arithmetic to work out how much my session in the meeting, along with all the preparation and back-office work might actually cost! I must admit that at times I wondered if some of these highly qualified and very capable consultants, pathologists, and other hard working-professionals – all utterly committed to serving patients' needs - operated in a kind of bubble, without the necessary oversight of the environment in which they were working, and the resources they were consuming.

One example of seemingly unnecessary but resource-intensive bureaucracy in this process, which puzzled me early on, was the strict requirement that I complete two four-page vaccination and medical history forms. One was entitled "Occupational health assessment questionnaire" and the other was "Durham University, Occupational Health and Safety, Pre-Employment Questionnaire". I found answering questions on 'fitness for work' gratuitously intrusive as I was never to be 'employed' to do this work. The occupational health nurse suggested that I ask my GP for details of my full vaccination history, which I dutifully did, but it struck me that the most contact I would ever have with patients was sitting with them during interviews - I might have greater and closer contact with NHS patients if I sat for half an hour in a busy GP's waiting room!

The NHS Research Ethics Committee wanted exact answers about every intricate aspect of the research. I found it difficult to balance their approach with the need to be flexible, fluid, and adaptable at the early stages of this project when I did not yet know who would be willing to participate in the study and what they might

want to talk about. The NHS required a very wordy information booklet, which was far more complicated than my supervisors would normally recommend students include (see appendices C and D). My supervisors cautioned that participants would switch off quickly and the complexity of the information might discourage potential participants from responding. There was to be no negotiation on the length of the information booklet because of the long list of compulsory topics which had to be included.

I know that the word 'bureaucracy' is often seen as pejorative, and the reality is that the many forms and procedures are in place for a reason, and are also needed for legal reasons to demonstrably show that patients', and indeed researchers' needs are properly met. We see for example, in the 'letter of sponsorship', drafted by County Durham and Tees Valley PCT for this project included a pledge that: "The statutory responsibilities of sponsors set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 will be undertaken in relation to the trial." (County Durham & Tees Valley Primary Care Trusts' Research Management & Governance Unit 11 March 2010). Given that my own project is by no stretch a 'clinical trial' I wonder whether such mistake would render the contract invalid. This pledge seems to highlight what I have come to realise is a blanket approach taken by NHS Ethics - where the requests made for letters, CVs, and evidence of insurance records to support my NHS Research Ethics application seemed disproportionate to the study being undertaken. There needed to be simpler and more straightforward information communicating the purpose of each form. This communication would help to get researchers on board with the process and better recognises that humans like to ask why, and can become disenchanted by all the bureaucracy.

I find it very hard to explain, but having spent so many months labouring through the NHS Ethics approval process, I very occasionally found myself in a peculiar 'triumphant' state of mind. Somewhat bizarrely, and surely not to my credit, I believe I was starting to feel that I was 'winning'. I felt that the barrier to entry for research within the NHS was set so high that I was somehow being super-productive in all the work I was doing so that I might finally be ushered into the inner sanctum of ethical researchers! The hilarity of my own mental processes, and the occasional personally perceived nonsense of the NHS Ethics procedures soon became apparent

once I learned that it was in fact childishly simple to side-step the lengthy and painstaking ethics procedures. Another student, working under the same GP as myself, and interested in many of the same patients as myself, approached a council-run leisure centre to which patients had been referred by the GP. The student was able to instantly gain access to many of the same patients I had spent months pursuing. It is important to note that I am not suggesting, even remotely, any form of misconduct by either the GP or the student – indeed the approach seems potentially sensible.

I often worried that the need to provide such detail and to meet such strict and seemingly arbitrary requirements might dissuade some researchers from progressing with their studies and restrict the number and type of projects undertaken. I was anxious of the NHS Research Ethics bodies, they had power to veto the project and there was nobody on the Committee sensitive of my approach: no one had a background in the medical humanities. I particularly questioned whether their strict requirements to have the 'facts' before the research has taken shape distort the body of literature towards approaches which aim to test theory, rather than start out to build theory.

3.5 Data Collection

I felt that interviews should be held in participants' homes and not in the spaces of the GP surgery to encourage openness about feelings and experiences. The Research Ethics Committee (REC) did not agree; they saw researcher safety as a higher priority despite it being the norm for nurses and health visitors to visit patients at home. They also did not seem to understand how my apparent affiliation with the GP surgery would affect responses to my research. I found that the surgeries did not have private rooms available in which to conduct the interviews, but fortunately, after some worry that they would veto the project, REC came round to the idea of conducting the interviews in participants' homes.

At the start of the interviews, I explained to participants that I had no medical training and would not be able to give them any health advice. I also reassured

participants that I was affiliated with the University rather than their general practice to encourage them to be open about their positive and negative feelings for the NHS Health Check and their medical practice. However, I worried that the NHS Ethical guidelines I had to follow may have led them to believe that I was affiliated with their GP surgery and, indeed, I increasingly felt that my research was being pushed in this direction. For example, I had to print the letters of invitation and the consent forms on practice letter-headed paper and I was told to address the letter of invitation I had written from a practice GP. Due to NHS ethical requirements, participants may have been wary about how their feedback at interview would affect their relationship with their GP surgery, despite my reassurance.

Interviews were digitally recorded so that I did not have to make notes and could instead concentrate on understanding participants' points of view and asking appropriate follow-up questions, including seeking clarification if something was unclear. Interviews were semi-structured, face-to-face, one-to-one and individualised. I felt rapport with most participants, but due to the nature of personality dynamics some interviews seemed more successful than others. Some participants were happy to speak for a long time in response to a question like 'How do you feel about your health?', while others were more reserved and did not reveal too much. I did not try to set a time frame on interview length but some participants appeared to have more time to talk than others. The differences between participant-interviewer dynamic is evident when you consider the different time lengths of the interviews: a few interviews lasted for fifteen minutes while others lasted for about an hour.

Using interview methodology, I sought to gain an in-depth understanding of participants' attitudes, experiences, and opinions about their NHS Health Check, their general practice and their health. Like other qualitative researchers, I collect qualitative data because I believe it can enhance understanding of the complexity and subtlety of human action and motivation. My interview questions were individualised and open-ended so I could allow participants to shape the tone of the research and create the topics which are tackled in the thesis. At interview I also sought information to support some of my prior research assumptions and interests. Appendix G shows the question guides and prompts taken to the interviews. At some

of the first interviews this guide was referred back to regularly but after the fifth interview it was often not referred to at all, the spirit of the interviews becoming as intended: individualised and semi-structured.

The route the interviews took around the topic varied, the starting question depended on what had been said before the digital recorder was set and from this point the rest of the interview went off in a unique direction. For example, interviews started with anything from: "Did anything particularly encourage you to take part in this study?" (CM9, male) to "How did you find out about the health check programme?" (CM8, male) and "Can you tell me a bit about what it was like when you went for the health check?" (CM12, male). A successful interview often started with the interviewee asking a question about "What encouraged you to participate in the study?" (OC1, male) because it encouraged participants to talk about what they felt they could contribute to the study. Often participants had replied to the letter because they had something particular they wanted to say so this question was a good way to show participants that the study was about listening to their opinions. This message seemed to encourage participants to speak more freely throughout the interview.

Open ended questions were also used to encourage participants to give an in-depth answer to each question. Starting with openers, such as 'can you tell me about...', 'what were/are your thoughts about...' and 'how do you feel about...' facilitated this approach (Valentine 2005). Simple prompts also encouraged participants to elaborate on their ideas, such as "can you think of any examples of this please" "can you tell me more about that please" and "is there anything else you'd like to say".

3.6 Analysis

The purpose of analysing interviews with participants was to portray their individual and shared experiences of the NHS Health Check. This analysis both suggests ways of reading the data and through the use of extensive quotations gives

readers access to some of the data so they can contribute to the interpretation themselves. The analytical approach involved both inductive and deductive reasoning: pursuing the research objectives of *a priori* interest and looking for emergent themes arising from the interviews to broaden the scope of the research.

I was interested in finding out:

1. What participants expected from their NHS Health Check?
2. Whether participants supported the premise of the programme: did patients agree that the NHS can have a role in prevention of chronic disease, and to what extent did they value an assessment of the body for chronic disease risk?
3. Did participants agree with the methods the NHS Health Check used to assess their body and their health?
4. How did participants respond to the way the check measured and defined their health?
5. What did they think of the advice offered at the NHS Health Check and the feedback received after the check?

The research objectives helped to guide the questions asked to participants at interview and these objectives were drawn on to construct an initial selection of themes to investigate. Then, during the collection and analysis of the qualitative data, these themes were built upon and other themes were inductively drawn out of participants accounts (Britten, Jones et al. 1995).

I transcribed verbatim all the in-depth interviews and carefully read the transcriptions several times to keep the participants' words as close as possible to the analysis and to gain an appreciation of the interviews as a whole text. I listened to the interview recordings several times to become "sensorially engaged" with my participants' experiences of NHS Health Checks (Nichter 2008: 178). I took notes about the intonations, flow, emotions of the voices, other sounds of speech and silences as a way of perceiving the sensorial experiences of participants. This method was also used to address the problematic loss of sounds as the interviews change in form from spoken conversation, audio-recordings, to written narrative, transcriptions (Mishler 1984). I also made notes after listening to the recordings

about my personal responses to the discussion and the interviewee, including my own reactions, interpretations, and opinions, as recommended by the voice-centred method of data analysis (Mauthner and Doucet 2003: 419). This method helped me to reflect on how my own attitudes towards the interview shaped my interpretation of each interviewee's responses.

NVivo, a qualitative indexing software package, was used to help with data coding and retrieval: all the transcripts and my research diary and notes were coded using this qualitative indexing package. NVivo aided thematic organisation of participants' interview responses, NVivo helped to highlight the recurring themes and the variety of experiences participants had discussed. The thematic areas of analysis were then expanded into the findings chapter of this thesis. I examined the emerging categories of data and thought about their significance.

Interviews were coded and analysed using two approaches: first by extracting themes across the interviews using NVivo and secondly returning to each interview as a single unit. I found that I could not take one approach without the other. It was helpful to see particular comments in light of personal circumstances and individual narrative as much as it was important to find shared themes. I also found that there were important insights to be gained by analysing the interview as a whole which were lost using the first approach of extracting short and fragmentary elements of speech. At the start of data coding, I went through the interviews individually and started to organise select quotations into specific topics mentioned during interviews, which summarised their content or meaning. This resulted in the creation of fifty-eight topics or themes (see appendix I). Many of the codes were informed by my prior reading and established research interests. As analyses developed, my coding became increasingly influenced by participants' shared experiences and the theories I began to arise at after studying the data. NVivo allowed me to revise and change the codes and the quotations linked to individual codes as the interpretation of the data progressed. Broad categories were then created which each drew on a number of these specific themes and linked them into wider areas of patient satisfaction. These broad categories were defined and built in-situ: I began to refer back to NVivo and the original recordings, whilst the pages of the draft thesis were used to present quotations, evolve the narrative, and discuss theory grounded in the data. It was a

long, complex, and changing process; but working with the quotations, themes, and ideas within the thesis helped me to integrate my analytical ideas with the rich text format in which it is now presented.

3.7 Reflexive Practices

Being reflexive involves introspection about the assumptions and influences which ground the research methods, data analysis, and representations of the data. A wide range of academics from different disciplines and theoretical perspectives have been concerned with reflexivity, including feminists and postmodernists (Haraway 1988; Harding 1991; Wolf 1992; Atkinson 2003), philosophers (Rorty 1980; Derrida 1991), sociologists (Hammersley and Atkinson 1995; Mauthner and Doucet 2003) and anthropologists (Clifford 1986; Marcus and Fischer 1986; Keesing, Crick et al. 1987; Geertz 1993). Those who have influenced the reflexive project have argued for cultural research that “refracts multiple images of ‘reality’, reflects complexity, and fractures certainty.” (Atkinson 2003: 39).

Approaches where the need to be reflexive have outweighed the core aims of the work have been described as “self-congratulatory, narcissistic decadence” (Sangren 1988: 423). This research has aimed take a balanced approach to the reflexive project. The practicalities of funding for this project have supported the case to balance the focus of pursuing the core aims and objectives of the study with the importance of reflexive practice. My data analysis centralises a positivistic rendering of my narrative of findings to assist my practical goals. I also include my introspective, “conjectural and provisional” commentary throughout the thesis (Swann and Pratt 2003: 6). I use a fieldwork diary (see appendix H) to record my experiences of interviewing each of my participants and to highlight my role in constructing the account (Dowling 2000: 28).

Reflexive practice argues that transparency about research conceptions is important (Mauthner and Doucet 2003: 424). I assume that participants' experiences can be understood, to some degree, from what participants say at interview. Participants are viewed as sources of self-reflexive accounts, their interview

responses are seen as a gateway to their experiences. There are limitations to interview data relating to existential positioning. Firstly, interview responses do not necessarily represent participants' definitive answers; interview data is a momentary framing of embodied experience as speech (Keesing, Crick et al. 1987: 269). Secondly, it is possible that the data analysis will construct participants' experiences in a way that misunderstands their intended meaning (Wolf 1992). I interpret the themes which emerged at the stage of data analysis as a creation heavily influenced by many factors including the "epistemological assumptions underpinning" the methods of analysis and "the ontological nature of subjects and subjectivities" used in the research (Mauthner and Doucet 2003: 416). The themes discussed and meanings presented are assumed to have been both constructed and discovered out of the interview data. Like a complicated ecosystem, participants, the researcher, and the reader are all agents in data analysis and research documentation.

I frame this thesis as a narrative about the people who have been studied, which is "guided by an implicit narrative structure" (Bruner 1986: 139). The conventions I adopt follow the 'Western' cultural emphasis on realism and on sensory perception, I use logo-centric interview methodology and quote empirical evidence (Marcus and Fischer 1986: 168). Cultural accounts use realism to re-write social reality, because they developed within a scientific and rational tradition of knowledge (Rapport 1994: 18). Although I aim to portray a realistic formulation of patients' experiences and responses to NHS Health Checks, I see this thesis as a fiction. It is a fiction in the sense that it is "something made," "something fashioned" (Geertz 1993: 15). My research, seen as writing about culture, should be treated "as partial constructions" of the lived-world (Clifford 1988: 97), with the entire path of research guided by 'situated knowledges' (Haraway 1988).

Following Derrida's (1991) work, I also conceptualise readers of this thesis as agents: they may interpret this account in ways I had not imagined. A text continues "to 'act' and to be legible even if what is called the author of the writing no longer answers for what he has written" (Derrida 1991: 91). Drawing on thought about reflexivity, I present to the reader "a historically self-conscious document that recognises the possibility of multiple receptions, and of relevances to several possible discourses." (Marcus and Fischer 1986: 166).

CHAPTER FOUR: RECRUITMENT TO THE NHS HEALTH CHECK PROGRAMME IN GENERAL PRACTICE

The following section of this thesis describes the process and strategies of recruitment to the NHS Health Check programme. It reports findings from participant observation conducted at the two general practices involved in the study. I recorded practice data about recruitment and discussed the recruitment process with staff members. Patient quotations are also drawn on as part of this discussion. All quotations are taken from one-to-one interviews held with participants of this study in their own homes. The quotations are followed by an acronym to identify the medical practice where the participant is registered and the individual participant's unique identifying number (n) (CMn=Carmel Medical Practice; OCn=Orchard Court Surgery).

4.1 Practice Recruitment Strategies

NHS Health Check recruitment methods were quite similar at the two general practices in Darlington where this research has been conducted. Both practices used a combination of opportunistic and systematic recruitment methods, both inviting patients for an NHS Health Check by letter and inviting them face-to-face whilst the eligible patient was seeing a practice doctor. Some patients also asked for an NHS Health Check without prompting from their practice: sometimes because of advertisements, word of mouth, or simply to repeat a health check of years past. Also some patients within this group asked for specific tests, such as cholesterol or blood pressure tests, but were put forward for the more comprehensive cardiovascular clinic by a practice doctor or nurse.

At both practices the office staff began to recruit patients for NHS Health Checks in early 2009. At Orchard Court Surgery a list of all registered patients aged between 40 and 74 was generated, and these patients were invited by letter to attend a cardiovascular risk assessment first appointment. The list excluded those whose blood pressure and cardiovascular risk factor had been recorded in the last year, and

those taking statins. At Carmel Medical Practice they started their recruitment drive by sending out a first letter to the youngest patients in the 35 to 74 age category. All patients with an existing diagnosis of diabetes, renal dysfunction, or hypocholesterolemia were excluded from the list. At both practices the administrators sent out approximately forty letters per week until they reached the eldest in the age category. Many people did not respond to this letter so once all those eligible had received first letters then they began to send second letters to try to recruit the remaining patients who had not responded to the first round of invitations. At both surgeries those patients who received three letters of invitation to the cardiovascular risk assessments but did not reply or get in touch with the surgery were defined as patients who 'failed to respond'. Those who booked an appointment but did not attend, where the practice staff had failed to be able to re-organise another appointment, were classed as 'failed to attend'. Those who telephoned or wrote to either practice to decline the invitation were 'patients who declined'.

Patients of Asian ethnicity from the age of 30 were all invited early on in the recruitment drive to participate in the NHS Health Check programme at Carmel Medical Practice. This strategy was adopted because the doctors understood that patients of Asian ethnicity have a greater tendency to be at high risk of developing a cardiovascular disease in the next ten years. In other practices it has been difficult to target particular 'at risk' groups because they have not collected comprehensive information about registered patients' ethnicity or family health history, which was the case at Orchard Court Surgery. In this situation Pill et al. (1988) suggested practices have the resources in place to screen high-risk groups while they are attending their practice for other reasons. This method of face-to-face immediate recruitment can result in very high uptake rates as found by Goyder et al. (2008) during their study of a diabetes screening pilot programme (Goyder, Carlisle et al. 2008: 52). Both practices did operate policies of face-to-face invitation to an NHS Health Check. After appointments doctors could pass patients immediately over to a practice nurse when they were available. The practices involved in this study did not take comprehensive records of these invitations so it is difficult to assess the impact and success of this recruitment strategy from practice records alone.

4.2 Practice Records about Attendance

The table below shows the number of people who have had an NHS Health Check at the two practices involved in this study. The statistics at both Carmel Medical Practice and Orchard Court Surgery refer to the period between 13th March 2009 and 27th July 2010, the time between the two practices beginning to implement the NHS Health Check programme and a database report being produced for the purposes of this research.

Table C. Attendance for NHS Health Checks / Cardiovascular Risk Assessments

	Carmel Medical Practice		Orchard Court Surgery	
	Male	Female	Male	Female
Patients seen for a Cardiovascular Risk Assessment/NHS Health Check first appointment	165	169	217	54
	334 (m:f ≈ 1:1)		271 (m:f ≈ 4:1)	
Of the patients seen for a first appointment the number whose actual risk was >20%	52 (16%)		175 (65%)	
Patients who declined, failed to attend, or failed to respond	23	27	97	28
	50 (m:f ≈ 1:1)		125 (m:f ≈ 3.5:1)	
Total patients who either attended a first appointment or were classed in the 'declined, failed to attend, or failed to respond category	188	196	314	82
	384 (m:f ≈ 1:1)		396 (m:f ≈ 4:1)	
Percentage who declined, failed to attend, or failed to respond' from above total	12%	14%	31%	34%
	13%		32%	

In light of the similarity of their recruitment procedures, the table shows some unexpected differences between Orchard Court Surgery and Carmel Medical Practice. The differences between practice figures for the table row entitled 'Of the patients seen for a first appointment the number whose actual risk was >20%' raises questions about the different patients attending the NHS Health Check at the two practices. Inviting patients to have an NHS Health Check from the age of 35 years at Carmel Medical Practice, but from the age of 40 years at Orchard Court Surgery is likely to have affected this data, because age is one of the main determinants of risk of cardiovascular disease (Wald, Simmonds et al. 2011). Another reason for the difference between levels of risk found at the two practices may be due to a variation in levels of deprivation and life expectancy between the two study populations. The 2004 Index of Multiple Deprivation tells of the significant differences in prosperity between these two neighbouring areas in Darlington. Among Darlington's 24 Wards, Hummersknott, Carmel Medical Practice's Ward, is the least deprived, whilst Pierremont, Orchard Court Surgery's Ward, is the 11th most deprived (Darlington Borough Council 2007: 6). Visiting the areas I got a visual indication of these differences. In the vicinity of Carmel Medical Practice I could see many large, desirable houses, new builds and period housing, the houses are situated on wide leafy streets and have large driveways. There are few signs of vandalism. Closer to Orchard Court Surgery the housing is mostly terraced, very few of the houses have driveways and some show signs of dereliction. Local youths play on the streets and in the local park there is evident vandalism. Although purely anecdotal, I feel I should remark on an event I happened to witness whilst waiting in the park, nearby Orchard Court Surgery, between interviews. I was astonished to see a thirty-something adult engaging a boy of around ten in a conversation about smoking cigarettes, before offering him one. As the atmosphere at the park was playful, I felt able to talk to the two about it, but was told by the adult "I know I probably shouldn't have, but I started smoking when I was his age". It seems likely that the different levels of cardiovascular disease risk charted by the two practices in some way relate to the statistical data and anecdotal telling of community deprivation.

The NHS Health Check programme acknowledges that both men and women are equally 'at risk' of cardiovascular disease, so it is surprising that the table shows

an unequal ratio of male to female NHS Health Check participants. At Orchard Court Surgery approximately 4 in 5 NHS Health Check attendees were male, compared to 1 in 2 at Carmel Medical Practice. After informally questioning the administrative and health care staff at the practices, I struggled to find a definitive reason for this difference. No one at the practices seemed to have complete oversight of the recruitment process. Some suggestions for Orchard Court Surgery's higher rate of male attendance for an NHS Health Check may relate to the popularity of their now redundant Wellman Clinic. The Wellman check was well resourced to try to tackle poor male life expectancy rates in Pierremont Ward compared to the national average (North East Public Health Observatory January 2007: 4). In Pierremont Ward, female life expectancy is more on par with the national average (North East Public Health Observatory January 2007: 4). I learned that many of the men who went on to have an NHS Health Check had initially approached the practice regarding the Wellman Clinic. It is possible that replacing the established and popular 'health check for men' at Orchard Court Surgery with the NHS Health Check programme caused the difference in attendance figures between men and women. The practice administrators did not have the information to differentiate those patients who had invited themselves to a health check, from those invited by the practice, face-to-face or by letter. Had this information been available it could be used to test my theory about the attendance levels of men and women and would help other interested parties to analyse the success of different recruitment methods.

Table C shows that compared to the number of people who attended an NHS Health Check a low percentage of patients 'declined, failed to attend, or failed to respond' to their invitation to have an NHS Health Check. The small number of patients in the 'declined, failed to attend, or failed to respond' category relates to the ongoing nature of the recruitment drives at each practice. When this data was compiled many patients had not received the three letters which would be sent to them about having an NHS Health Check. There were one hundred and forty-five patients at Carmel Medical Practice and eighty patients at Orchard Court Surgery 'missing' from the above table because, by the 27th July 2010, they had received first or second letters with no response, but had not yet received their third and final letter.

At Carmel Medical Practice I also found that at least one patient in the 'declined' category was not actually eligible for invitation but was sent a letter of invitation in error. I interviewed this man who featured in Carmel Medical Practice records as having 'declined' an NHS Health Check who had been diagnosed with diabetes two years previously and since had been regularly monitored (CM6, male). This participant did not remember receiving a letter to an NHS Health Check. It was not clear what happened to cause a patient who did not meet the defined recruitment parameters to be targeted and the administrators did not know how many people had been affected by what they saw as a mistake. It is interesting to note that CM6 was interested in the check and felt he would have benefited from it had he been eligible. This study perhaps should not have limited itself to just those that attended or were eligible for the NHS Health Check. A further study could investigate whether those patients who are technically ineligible for the check feel they could benefit from a health check.

4.3 Participant Experiences of Recruitment

The sixteen participants within this study gave a wide representation of general practice recruitment methods; they were prompted in a variety of different ways to book an appointment to have an NHS Health Check. Five people had been invited by their doctor face-to-face whilst they had been visiting the practice for both related and unrelated reasons (CM1, CM5, CM8, OC1, OC4). One of which had latterly received a letter inviting him to the checks despite having already undergone them at the advice of his doctor (OC1). Four participants of this study were prompted to have an NHS Health Check because they received a letter of invitation in the post (CM7, CM12, CM13, OC3). Five people invited themselves to an NHS Health Check, without invitation from the practice (CM2, CM3, CM4, CM9, CM11, OC2). Three of which described asking for a health check-up and then being put forward to attend the special cardiovascular clinic by a doctor (CM3, CM9, CM11). One member of the group who invited themselves, latterly received a letter of invitation in the post despite having already undergone the checks (OC2). One

individual's NHS Health Check had been initiated by her husband; he booked her appointment without being prompted by the practice (CM10).

It is, perhaps, unsurprising that the practice records, administered by practice staff, did not record the actions and motivations of patients to drive attendance at the NHS Health Check. Most participants of this study thought that they had attended the NHS Health Check because they wanted to; they were 'ready' to have a health check, and their surgery had provisioned the booking arrangements. Some participants felt that the surgery's letter of invitation to the NHS Health Check programme gave them impetus to get round to organising the check. Others described how the surgery had arranged their NHS Health Check in response to them asking about provision of health checks:

"I made an appointment to see the nurse to have my blood pressure checked and I saw the doctor at the same time I think and erm just during the questioning I said that my father had had heart disease and had died after a stroke and my mum had also had had several little strokes and her heart had failed and so they suggested that I was probably a candidate for the cardiovascular thing and would I like to do it. So I said yes." CM3, female.

*"I went to see doctor *** with Tennis Elbow and after he treated that I mentioned that my father's health wasn't particularly good and he's had restricted blood flow in his legs and poor liver condition and I'm approaching that age when things like that might be happening to me as well so I just wanted to make sure that my health was okay so I mentioned it to Doctor *** at the time and he recommended that I go for the health check."* CM9, male

One person who had been invited to have an NHS Health Check whilst visiting his doctor for an unrelated reason questioned Orchard Court Surgery's use of opportunistic recruitment. This participant found the process emotionally and psychologically wearing. He felt very shocked to be passed on to the practice nurse to have an NHS Health Check and was concerned that his doctor thought he might have diabetes:

"As soon as I mentioned the numbness in my left hand and strange feelings in

both legs I read about diabetes symptoms. Well okay fine, but that's not really what I came for. I'm not complaining it's just it did concern me...In a nutshell I would have liked to be informed why I had to go next door to see the nurse, which don't get me wrong it was a bloody good job that I did because as I said I wouldn't have found out that my blood pressure was sky high. Which I've now addressed that problem, but as I said I had to sweat it out and I suffer from anxiety so it's always at the back of your mind. Oh God, you know, it's another two days until the results come in and you've got to ring up the surgery." OC1, male

Perhaps the very little time available for the patient to consent exemplifies partly why opportunistic recruitment can be so successful. On the other hand, the strategy prompted this person to feel anxious and worried. He was not given information about the purpose of the check and so he worried that he was being assessed for a serious medical condition. The patient did not feel he had the time or space to discuss his worries with his doctor because everything happened so quickly, it was only when he got home that he became anxious about his situation. Clearly this reaction was not anticipated by his doctor but it raises questions about the ethics of this method of recruitment. In ethical thought it is understood that informed consent involves giving patients enough time and information to decide if they want to take part in any medical interventions. This participant did not feel that he gave informed consent. Other studies tell us that preventative services should not rely on the content of the letter of invitation alone, a multi-pronged recruitment drive is thought to create more equality in uptake of preventative service (Marteau, Mann et al. 2010: 6). The professional implementing opportunistic recruitment may have been focused on helping the patient based on his Framingham screening result, and perhaps, increasing uptake of NHS Health Checks. But, at the same time, seemed to have lost focus on the emotional life of the patient and may not have fully considered the psychological impact of the strategy.

Those participants who did remember receiving a letter of invitation to attend the NHS Health Check found it to be clear and unambiguous, and in retrospect gave a fair and restrained impression of the benefits of the NHS Health Check. The two practices who were involved in this study used versions of the template letters

provided in the 'Handbook of Risk Reduction and Risk Management' (Davies, Khunti et al. March 2008). These template letters of invitation were used to provide patients with 'tried and tested' clear and easy to understand information. A participant who had an NHS Health Check after being invited by letter felt very pleased to have been given the chance to do something she would not have otherwise thought about:

"No because I never really thought about it, about going and having a full health check, I hadn't, I'd never thought about it so when they give me the chance I thought I'd take that chance and go. I think you've got to take a chance some time in life, I do and if the results come back and if you take that chance and it's good results what have you got to lose." OC3, female

Others echoed this feeling, for example the following participant felt that he had been lucky and privileged to be one of those selected:

"I said why did you have to call me, thousands of people. She said we selected certain criteria. My background and my age." CM12, male.

This participant sounded overwhelmed about his good fortune to have this opportunity. His reaction was revealing of the general lack of background knowledge that participants had about the NHS Health Check programme, most thought it was a local initiative. Participants of this study were not familiar with the national age-based scheme.

"Yeah that's another thing if maybe I had a few problems then maybe I thought perhaps I should go and ask for a check-up but to be honest I didn't actually know the doctor's did them. My husband kept going on about them but I thought well I've never heard of it so I wouldn't have enquired to be honest." CM10, female.

It may have been beneficial for more participants of the programme to know of its national availability so they could recommend their friends and relatives proactively ask for the check. Responses to the NHS Health Check were generally positive and participants felt that they could recommend the check to at least some of their friends but they did not really think it was widely available for free with the

NHS. Many thought of an NHS Health Check as something you should do, if invited or if it is recommended for you by a doctor, rather than something that you should proactively seek out:

*“If they, like me with this, **if you’re invited** to do something I’d say well yes just do it.”* CM1, female.

The potential to use word-of-mouth as a national recruitment strategy seems to be underutilised. It is recognised in some NHS documents about the NHS Health Check programme that word of mouth is an important recruitment device: “‘Word of mouth’ is a very powerful tool in getting people to attend clinics, as they hear about the value of the service from their peers.” (Mayhew and Buttery 2010: 2). It is also noted that word of mouth recommendation is one of the more cost effective recruitment strategies: “In terms of cost effectiveness, a personal communication via a letter of invitation from their own GP, door drops, word of mouth recommendation, direct marketing, outdoor advertising and finally posters are most to least cost effective in this order.” (Healthy Foundations Lifestage Segmentation Research 4th November 2009: slide 34). This reference applies previous work on social marketing and health to the NHS Health Check programme, but does not relate to original research on the implementation of NHS Health Checks and social marketing. Although the NHS has published a guidance pamphlet relating to the branding and representation of NHS Health Checks to patients, this brand identity had not successfully registered in the minds of participants of this research (Crown March 2010).

It could be argued that the goodwill being built in NHS Health Checks as a brand is not being best utilised as long as those who are prepared to recommend it think of NHS Health Checks as somewhat ‘exclusive’ or ‘invitation-only’. More effort is needed to persuade organisers that asserting the brand identity of NHS Health Checks will have a positive effect on take-up and will help encourage ‘word of mouth’ recruitment. Additional research might be useful to identify why some organisers do not utilise the NHS Health Check branding. There is also scope to look at other ways of encouraging social marketing of NHS Health Checks.

CHAPTER FIVE: EXPRESSIONS OF SATISFACTION WITH THE NHS HEALTH CHECK

In this chapter I analyse and reflect on the contextual and personal dynamics influencing the expression of satisfaction with NHS Health Checks. I draw on study participants' responses at interview to focus on this area.

5.1 The Ethos of the NHS Health Check Programme

The NHS Health Check programme asserts the role of the NHS in preventative healthcare and requires general practices to actively contact their patients and invite them to have a check. Its guiding principles are not innately 'good' or 'right', the public will play an important role in assessing how well the programme fits with their own views about the role of preventative healthcare and how much the NHS should be involved in their lives. Public support for the ethos of the programme is important in terms of patient health outcomes, the programme justifying itself, uptake levels, and for health professionals to feel happy to take ownership of the programme. This study revealed that some patient participants were undecided about their satisfaction with the ethos of the programme.

The following section shows how participants debate the policy of NHS Health Checks contrasting their doubts and questions of the programme with its individual and societal benefits. Participants expressed their disagreement with the ethos of the programme when questioning the way scarce NHS resources are used, their conceptions of the role of the doctor and the place of self-help, and their happiness with the status quo.

One participant could both see the NHS Health Check programme as a social 'good' which could really help people, in general, to live longer:

"And I just think, that sort of thing, which is quick to do and presumably relatively cheap to do and it could save lives and make a real difference. I like the idea of it." CM7, male

And wondered about the morality of attending the GP surgery for a preventive reason in an environment of scarce resources:

“Intellectually about putting into prevention has got to be the right one, but at the point when you need to be cured it can never be the right one. If you got that illness, and there was something in the press this week about NICE not accepting a particular cancer drug. I mean whether you accept their argument for that or not because they can't accept everything. If it comes to a point where the cost of a drug that's available to treat an illness can't be funded because of up front preventative care. You can see that from society's point of view that may well be the right thing but if you're the one with that illness it isn't the right thing. And you can't square that circle I'm afraid.” CM7, male

This participant took a broad societal view on the programme and described his concern about the political working of this policy. Patients are concerned that NHS Health Checks take scarce resources from people who are actually unwell. Showing the public the financial benefits to the NHS of preventative schemes could be one approach to justify attendance at an NHS Health Check but dealing with views about the allocation of resources using epidemiological figures is not going solve this moral conundrum for all.

The concept of an NHS Health Check challenged some people's expectations about the role of the general practice. This participant raised her doubts about attending the NHS Health Check when she felt fit and healthy:

“... suppose I'm like a lot of people. Don't want to waste people's time. Do you understand that? You know sometimes you have a cold and you think this is getting a bit bad, maybe I should go to the doctor's and you think no, just drink lots of juice, take a couple of aspirins and you'll be okay.” CM10, female

The space in which the NHS Health Check took place was loaded with feelings and associations affecting choice to participate in the programme. In this case the doctor's surgery was seen to be a place for people who were really unwell. CM10 felt guilty about attending the doctor's surgery when she was not ill, she was

unfamiliar with this concept and so thought she would feel out-of-place in the surgery.

Older people, as well as those who thought of themselves as fit and healthy, also had reason to believe that the doctor's surgery was not the place to raise their health concerns. One participant described how she did not visit the doctor although she was experiencing tiredness because she felt older people had to be stoical about occasional poor health.

"I suppose when you get older you'll get good days and you'll get bad days and you've just got to put up with it." CM5, female

Self-diagnosis, self-administering health treatments and self-regulation of lifestyle behaviours were conducted by all participants in this study; in fact, interviewees described how they always tried to help themselves before seeking the help of medical professionals. Participants were familiar conducting these practices of self-help in mainly private settings, often in the home, among close family and friends. The NHS Health Check brought these practices into an unfamiliar, more public, institutional sphere, which encouraged some people to ask themselves whether they felt happy about the NHS exerting more active enquiry into their lives.

"I suppose the one thing I did fear before I went to the clinic, it wasn't particularly an illness or anything it was just the fact that sometimes you get, on the one hand fine, if there's something wrong with me then they need to address it but on the other hand it's the investigatory side of things, often if there's just something slightly wrong with your blood, or if there's blood in your urine or something then you start going through all these procedures... and the one doubt I had in my mind before the check was that if something's not quite right and they start putting me through all these procedures. I feel okay should I really be, not tampering, but do I really need to know, should I wait until I'm not feeling 100%." CM2, male

Another participant's uneasiness about this medical probing into his comfortable world led him to decline the cholesterol check:

"But when I was offered the cholesterol check I thought oh no because it

might be sky high and I'll have to stop eating cheese and stuff like that and eat bloody lettuce leaves or something so I was scared about that... but you get this, this thing 'oh God what will they find'... too scared of what can of worms it might open up.“ OC1, male

Some people felt uncomfortable with the way these tests could intrude into their lives. These participants were worried about upsetting the status quo and feared the unknown. There was not universal acceptance of the ethos of the programme to better inform people about their health. The views discussed in this section are likely to have an important influence on choice to attend an NHS Health Check and general satisfaction with the NHS Health Check programme.

5.2 Understandings of the Concept of an NHS Health Check

The NHS Health Check programme was created to respond to concerns about rising levels of cardiovascular disease. Patients did not seem to share these concerns. Patient participant understandings of the concept of an NHS Health Check were focused on their more general health and wellbeing. There were mixed responses to the concept of the NHS Health Check, some people felt it was about finding out about present health so their doctor could provide pharmaceutical treatments or monitor the issue if necessary. Some hoped the NHS Health Check would help to catch something early, like cancer or diabetes. Most participants were open to changing their lifestyles and saw it as a good opportunity to find out how essential a change of lifestyle might be. Participants generally felt that their test results would directly affect their decisions about drinking, smoking, exercise, or eating habits. NHS Health Check participants valued empirical evidence about the body for what it could newly reveal about their individual health.

The NHS Health Check reminded participants about general good practice health messages and made many people consider what they do or could do to lead a healthier lifestyle. However, most participants viewed the general health advisory information as 'common knowledge', and they had already decided on their

approach towards managing this advice within their daily lives. If participants were already aware that their behaviours are known to be generally unhealthy they would not significantly reconsider their behaviour unless the test results found cause for concern. There was no interest among patient participants to use their NHS Health Check to improve knowledge of cardiovascular disease.

5.2.1 Patients' Health Concerns

Participants expressed their dissatisfaction with their health assessment when it did not assess health issues that they were anxious about. Participants had expected a general 'health check' which addressed their anxieties about particular diseases or health complaints. When some of their health issues or worries were not addressed this affected satisfaction with the health assessment. The term 'health check' was associated with a general wide ranging assessment of health and not specifically with cardiovascular risk assessments. Patients' ideas about the concept of a general 'health check' led them to express dissatisfaction with the less than comprehensive health assessment they felt that they received. For example the lack of tests for cancer and particularly prostate cancer among the men was a reason for dissatisfaction with a health assessment.

"I think that the worrying thing that I would be thinking about is the silent killer like the prostate. I'd like to know more about that because it is, you just don't realise that you've got it in some cases until it's too late." OC2, male

One participant described how he had expected the information gathered at the NHS Health Check to be used to pin-point targeted follow-up tests. He was disappointed when he found this did not seem to happen. In his case the nurse expressed her concern about his drinking behaviour but he did not think he was offered a liver functioning test to prove to him that he was drinking too much, instead it seemed to him that this concern was left open-ended.

"One thing that did cross my mind afterwards, you know there's a test for

liver function, I thought well maybe she should have said we'll do a test for liver function. She might have said that there and then or she might have taken a look at me and said well I don't look as though I need it. I didn't get any feedback on that, so the feedback would have been helpful." CM2, male

A liver-functioning test would have been conducted as standard during the NHS Health Check so here dissatisfaction seemed to relate to lack of communication about the content of the check. This example also highlights the expectation that health screening will provide conclusion, proof or answers. This participant was surprised that the NHS Health Check caused him to feel uncertainty about his health and the amount he should be drinking.

Some participants would have liked their NHS Health Check to cover joint and back pain. One participant was more concerned about his joint pain than his cholesterol levels. Joint pain had an immediate impact on his wellbeing – perceivably affecting his leisure time and exercise – so it being ignored in his health assessment was a reason for dissatisfaction:

"I never think about it [high cholesterol] because when you're walking up hills that are like that [makes a steep hill-like gesture] I'm more concerned about the joints and the knees especially when you're coming down and you get the pain in the knee there." OC2, male

"I take glucosamine and cod liver oil because I really do think it's important to keep my joints moving. I have got bits of arthritis and my mum had terrible arthritis and found moving about really difficult when she was older and I don't want to get to that stage. Yes, it would worry me if I couldn't exercise and get out and about and things." CM3, female

Another participant talked about the link between his felt symptoms and his health concerns:

"I wasn't even worried about my high blood pressure because I've never been ill." CM8, male

He was unable to perceive any symptoms so he did not worry about his high blood pressure. Ailments that caused most concern were those that immediately impacted

on daily activities. One participant described how being diagnosed with high blood pressure and high cholesterol would not worry her as long as she could continue looking after her husband and older children and doing the housework:

"I'm not worried about it so long as I can do what I have to do here [in the home]." CM5, female

A man of Middle Eastern origin who had immigrated to the United Kingdom some years ago also spoke of his priorities: he said that fulfilling his role in the family as provider came first before health. He described health conscious behaviours as a luxury which could only recently afford his time and attention, but the demands of work, as a matter of family survival, had to be his biggest priority:

"Yes you have to make a living to have a good life. When you have a good life then you can go move to do sports you know what I mean, priority." CM12, male

Participants were concerned or worried about their immediate 'felt' health complaints, for example joint pain or tiredness, and their wider financial and practical daily duties. The majority of participants felt that the focus of their NHS Health Check results, which told them about their cholesterol levels and blood pressure readings, did not directly associate with these concerns.

5.2.2 Health Check as an MOT

Among those who invited themselves or were prompted to have an NHS Health Check because of a postal invitation there was a strong emphasis on the NHS Health Check as an 'MOT'. Justifications for attending the programme or needing the NHS Health Check related to this imagery, the body viewed as machine needs regular servicing, which it was believed could be provided by the NHS Health Check. These beliefs seemed to be held by many of those who attended an NHS Health Check:

"The body is like a motorcar so if you don't look after the motorcar, keep it

well oiled and wash it, it's like a love affair you have for the motorcar. That's how the body should be, if you don't look after the body, well no one else is going to." OC2, male.

"Well I looked at it as a sort of mid-life MOT almost. At a point where things could start going wrong and you don't sort of monitor it yourself. I know they only sort of check the basics but its prevention rather than cure almost you see." CM7, male.

"Peace of mind as well. It's a full MOT for the body. I felt happy and good when they didn't phone me. I was worried that I had diabetes, with my age and my family history I think that it is affected by family members, so I'm ok." CM12, male.

It appeared that many patients could relate to the metaphor of the body as machine used in official NHS Health Check leaflets. The image of a simple outline of a body shape containing cogs in different colours to represent the areas of the body each of the four main cardiovascular diseases affect is used on the front cover of a leaflet designed for patients and another for health professionals, see: (Crown 2009), (NHS Health Check Programme 03 April 2009). The image conjures the impression of the body as machine, inside the body are cogs, which reflects the popularity of the body as machine metaphor. Many patients were keen to participate in an NHS Health Check, based on the claim that it would provide the servicing that the body requires.

5.2.3 Patients' Familiarity with a Health Check

The term NHS Health Check is used in official leaflets and documents designed to be given to patients as the brand standing for cardiovascular disease risk assessments, the use of this term appears to make patients feel more familiar with the tests (Crown 2009). Part of what makes patients feel so much more comfortable having an NHS Health Check over a cardiovascular risk assessment lies with their familiarity with the concept of a health check. These tests are routinely performed in

doctors' surgeries and in fact many participants in this study thought they already routinely had health checks.

People in this study discussed their familiarity with the concept of a health check. A number of our participants had been regularly attending check-ups at their doctor's surgery for a number of years. They had in the past attended yearly women's and men's health checks, blood pressure checks and cholesterol checks. Some of those participants who had already attended these other checks reported having the same checks twice over a short time span, because they had been included for invitation to both the 'Wellman' checks and the NHS Health Checks, which included most of the same tests. One participant felt that this current brand of NHS Health Checks was grounded in political motivations, he saw it as "a bureaucratic tick-box labour government exercise" (OC1, male), because health checks had already been made available to him for many years.

One of the participants who took part in this research had asked his practice for a health check, but had been told that he should attend the cardiovascular clinic, which he felt sounded more serious and scary than a simple health check.

"Yeah, when I [asked] originally, I never expected the health check would turn out to be a cardiovascular check as such, so when they mentioned this cardiovascular clinic or something it kind of scared me off thinking is something serious going to happen or something. It's simply a health check but just refreshed it, so when I realised that it's no different from a normal health check." CM11, male

The use of cardiovascular checks in place of health check could cause confusion and uncertainty. In general, people were more comfortable and familiar with the concept of a health check. Having an NHS Health Check was seen as something for everyone, the term 'cardiovascular' check was viewed as more specialist and less universal:

"I wouldn't have thought I'd have any problems with cardiovascular. In fact I still don't understand why I went into the cardiovascular clinic." CM1, female

For some patients their NHS Health Check was incorporated into a routine

check-up. Patients were happy that their NHS Health Check felt normal and innocuous and was flexible:

"I wanted my cholesterol checking anyway. It needed to be checked and I wanted to check my blood pressure. Yes it was good I needed it." CM1, female

"I always want to feel that I'm alright for the coming year... So I just like to keep in touch with the doctor like and he knows who I am and that he's quite happy and quite pleased that I look after myself and I'm not going to be a burden on the surgery sort of thing. Like some people are. And I think that it's just keep the connection, that personal thing." OC2, male

The NHS Health Check was also seen as a personal and need-driven ritual by those patients who asked for the check. They saw it as something to fulfil their interest in finding out information about their overall health:

"Well I instigated it really because of my birth background, I'm adopted and I've just recently found that my birth mother was very much like me. Very healthy fit and died at 72 of heart trouble. So I thought I'd better do something about it really. Just in case there was anything that was going on that I didn't know about" CM4, female

"So I had my parents, friends telling you better get it checked out, how healthy you are and things like that. That's why I went and made an appointment and I live really close to the GP, an appointment to just have a health check. And then someone within the practice suggested that I do a cardiovascular check, make it more serious you know." CM11, male

The above four quotations illustrate that participants felt they needed a health check for diverse and particular reasons, such as because of their medical history, family background, or routine level of contact with their general practice. Participants thought they should be eligible to have an NHS Health Check as a consequence of their own 'need' or personal preference; age did not feature dominantly in perceptions about eligibility.

Participants did not have complete affinity with the concept of an NHS Health Check exclusive to those in a defined middle-age group. Drawing on preventative

philosophy, one woman could see the NHS Health Check benefitting young people:

“As I say for young people as well because older people tend to know what’s going on whereas younger people when you tell them they’re not really going to take any notice. But the damage can be done in younger years can’t it. I think that’s a good idea, do some sort of healthy check for people about 25, do some kind of health check on them as well.” CM10, female

Patients thought of a health check as something that should be provided to those who needed or wanted one. Many thought that an NHS Health Check could benefit people at any stage in their lives. NHS Health Checks provided a service that many participants of this study thought was previously available to them.

5.3 Satisfaction with the Delivery of the NHS Health Check

Both practice nurses and health care assistants were used to deliver the NHS Health Checks at the practices involved in the study, these staff members were utilised pragmatically, according to the changes in staff availability. The member of staff conducting the check had certain procedures to follow, such as recording body measurements and reported lifestyle behaviours as well as talking the patient through basic lifestyle advice and often handing out a range of ‘take-home’ written materials.

5.3.1 Collecting Information about Patients at the NHS Health Check

Before or during the initial NHS Health Check, patients’ answers to questions about their current lifestyle habits and family history of cardiovascular disease are recorded on a questionnaire-based form. Only shortened or bounded answers are used to calculate the risk score, although the type of questions asked often prompted long and wordy responses. Participants found it useful clarifying the questions, asking “...*exactly what do you mean by this...*” (CM3, female), and discussing their answers face-to-face with a nurse or health care assistant.

The NHS Health Check was generally perceived to be worthwhile; most participants believed that it assessed an area of health that could be life-threatening:

“so I think if people when they’ve got the chance to go and get things done they should go because they find things out that maybe could save their life or put them on the right track to improve their life. So that’s why I went.” OC3, female

The majority of participants treated the NHS Health Check in a relaxed, stress-free way. The observation CM7 made was echoed by many participants:

“It felt exactly the same as making a normal appointment and going and getting a normal blood test or whatever.” CM7, male.

Some participants did mention that the blood pressure tests and waiting for their results were a cause of some stress and anxiety. Experiences of ‘white-coat’ syndrome were discussed by a few participants of this study, and this was seen as a consequence of being at the doctors to have blood pressure taken as part of the NHS Health Check:

“I have a problem going to the doctors that initial sat waiting it’s just God please hurry up and my anxiety and I know my bloody blood pressure’s going to be sky-high with the white coat syndrome and all this lot. So but you know I try to keep away until something.” OC1, male

A small number of participants were not keen on the delivery of the NHS Health Check as they felt anxious about certain tests, stress in the face-to-face context and disliked the delays of organising and waiting for an appointment. Some patients would prefer approaches which effectively manage their risk but are less confrontational, intrusive, or time consuming than NHS Health Checks. Other patients did not feel any stress or anxiety and thought the service was quick and straightforward:

“Very well, the nurse at the surgery is very nice, she’s very professional, nothing to it. I was only in about 10 minutes and everything was done and me weight was fine.” OC3, female

Patients' experiences of attending an NHS Health Check were strongly influenced by their rapport with the person who conducted the check. Patients reported having a good rapport with the health care worker conducting the check when family life, leisure activities, and worries or concerns could be openly and sympathetically discussed. A few female participants found that the rapport they had with the nurse at this check distracted them from what was going on so they did not experience any nervousness.

"That was absolutely fine the nurse was great. The previous few times my blood pressure had been up a little bit and when I went for the actual check with the nurse, she, we were talking about other things completely. I run a business for children and we were talking about her son and my blood pressure was absolutely fine, it was great, it was very easy and professional."

CM3, female

"...they call it the white coat syndrome don't they. I didn't feel it because as I say she [the nurse] was so nice and we were having a laugh."

CM4, female

Rapport was not just determined by the personalities in the consultation room but was influenced by the type of information and use of medical terminology expected of the health care worker and how this was then interpreted by the patient. Participants acknowledged that their positive opinion of the check and the nurse who conducted it may also have related to fact that they received good feedback about their health:

"[the health check was] Very good, the nurse was lovely. No problem at all but the results were good as well [laughs]."

CM4, female

Trust and rapport could be disrupted when patients felt their perceived 'normal' body shape and behaviours were poorly represented by the guideline figures, such as for ideal waist measurement or alcohol consumption. A couple of participants who had been told they were outside the guidelines felt disbelieving of the risks and were even questioning the categories themselves. These participants were generally self-approving of their current body shape and behaviours so found it difficult to accept the labels 'excessive drinker' or 'obese'.

“I didn't come away particularly worried, because I know in myself that I feel happy drinking that particular amount of alcohol. It was just the way she reacted, it was kind of quite strange really.” CM2, male

“When I saw red I thought oh I'm in danger. But the thing is and I'm quite happy with the 36 inches just because the tape says to me I should be a 32 or a 33 I really cannot see, you know what I mean. I mean sometimes these rules and guidance are just, you start to believe how true or strictly true they are because I don't want to go in the slim. Because 36 inches I'm quite happy with. If I want to change to 32 then I've got to change all my trousers [laughs]. I'm quite happy with the dimension I have.” CM11, male

Patients are not confident of measures of their health which categorise them in terms foreign to their own opinions about their health and behaviour; such measures of health, like waist circumference, Body Mass Index, and 'sensible' drinking guidelines, were applied to everyone attending an NHS Health Check.

One participant reported that he had come to expect from general practice a lack of understanding and lack of funding to support him through his drinking disorder. He felt that he was blamed for his problems and that there was too much reliance on self-help. In his experience the National Health Service did not provision the kind of support he felt he would need to help himself:

“alcohol seems to be, it gets a bad press, and it's a chronic disease, you don't want to, it's not that you want to you have to and all the years I've had from doctor basically 'For Christ's sake pull yourself together'. That's the worst thing you can say to a person who's got a problem with alcohol and I don't think it's addressed enough. If you look at all the things [in the medical record], It's the underlying problem, it's some mental illness i.e. anxiety, depression and silly people like me think they can sort of counteract it by the drinking of alcohol and you can't. It just makes it worse so you know I think patients' records should be more looked into all the way through. He's been abusing alcohol for bloody 25 years and you know we're still giving him tablets and I think Christ lets. And then at the end of the day it's always cost. I'm sorry I can't send you to a bloody drying out clinic or something it's

bloody £4000 for a week, that type of thing. So I think the National Health wants to help but it's the money. ” OC1, male

This example shows that patients might be more satisfied with delivery of services if more emphasis was placed on providing patients with the emotional and psychological support they want or feel they need. After their NHS Health Check some patients are referred by their doctor to a lifestyle intervention programme, normally organised by the Primary Care Trust. These lifestyle intervention programmes could include: weight management programmes, physical activity initiatives, smoking cessation, mental health, and drug and alcohol misuse services. None of the participants of this study were offered referral. Currently the individual personality or approach of the GP is a powerful influence on who gains access to lifestyle intervention programmes. Clearly, patients like OC1 do not find that access to these programmes is determined by their perceived needs.

5.3.2 Providing Lifestyle Advice at the NHS Health Check

Officially, NHS Health Checks are said to include lifestyle advice appropriate for the patient. The general approach told everyone the same general advice and then went into greater depth depending on each person's circumstances. The health advice was already known by most participants, but a small number of both those at high risk and those at low risk thought of the advice as a very useful element of the NHS Health Check:

“So I thought it was very helpful it was very informative and it was thought-provoking, it just gave us some fresh view on things, because you can get very easily into doing what you think is okay, whereas really no matter how you feel now you've got to be doing things that will help you in the future or preventative action, rather than letting yourself get to a situation where it is very difficult to reverse and getting problems.” CM2, male

A number of people had not thought of the advice as a significant aspect of their NHS Health Check.

“I mean there wasn't a huge amount of advice because the things that I do seem to fall into what was required if you see what I mean.” CM3, female

Patients found that the health professional at the NHS Health Check appointment did not give them unwanted or unnecessary advice. The advice was well customised so it suited their individual needs and so it was not perceived to be didactic.

One person described the advice as a way of helping others in society gain a better understanding of the risks and possible consequences of their behaviour:

“So I think like most things in life as long as you have knowledge of the facts and the consequences then any grown-up should be able to make their mind up within those parameters.” CM7, male

This participant viewed the advice element of the NHS Health Check as a way of addressing societal inequalities in knowledge, but he was cautious that this would not happen if the 'hard-to-reach' group do not attend the NHS Health Checks.

Other participants could give examples of new facts they had learned during their NHS Health Check. One man was more able to follow a low cholesterol diet after finding out that pork is classed as a red meat:

“I mean I knew that your poultry and that was a white meat, but I'd always classed pork as a white meat. And that's one of me big meats I do eat, pork actually.” CM8, male.

This patient was very happy with the dietary advice. He was pleased that the NHS Health Check helped to correct a misunderstanding he had about low cholesterol foods.

Both practices followed the official guidance about the information leaflets to give to NHS Health Check attendees (Department of Health 03 August 2009; Department of Health 3rd August 2009). The practices distributed official Department of Health leaflets and brochures and advice sheets created by 'www.patient.co.uk', an influential health website in the United Kingdom which creates health information resources for the use of patients (EMIS and PiP 2006). When asked for their feedback about these leaflets, many participants of this study

said that they didn't read the advice literature, skim-read it, or found it a little complicated.

Overall, face-to-face advice was preferred by most over the information literature, but the literature was seen as a useful addition because of the time constraints of the appointments.

"Face-to-face, it's easier when someone's sort of telling you this is what you should aim to be doing rather than read that. I mean you can go home and read it but it's nice when someone sits and says look try doing this and try doing that, it might help." CM1, female

"No the face to face because it's explained to you better. Told what actually was what, whereas you read it, it's not the same, somebody telling you and explaining to you is much, much better. It's much better to be explained by a doctor or somebody that knows." CM8, male

Patients liked the immediate and personalised quality of face-to-face advice although many did not feel that they particularly needed any advice.

5.4 Engagement with Test Results

Results of the NHS Health Check were presented in a variety of formats. Initially spoken feedback was given at the NHS Health Check, based on participants' answers to lifestyle questions, their Body Mass Index and their blood pressure reading. Then some patients took the opportunity to ring their practice to find out the results of their blood test in three to five working days. NHS Health Check attendees should receive their overall results letter within a couple of weeks, although some participants of this study did not remember receiving any results after they had been for the NHS Health Check. The results letter invited patients for a follow-up assessment at the practice if their cardiovascular risk score was defined as high, or if elements of the health assessments revealed concerns, such as high cholesterol or high blood pressure, despite an overall lower risk score. I focus here on the preferences participants expressed about the format in which results should be

presented and the content of the results they receive.

5.4.1 Preferences about Method of Feedback

Patients had varying views about method of feedback. One participant expressed the view that patients should be given more choice about the way in which they communicate with their surgery. He found face-to-face consultations stressful and expressed the preference for email communications, which was not offered by the practice.

When asked: *"How would you have liked the results to be presented to you, letter, face to face, telephone with all the figures?"* He replied: *"[Pause] I think a patient should get the option especially someone like myself."* OC1, male

He particularly thought that email could be better utilised as a quick and efficient form of communication between patient and doctor.

"So you know I think the internet and emails and stuff like that can be used a lot more for the patient. It just to me speeds communication up." OC1, male.

Perhaps surprisingly, email communication was not requested by any other participants. Face-to-face communication with a doctor or a nurse was valued most highly by the majority of participants, but most patients could understand the cost and time effectiveness of letter communication if their results were low risk. Many participants felt that a face to face follow-up appointment was not essential because the letter provided the advice and information they needed:

"...because the advice in the letter it wasn't alarming it was straightforward." CM2, male

Others who were not given a follow-up face-to-face discussion with a doctor or nurse felt they may have benefited from one.

"I would have benefited from a sit down discussion with a nurse or a doctor just to go through it and I guess it's a bit of a shock when you're told the

information just in a letter and to follow that up with a discussion would have been far more beneficial.” CM9, male

This participant did not feel comfortable contacting the practice for an additional discussion about results that was not routine, although his letter of results invited him to do so. This example shows that opening up different options for patients in terms of their communication preferences does not necessarily mean they will feel able to choose freely. Social pressures, convenience, and work responsibilities can all impact on choice.

5.4.2 Preferences about the Provision of Results

The two practices involved in the study took two different approaches to represent results. After the NHS Health Check the doctors calculate each attendee's cardiovascular risk using a validated Framingham Risk Calculator. Despite recording this information about patient's cardiovascular risk on their databases, in line with NHS Health Check programme policy, individual general practices could decide whether to routinely provide this information to their patients. Carmel Medical Practice decided not to focus results on cardiovascular risk. The feedback letters provided by Carmel Medical Practice often focused on cholesterol results, and only briefly, if at all, mentioned risk. An example letter said,

“Thank you for coming along for your recent cardiovascular risk check, your blood sugar was normal. Your BP was a little bit raised. Your cholesterol was just over normal at 5.3 but the ratio of good to bad cholesterol was normal. Overall your cardiovascular risk was quite low but I would recommend you follow a low cholesterol diet advisory sheet for guidance and I would be grateful if you could make an appointment with the healthcare assistant for a blood pressure check in three to four weeks time. If it's still high then you'll be advised to see a GP.” CM5, female

Only one participant from Carmel Medical Practice could describe her cardiovascular risk, she had been told her percentage score face-to-face by a doctor:

“one of the lady doctors who I saw, she told me it was seven percent which is really, really low.” CM3, female.

In contrast Orchard Court Surgery did disclose patient's cardiovascular risk scores and all participants from this practice could describe their risk score. These patients used a variety of different terms to express their risk: one remembered this in terms of risk percentage, he had a 20% reading although he felt pleased with this and did not know it could be called high risk, another participant knew he was 'high risk', but could not recall his actual percentage score, whilst the remaining two used the vocabulary of 'borderline' risk.

When risk terminology had been provided participants generally viewed this information positively and took an interest in their level of risk:

“And just the way he did it in percentages made me feel better and made me feel more relaxed. You virtually want it to be clear, you want it [your percentage risk] to be nothing at all.” OC4, male

The use of risk terminology was also viewed very positively by another participant. He was very happy with a score of 20%, and had not been told otherwise, although the Framingham Risk Calculator treats 20% as a high risk score:

“oh he's only got 20%, typical Americanised thing 'he's only got 20% risk of major illness'. And so ha, I feel great now I didn't sort of think how the hell did they do that, how can they, obviously it's research, through 10000 people or whatever and you think. I was very, very pleased by it, it was better than them saying you've got an 80% risk you're going to have a major thing, oh Christ almighty and that to me, I don't know what I would have done, I would have literally gone off it. I need encouragement, that was encouragement, you know, I must be doing something right.” OC1, male

By not telling him he was classified at 'high risk' this participant felt reassured and less worried about his future. Another participant had similar views about the meaning of risk in percentage terms:

“For me it was but I came out on the good side of it didn't I. If somebody got

'well you've got a seventy-five percent chance of having a heart attack or a stroke' it might be absolutely terrifying." CM3, female

These two participants felt that had their risk percentage been calculated at 75% or 80% then this would be absolutely shocking. These examples show that the Framingham definition of risk when termed as a percentage is not necessarily shared with or understood by the public. Although many patients thought of an ideal percentage risk in single figures, their percentage definition of high levels of risk did not correspond closely to those used in the Framingham Risk Calculator.

Patients of Carmel Medical Practice who did not know their risk of cardiovascular disease were able to talk more lucidly about their cholesterol or blood pressure readings. As found with cardiovascular risk terminology the medical understandings of cholesterol and blood pressure were not shared with participants. Participants commonly found the meaning of these results confusing. Many participants did not understand their cholesterol and blood pressure results in terms of what ailments they could cause. I was asked by a participant diagnosed with 'high' blood pressure: *"As regards blood pressure, what ailments can you get from it, or what will you get?"* (CM5, female). Instead, cholesterol or blood pressure readings were used in participant conversation as popularised indicators of general health, with 'high' measurements seen as bad or not ideal.

Actual figures and more vague descriptions of cholesterol levels are swapped in and out of use by participants, CM8 describes his cholesterol as 'quite high' and '6.7' within the same conversation:

"He said it was quite high like, it was 6.7 and I know it should only be 4."
CM8, male

One participant talked about their 'borderline' high blood pressure as a concern of his doctor, but he did not feel able to engage with his diagnosis, instead he trusted the doctor to care for him:

"Well it concerned the doctor more than me because he said it was just borderline, it wasn't way above, but they couldn't get it to its normal level without the tablets. But as soon as I've taken them it's spot on." CM8, male

Another participant who did not need a prescription described how she did not understand the medical meaning of her cholesterol results but she used the fact that she had not been prescribed medication as an indicator that she was okay:

“I suppose I don't understand the ratio of the cholesterol. So know the high bit is 5.5, the excellent bit is 1.6, now I don't know if that's good, bad, or indifferent really, but I mean I don't need medication so I'm assuming everything's okay even if it's borderline, it's not too bad.” CM4, female

Participants found that medical descriptions of cholesterol were most helpful for medical professionals in order they could best take care of patients. They did not think it was necessary for patients to understand as they could trust in their doctor's decisions. Participants commonly wanted to understand the meaning of their results and their doctor's decisions regarding their treatment. However, they did not expect their doctor to fully explain their results or treatment plan. CM4 (female) said that she *“would like to, I suppose it's just because I'm nosey, you know to understand.”* The use of asides like *“because I'm nosey”* suggest that she felt embarrassed to admit she would like to understand, let alone expect her results be fully explained, an attitude probably shared by others.

Although participants often felt that they did not have the knowledge about their test results to judge their health many were happy with the feedback provided and trusted their doctor's decisions:

“Oh yes and that's fine I think if there had been anything to worry about they would have called me in, I feel quite happy that they would have done that if there was anything too wrong.” CM4, female

For some participants receiving results from the doctor was actually viewed in a negative light. These two participants explain how they felt that if the doctor contacted them about their results it probably indicates that something is wrong:

“Oh yes it's very good - no feedback because feedback means something wrong and then you have to worry about it.” CM12, male

“No not really, because I think no news is good news, whereas if you get a call

and they just say we would like to see you, your mind works overtime then, what's wrong, have I got something else, have they found something else. So I always say no news is good news, so I don't worry about it." OC3, female

Patients had varying expectations about the content of feedback they would have liked to receive after the NHS Health Check. Some participants expressed their dissatisfaction about the general approach the practices involved in this study took to communicate test results. A number of patients would ideally have liked more of a breakdown of results.

"All they were concerned was if there was a problem whether I've got the diabetes or I've got the cholesterol or have I got any heart issues, but they were clear so they are happy in that sense. But what I wasn't sure is because there are limits for all these readings you know, which range you are in, things like that, which perhaps didn't come across as clear as you would expect. All I was told was there's no problem, if there's a problem they will contact me but there is no problem." CM11, male

This participant said that he had "passed" his NHS Health Check; he felt that the surgery seemed most interested in finding out whether he currently had diabetes, high cholesterol or any other cardiovascular issues. More feedback from his GP was important for him, he wanted the surgery to tell him more about how his specific test results compared to the 'normal' person in his age bracket. In his experience the general practice only gives feedback if you 'fail' a test, feedback after the NHS Health Check seemed no different to him:

"I think that the general practice attitude generally is if there's no problem they won't tell you anything" CM11, male.

This participant wanted his results to pinpoint health issues that could be a problem for him in the future. He felt that the ethos of NHS Health Checks as a programme focused on preventative health care was not apparent in practice.

One man who received his results after he telephoned the practice was equally disappointed about the lack of information he got from the practice receptionist, he implies that a health professional would have been the best person to

give him his results:

"I thought, I didn't know what the results were and I didn't know what the tests were for originally. All I got was 'yeah, fine, no problem'." OC1, male

In contrast, another patient at Carmel Medical Practice did remember the letter giving him a good explanation of results:

"I think the information that it did give me came with the context behind it as far as it needed to." CM7, male.

However, he acknowledged that this did not really happen when the nurse told him his blood pressure reading at the practice:

"The point to me is going to get me blood pressure done and telling me it's 130/85 or something. Well, I can think that doesn't sound too far away from what the numbers should be, what is it 120/80? But is it? Is it fine? Is it perfectly fine? Is it sort of fine? Or is it getting towards worrying? And you don't automatically get that I don't think." CM7, male

Another participant found that during his NHS Health Check appointment the information he had expected to learn was not automatically given to him and he did not find that the information he got was very clear:

"It was a bit airy fairy and I seemed to be asking the questions because I do, I want to know. But someone else will probably just go, oh okay, and that's it and might not address problems that you know." OC1, male

Each of these three participants shared the view that results should be paired with a suitable explanation about their meaning. The participants felt that lack of information during and after the NHS Health Check had caused them unnecessary confusion and uncertainty. Participants wanted to be able to pinpoint the health benefits of making changes to various areas of their lifestyle. They had been told the general advice but many NHS Health Check participants had wanted to find out if making changes was necessary for them on an individual basis. These expectations were not fulfilled and this left some participants disappointed and still questioning of the health advice for them as individuals. Participants wanted to be treated as

individuals, but they did not think this happened.

Participants had very different, even idiosyncratic, ideas about content of feedback and I found that individual opinions were fleeting and subject to circumstance. CM11 provides a good example of some of the contradictions that arose in patient viewpoints during the in-depth interviews. He was critical of the Body Mass Index which makes comment about the body based around 'normal weight', but said of the tests that did not feature such contextualised information that he felt context would have been useful:

"Yeah, if I go down to 80kg according to the chart it looks perfect but if I go down to 80kg I know I was ill I was down to 80kg I was feeble and not fit so I ask how truthful all these things are sometimes, I mean 85kg I was trying to 85kg but if I get down to 85kg will I be healthy? So perhaps 90kg is the right weight for me, I don't know. Sometimes all being well we'll all look up to the research and nice diagram drawn but in reality, in practical wise, I think I'm classified as overweight but has it been fair, I don't know." CM11, male

But what I wasn't sure is because there are limits for all these readings you know which range you are in things like that which perhaps didn't come across as clear as you would expect." CM11, male

Although patients expressed an interest in their health assessment comparing them to the 'normal', the criticisms which surround the Body Mass Index tests show us how contentious this approach can be (Evans and Colls 2009). The interviews highlight the challenging nature of providing results after an NHS Health Check which satisfy a range of different people with changing circumstances and viewpoints.

This study gained a sense of the narrow tightrope that medical professionals walk on when trying to explain results to patients. Medical professionals are mindful of the body of literature warning of the misunderstandings and psychological consequences of using risk terminology. It was their responsibility to balance this evidence with their work to assess cardiovascular risk and promote health under the NHS Health Check programme. As part of the NHS Health Check, medical professionals place great reliance on the process of communicating results, which

can have unintended behavioural and psychological impacts. Routinely providing results by letter did not give patients any opportunity to ask what they could do given their individual circumstances, nor to clarify their doctor's thoughts about their results. A conversational approach to this process would give patients and health professionals shared input and influence into need-driven, effective health care. A conversational format could be achieved by offering more follow-up consultations, which could be budgeted into the costs of the NHS Health Checks.

CHAPTER SIX: TRUST AND DOUBT: BELIEFS ABOUT MEASURES OF HEALTH AND BELIEFS IN OUR POWER TO PREVENT DISEASE

6.1 Measuring 'Normal' Weight: Trust in BMI

Participants could be critical of the tests used to measure their bodies and assess health. The Body Mass Index score and the cholesterol readings challenged participants' current perception of their health more than other part of the NHS Health Check. Many participants contested the category the Body Mass Index imposed on their bodies and in doing so questioned the definition of their health produced at the NHS Health Check.

Results of their Body Mass Index test were treated by some participants as a helpful indicator or reminder that they should be actively trying to lose some weight. Participant CM13, thought that keeping fit now would help her health for the future; she trusted the Body Mass Index test:

“Well I think in the long term, I’m thinking okay I’m growing older and I know I don’t have the perfect weight, I am overweight so I feel I should do a bit more to stay current weight and do things for myself and my wellbeing...Like I said I know I need to work out more. Definitely I’d like to reduce a bit more weight.” CM13, female

Others felt that the Body Mass Index as a representation of their health now or in the future was less relevant to their lives than some of their other motivators or attitudes. One participant explained how unhappiness about her body shape encouraged her to lose weight. She wanted to lose weight because she remembered when she was younger, thinner, and felt confident in a bikini and she wanted to experience that again instead of feeling 'fat':

“Because I’m too fat...I want to be able to wear a bikini next year.” CM10, female

Another participant felt happier and less concerned about being told that she was overweight because her husband could reassure her that he accepted her size:

“Well, my husband tells me that I’m not bad for my size” CM5, female

Participants both implied their disaffection with the way the Body Mass Index test judged their bodies and overtly questioned its truthfulness. A participant of South Asian origin openly questioned the reliability of the Body Mass Index test, judging it against his personal experiences of his weight history and the relationship between fitness and weight loss as well as his aesthetic judgements on body shape. Not only was he happy with his body shape, which was in the ‘overweight’ category, but he was doubtful of the medical advice about the healthy weight. He did not think his body wanted to shed any weight whatever exercise he might take-up. He could also see the health benefits of staying his current weight in light of his experience of feeling weak and fatigued when he was for a short time in the ‘normal’ range. He was doubtful that the general understanding of a normal, healthy weight could be applied to his individual case:

Interviewee: “I need to be 85 kgs to get into the right, into the BMI ratio is it 24.9 or something. So because I’m 90 kgs I’ve just gone over my limit so I’m conscious even this exercise of three weeks I was doing, I come back to weigh myself to see if I’ve come to 85 or not, but I’m not, I’m more or less staying at 90 despite doing regular exercise. So I don’t know whether that’s the right weight for me or not”...

Interviewer: “You’re happy looking in the mirror as it were?”

Interviewee: “Yes, all I want to make sure I don’t have any excess chubbiness and whatever cholesterol issues and exercise but overall my body shape I’m happy with. I don’t really want to go thinner because I can’t particularly go thinner. I don’t think so because it’s down to the bones, isn’t it.” CM11, male

This participant saw exercise as a way to get fit and keep healthy and wanted his cholesterol to be low. He felt that Body Mass Index measured weight rather than fitness or cholesterol so he questioned the relevance of its use as a measure of his health.

Those who found the Body Mass Index a fairer assessment could envision themselves losing weight in the future through exercise or diet. These responses raise

questions about the value of including the Body Mass Index test at the NHS Health Check. Some patients thought that Body Mass Index was a positive measure of their health, whilst many others thought that it failed to judge what matters most to them. Participants of this study wanted to lose weight or keep fit, not because their Body Mass Index score told them they needed to, but to achieve positive health and psychosocial outcomes. Participants were interested in their wellbeing, achieving health and happiness in old age, and maintaining their dignity and comfort in social situations.

6.2 Beliefs about Preventing High Cholesterol

Participant viewpoints about their cholesterol results show them questioning their trust in the programme's message about individual power to prevent cardiovascular disease through lifestyle modification. The cholesterol tests were one of the most talked about and contentious measures of health included in the NHS Health Check. Issues and discussion relating to cholesterol results were raised frequently without specific prompting during the interviews with participants. In a number of cases participants were surprised, anxious or confused by their cholesterol levels which were framed after the NHS Health Check as their main health issue.

Cholesterol levels were focused on by participants as something that they would hope to decrease but understandings of how this could be done were unclear. Cholesterol results as an outcome of the NHS Health Check were mentioned most consistently in feedback letters at both practices. It was a deliberate choice on the part of Carmel Medical Practice not to emphasise cardiovascular disease risk scores in feedback letters, instead they emphasised what action should be taken, such as to follow a low cholesterol diet:

“Overall your cardiovascular risk was quite low but I would recommend you follow a low cholesterol diet, please see the advisory sheet for guidance, and I would be grateful if you could make an appointment with the healthcare assistant for a blood pressure check in three to four weeks time.” CM5, female

- feedback letter

For some participants being told they had high cholesterol or that they should monitor their cholesterol surprised them. Participants tried to align the result with their behaviour. They read and considered the advice the letter gave them about how to follow a low cholesterol diet, but a number of participants felt they had been following a low cholesterol diet and could not think of what they could do to change or improve their eating habits. The surprise of being told they had high cholesterol caused them to feel a decreased sense of their own power and confidence to control their cholesterol levels:

“Yes it was a bit of a shock because I thought you know I live a reasonably healthy lifestyle. I do quite a lot of exercise so the fact that I have got high cholesterol was a surprise... I can cut down, I can improve my diet slightly but there's nothing else I can really do about it. So you just have to live with it and get on with things.” CM9, male

Many participants felt confused by the issue of their cholesterol, the practice had not given them the information they felt they needed to know: i.e. what they should be eating to lower their cholesterol in the context of their current dietary habits. Many participants who came away from the NHS Health Check being told to follow a low cholesterol diet felt confused about what they were currently doing wrong, they felt their diet was low in cholesterol so they were surprised that their cholesterol levels were of concern to their practice GP. Many concluded that a low cholesterol diet could not in itself prevent high cholesterol. In this case the medical advice about diet could not be easily aligned with participants' experiences of cholesterol. Participants reasoned from this position that the practical suggestions for dietary modifications could not be applied to their individual case, which also challenges trust in the overall NHS Health Check programme's message of individual control over disease prevention.

Interviewer: “So in your letter when you get to the advice section you're finding it's what you're already doing. You're already following a low cholesterol diet although it's come up as being something you should work on.”

Interviewee: *"I can't see, I'm not saying what else can I do, because as far as I'm concerned I've been doing, still doing, all the right things... When I came back and I said I've got high cholesterol to my daughter and said I have to do this, I have to do that, she said you're doing all the right things now, you can't do anymore, can you [laughs]. So I'm happy with what I'm doing and how I'm doing it and if it's anymore what can I do."* CM5, female

This participant felt uneasy about the results of her NHS Health Check, which said she had high cholesterol, she continued to believe that she was doing all the right things for her health. The general advice provided about self-help and behaviour change did not effectively support those participants who had reason to doubt that their cholesterol levels could be decreased through individual actions. These patients may have benefited from more individualised advice and support or an approach focused on facilitating practical actions rather than providing empirical test results, which they could do nothing about.

When participants raised this issue of perceiving to lead a healthy lifestyle, yet being diagnosed with high cholesterol they were asked how this could be explained. Explanations put forward included:

- i. inherited factors, whether or not the person knew of other family members who had been diagnosed with high cholesterol or cardiovascular diseases:
"Yes, because when she said I was on the borderline for high cholesterol I said that I don't know why because I don't eat a lot of fried stuff. I said and I don't drink a lot and she said, well you must have inherited it then. So I'll never know." OC3, female;
- ii. a poor childhood diet, such as eating *"scraps and chips nearly every night!"* (CM4, female);
- iii. age: a natural and expected build-up over their lifetime, even when lifelong healthy habits were described:

Interviewer: *"Do you find it confusing that these things came up as high despite feeling like you lead a healthy lifestyle?"*

Interviewee: *“No not really, it’s build up over the years. It’s still got to build up hasn’t it? You’re still going to have certain fats, saturated fats, through your body.”* CM8, male

Interviewer: *“Do you have any explanations as to why some people have high cholesterol when they seem to be eating a healthy diet?”*

Interviewee: *“No I haven’t. I always naturally assumed when you get older you will get things that you’ve never heard of and you have to expect.”* CM5, female.

Causal explanations about high cholesterol were anecdotal; whilst some participants questioned the accuracy of their knowledge and drew attention to their uncertainty others were happy to trust in their explanation. Whether you believe that high cholesterol is inherited, or a consequence of aging or a poor childhood diet, they all fostered the same belief that high cholesterol is inevitable. This belief was shared with some of those who did not ‘yet’ have a cholesterol issue:

“...my sister has got cholesterol so there are cholesterol issues because the Asian food if you like, always oily food. Which I’m concerned about and thank God when I did the test it was okay, but again I am worried about me getting the cholesterol issue but as I said doing the exercise, trying to do the balance of the food, which might delay the cholesterol issue.” CM11, male

The three scenarios described below show the various ways that participant beliefs about the causes of cholesterol and their perception of their diet affected the decisions they made in response to their cholesterol result. Two participants who could see and believe in the relationship between their high cholesterol and their food choices felt that now they knew more about their elevated cholesterol they could make better informed dietary choices, whether or not medication had been prescribed:

“I was only moderately above the level and there was no need for concern because my balance of good cholesterol and bad cholesterol was good. But they recommended I had it [a cholesterol test] done in a year’s time, just to monitor it really, just to see that it hasn’t gone up. So that was helpful because

I have started thinking, do I need to, I mean I don't eat chips or anything, but I do eat cakes occasionally and biscuits and I think do I really need that, so it has had an influence on me." CM2, male

"No, I think you've still got to worry about your diet, the statin is only there as a medical help, but I still think and I still do carry on with the diet as well. I mean I cut all the meat and I cut all the fat off any meat. If I barbeque, I barbeque with the fat but I cut it off before I eat it. Doing bacon for the bacon sandwiches I'll do it in the pan with the fat on but when I put it in the sandwich I'll cut it all off. So all that's stuck up here [head]." OC4, male

Those participants whose GP surgery had suggested that the cause of their cholesterol was not their fault took-up an intervention of medicines, however, these participants continued mostly to live the way they always had as they often felt that their only recourse was to take medication for their high cholesterol:

"Then yes I take them [statins] and it gives me a bit more confidence the fact that I'm fetching the cholesterol down." OC3, female

One health conscious participant took a different stance. He had a strong belief in the link between disease prevention and healthy living. He had always thought of himself as a fit and healthy person, and this identity did not fit with the description that he was at elevated risk of cardiovascular disease. He did not trust his doctor's assessment of his risk and he could not understand why he would need to take statins in light of his healthy diet and regular pattern of exercise. His lifestyle was much healthier compared to other people who he knew who had taken statins and he expected his longevity would be similar to his father's longevity:

*"When I saw doctor *** he said I'm within the borderline and I tend to dispute that at times because I don't do what a lot of the people that are doing that do have these heart attacks and strokes their lifestyle is totally different to mine and I'm thinking well I know my age bracket, I'm going on seventy-four. But my age bracket and I'm thinking well my father was ninety and I'm living my life just exactly how he did." OC2, male*

To some extent this participant's questioning of his results related to his trust in his

power to prevent disease, and his views about heredity and drug use. A cardiovascular disease risk management programme focused on prescriptions would need to be accountable to those patients do not want to use drugs and feel they should be able to manage their risks through their behaviours (Wald, Simmonds et al. 2011). However, Wald et al.'s (2011) approach could offer some of those patients who were uncomfortable with aspects of the NHS Health Check an alternative.

This participant felt that his NHS Health Check results labelled him an 'unhealthy' person and as he understood it, his results implied that he was to blame for his elevated risk:

"...wonder if I am a bit unhealthy" OC2, male

He was forced to begin to doubt his definitions of 'healthy' behaviour. The NHS Health Check left him with many unanswered questions about why those people who led a healthy lifestyle would need medical intervention. Despite the doubts this participant was having about his health, and his doctor's categorisation of him as borderline risk and as a candidate for statin medication, perhaps unpredictably, and contradictorily, this participant also said that the NHS Health Check had left him reassured about his health:

"Oh reassured because I know that if there's something that can be a danger to my health I think the doctors would let me know." OC2, male

This case demonstrates the idiosyncratic nature of responses to NHS Health Checks.

Causal explanations of cholesterol and cardiovascular risk play an important role in patients' decision responses to their results. I identified both positive and negative psychological and behavioural consequences of beliefs in the two key causal explanations: elevated risk can be reduced by the individual or elevated risk is inevitable, the individual does make the healthy choices so cannot do any more apart from take medication to reduce risk.

6.3 Lifestyle Choices and Disease Prevention

The majority of participants did not present the NHS Health Check as an event that changed their health beliefs or attitudes. Even those participants who had been offered a prescription or needed a follow-up appointment and who had previously thought they were in general good health still felt the same way. Many participants in this study thought of themselves as already health conscious before they had an NHS Health Check and continued in a similar vein afterwards:

Interviewer: *"Would you like to mention anything else?"*

Interviewee: *"I don't think so just lead a happy healthy life, that's all, live your life everyday as it comes and that's all I can say, like I do. To hell with it. Exercise, keep healthy and eat well."*

Interviewer: *"The health check didn't provide you with so much knowledge or advice; it was more you were treated with statins but you will continue to behave..."*

Interviewee: *"Just as I normally did, yes, yes."* OC3, female

OC3 was not the only participant who was prescribed medication after the NHS Health Check despite describing herself as a health conscious person. It is worth noting that the following participant, CM8, also had been prescribed medication. The NHS Health Check better informed some participants about particular health guidelines, such as to regularly eat oily fish, but for the majority of participants it did not change their pre-existing orientation towards leading a healthy lifestyle:

Interviewer: *"Did you learn anything about diet or exercise?"*

Interviewee: *"Yeah, but I did most of it actually anyway...I've changed onto fishes and things like that, now I'm doing that. But I've always had a good diet actually because I've had to, my wife's a diabetic so we've had to have a stable diet."* CM8, male

Living healthily was a common lifestyle choice among participants of this study. For those that were already concerned about their health, many felt they had been influenced by their social groups, such as their family or friends, lifelong

habits, or by the belief that health behaviours would lead to a longer and more fulfilled life which they aspired to. Rewards both measurable, such as weight loss or fitness, and rewards more intangible, such as the way you feel after exercising, or achieving cultural ideals for body shape and fitness levels, all served to motivate healthy behaviours. These attitudes and practices functioned to regulate risk of coronary heart disease, stroke, type 2 diabetes, and chronic kidney disease.

After their NHS Health Check the majority of participants still gave little consideration to how their lifestyle choices explicitly impact on their risk of cardiovascular disease. Participants particularly described immediate and medium term rewards which motivated them to behave healthily. Others, like CM8, told me he did not really think about living healthily, he just did it out of routine. Although, above, he describes sharing the eating practices of his wife who has diabetes, CM8 mainly felt that as a child his grandmother and the social conditions in which he grew up had been the strongest influence on his eating habits throughout his life:

“I’ve just done it all my life, it’s as simple as that, I’m just used to doing it. I’ve always had to work hard and I’ve just done, I’ve never really changed my lifestyle at all. For years and years. I mean I’ve always been one for a lot of exercise, I walk everywhere. We’ve always had dinners with veg, a pretty healthy diet...I think it’s been done through family all the way. It came from my grandmother. That’s what it came from.” CM8, male

One could question the way that the NHS Health Check programme combines health promotion with cardiovascular risk assessments so to imply that levels of risk should affect healthy behaviour. A previous study had raised questions about how the use of low risk categorisations can have a negative impact on the promotion of healthy behaviour but participants did not suggest this had happened as a result of the NHS Health Check (Adriaanse, Snoek et al. 2002). Participants of this study who felt that the surgery did not have cause for concern about their health told us that they would still make the healthy choices, as they had done in the past, rather than feeling they could be unhealthy:

“All the checks seem to be fine and nothing to worry about, obviously I need

to keep an eye on what I do rather than being complacent.” CM11, male

“No, no I’m still exercising, still eating fruit and veg and all the rest of it and conscious of the units that I’m drinking but that hasn’t improved entirely to the kind of level that the government say you should be drinking.” CM3, female

“After this test I felt very good. I know I’m still at risk. You still worry about it but you try to do your best.” CM12, male

After the NHS Health Check ‘low risk’ participants continued to believe that lifestyle habits, including diet, exercise, smoking, and drinking, will impact on individual health both in the present and in the future. This was a similar finding to that of a recent study into the ADDITION trial which found “very limited evidence of false reassurance among people who received a negative test result after attending screening for diabetes.” (Paddison, Eborall et al. 2009: 4).

Low-risk participants felt they benefited psychologically from the NHS Health Check. Many had gained “*peace of mind*” (CM12, male) and reassurance about their health and felt more confident about their lifestyle judgements:

“The main thing was that my cholesterol was fine. And I think I was doing the right things.” CM1, female

“...it was reassuring to know that everything else inside was doing what it should do if you were behaving yourself quite well.” CM3, female

“I’m quite happy with what I’m doing and hope I can carry on doing it for quite a long time.” CM4, female

“Yes, so I actually think it’s a really good thing because it did reassure me and I thought well I’m okay, it was good.” CM10, female

Without having knowledge of the resource costs of NHS Health Checks, those who previously felt healthy or were assessed as low risk felt that they had benefited from the check.

In many cases feelings about whether the patient had to worry about their results and whether they were being told to change their lifestyle appeared to be key

factors in patient decision-making about whether they should be more health conscious, rather just because lifestyle advice was given during the NHS Health Check. This attitude was raised by both patients whose results had required follow-up intervention and also by those where follow-up intervention was not required. One participant told me how he felt the advice the nurse gave him to cut down on his alcohol consumption was based around his inaccurate answering of the behavioural question, so her advice might not be completely necessary. In common with other participants, his drinking behaviour did not follow a particular routine so the question 'how much alcohol do you consume per week?', was difficult to answer on a glasses or pints per week basis:

"I think I maybe gave my summer alcohol levels rather than winter, because I tend to drink more in the summer, when the weather is nice." CM2, male

He could not trust his self-reported behavioural evidence as a reliable indicator of the damage he was doing to his body by drinking. He felt that evidence from an empirical test on his body, such as a liver functioning test, would have been more accurate:

"When I speak to my friends, well some are tee-total but not many they say we drink so and so and it's very comparable to what I drink and you just felt, well maybe they're drinking too much. A little bit more explanation would have been helpful, she did say maybe you should cut down a little bit, but she didn't say what she recommended. But I didn't go away worrying, I've not changed my habits at all. One thing that did cross my mind afterwards, you know there's a test for liver function, I thought well maybe she should have said we'll do a test for liver function. She might have said that there and then or she might have taken a look at me and said well I don't look as though I need it. I didn't get any feedback on that, so the feedback would have been helpful." CM2, male.

Although this participant had been told to cut back on his alcohol consumption he was not given the information about what this was doing to his body, he was not given results from his liver function test, nor was he told he had been given this particular test. More feedback on this issue would have helped him decide whether

or not he needed to change his habits. He felt that it was vital to know the reasons for changing behaviour. It was not enough to say with little explanation that he needed to cut down, especially as this advice conflicted with an understanding he held that his drinking habits were normal, in light of their similarity to his friend's habits. This response was echoed by another participant:

"...do I drink too much? Yes. I knew that. I suppose getting told that, is that likely to influence behaviour, and the bottom line is no, not unless they were going to tell me categorically that it was going to make a real difference at some point. Just sort of telling me the abstract, yeah you drink too much and that could put pressure on whatever, maybe it would be a good idea to cut it down a bit. Have you thought about cutting it down? To which my reply was no I already have and that was as far as it's going to get...You take your own view of risk on things like that." CM7, male.

During the delivery of the NHS Health Check facilitating behavioural change is an exercise of persuasion, patients do not automatically trust the advice they have been told. Patients tend to question the merit of the tests or evidence used to inform medical judgements about their bodies. Understandings of the reliability of the tests used during the NHS Health Check strongly affected trust in advisory recommendations.

Trust for a named 'family' doctor was a significant reason to follow the given lifestyle recommendations:

*"Yeah I think it's because it's doctor *** and I've got on so well with him and I trust him, I really trust him, I do... You don't feel like you're just a patient, that you are somebody that he cares for, he's there to care for you, he's there and he's doing his best to care for you."* OC4, male

Persuading patients to believe in the positive relationship between a particular behaviour and future poor health served to promote lifestyle change. An example of one participant who was persuaded to make dramatic changes to his lifestyle was OC4. He was shown two diagrams representing his risk, one when he was first diagnosed at high risk and the other after three months abstinence from alcohol. The

two diagrams showed 100 faces, happy or sad, the fewer happy faces the higher the risk. The diagram three months later showed more happy faces indicating to him his risk was greatly reduced, which served to establish a link between his alcohol consumption and his risk.

“And then they could show you in that sort of diagram the way that you’re going with your health, it makes you sit up and notice, I think yeah.” OC4, male

The use of diagrams had made the abstract and unseen nature of risk both visible and real and had helped him feel positive about his ability to get rid of more sad faces in the future. For all other participants the link between behaviour and risk had not been so clearly presented or so starkly lived. In creating such a visual and relatively immediate causal link between alcohol consumption and risk ‘of major illness’ the doctor had really inspired his patient to make lifestyle modifications. The patient perceived his risk as something that he could change, by altering his behaviour:

“So that was [more sad faces] and that’s the one after [less sad faces] so I did well but still at risk. He was saying about the percentage should be this, but I’m still on the second line. Dum dimmy can sit and see the difference about how you’re improved. You’ve taken away the alcohol, you’ve listened to what he [the doctor] said. It’s reduced it by that amount but you’re still at risk.” OC4, male

After this feedback this participant went forward making changes to his diet as well as drinking in moderation. He felt that these behaviours would help him to live a longer, healthier, more enjoyable life:

“I like to go on holiday and drive on holiday sort of thing with a caravan and I thought well if they turn round to me and take the license off me then all that’s gone. If they say well you’re not medically fit to drive then I didn’t want that to happen and it’s the scare also that it’s going to shorten my lifespan. The fact that somebody says to you, ‘you are in the high risk bracket of having a heart attack’.” OC4, male

The time the doctor spent with participant OC4 seemed to tap into his psyche.

One of the health advice leaflets handed out to NHS Health Check participants at Carmel Medical Practice in Darlington, entitled 'Five Choices', presents the message that a healthy lifestyle is the choice of the individual. There are five choices to be made, each have an instructional tone: "you should not smoke", "do some regular physical activity", "eat a healthy diet", "try to lose weight if you are overweight or obese", and "don't drink too much alcohol" (EMIS and PiP 2006). This message of individual choice and decision-making was created and provided for the use of general practices nationwide by the web-based company 'patient.co.uk'. Many participants of this study did not think they could make all five of these 'choices'. Instead they focused on performing some of these instructions but not others, or moving towards these 'ideals'. Participants spoke of how the process of self-monitoring health often involved adopting strategies to make the advice fit with their preferences and lifestyle.

"I think it's all doing things within reason. So I certainly wouldn't eat fatty foods every single meal of every day and when I go to the canteen at lunchtime if there's a healthy meal that I like I will choose the healthy option rather than the fatty option. But if I'm out for a meal and I'm tempted by something on the menu then I'll have it." CM9, male

One female South Asian participant had developed her own Asian cooking style, which was a less oily and spicy variety:

"Yes, even some of my Asian friends, they get surprised when they see me cooking because I use so less oil and I think I've just adapted techniques to minimise oil consumption and even spices, of course we use spices but not to that extend. It is Asian cooking but of a very low spicy, oily variety, a more healthy variety." CM13, female

In another South Asian family the parents ate Asian type foods because they liked to, even though they were very familiar with cooking Western dishes for their children. The father in this case wanted to be healthier. His parents' concerns about his health and his worries about being unable to work and support his family had

inspired him to act, but he could not imagine changing his traditional Indian diet so had concentrated mostly on doing more exercise:

“So I took up gym membership, you know, started to go to the gym 5 days a week kind of thing, but I’m conscious about my food habit but I’m not really strictly following a diet as such, I eat anything that comes along...Well obviously if I don’t take care, that is again advice from my parents that prevention is better than cure so, if I don’t do this exercise and don’t balance my diet I’ll end up sick which means at the moment I can still maintain a job but if I end up sick I won’t be able to do my job, I’ll be hospitalised and also I’m going to cause unnecessary stress on the National Health Service being a patient rather than being a healthy person.” CM11, male

Another male participant also wanted to make changes to improve his health. For him smoking was a necessity in stressful times, particularly when his ability to provide for his family was being threatened, so he did not feel he could change that, neither could he fit more exercise into his routine, he worked unsociable hours seven days a week. He also told me how he had inherited a preference for the sweeter, richer foods from the Middle Eastern culture so he could not drink tea without sugar nor could he eat margarine, it had to be butter. Instead, his strategy involved keeping the foods and cigarettes he felt he could not go without but reducing the quantities. For example he chose to drink his tea in smaller cups so less sugar was needed per cup and he ate a small amount of butter with his bread rather than switching to margarine and he also rolled his own very small cigarettes:

“Yes, sometimes just a couple of drags in it and it’s finished. Sometimes when I roll them they don’t stick together, I deliberately make them small. Cos when you smoke you need the first two drags, that’s what you need, the rest you don’t need it. I know that, I know everything but it’s difficult to control.” CM12, male

The above quotations illustrate how patients appropriate the NHS Health Check to suit their own behavioural and belief preferences. Participants believed they could improve their health without following all the recommendations given by the health authorities. They discussed ways they had personalised the advice to suit

their work routines, family setting, leisure activities, and dietary and exercise preferences.

6.4 Ageing and Disease Prevention

The NHS Health Check programme tells us that leading a healthy lifestyle would improve our wellbeing and help us stay healthy and live longer. I consider whether participants of the programme had trust in this assertion, given that death, decline or disease was seen as an inevitable element of ageing. I explore how fatalist views about ageing impacted on trust in being able to prevent disease.

There was acceptance of decline; one participant told me how it was impractical to aim to be as fit and healthy as her younger self, so she compares her health and fitness levels with her peers to check how healthy she is:

“I mean I’ve reached 65 now. I mean it’s inevitable that you’re going to deteriorate a little, you just can’t help it, can you. I mean I can’t do as much now as I could 20 years ago but in the big scheme of things I’m a lot fitter, I know that, than some of my friends of the same age. So I feel happy in that respect, but you’ve just got to accept these things, there’s no way round it really. I mean, I’ll go on as far as I can but it will get me in the end.” CM4, female

Other participants agreed that with time would come an inevitable decline but still spoke of what they could do to keep fit and live longer.

“You have to when you reach my age, it’s like a car when you do too much mileage it needs more attention, more attention. You have to use it less so it lasts you longer. I know everything, but the thing is putting it into practice.” CM12, male

“I think like all people approaching late middle age, 50, 60, you’ve got to keep more of a watch on what you eat and how you exercise. And your lifestyle choices, whereas at 30 you can get away with things moderately so, at 40 it

becomes more difficult and at 50 it becomes more difficult to sustain a healthy lifestyle, so I personally feel I've got to be more focused in terms of watching what I eat, making sure I do keep up regular exercise...I'm used to having good quality of life and a good standard of health and I think if you've got that it gives you a good incentive to try and keep it but I would imagine if you start on that slippery slope where you start putting on weight and you start feeling less energy it becomes extremely difficult to correct that." CM2, male

Participants stated that now their bodies were older their unhealthy lifestyle choices would affect them more than ever before. They believed that being more careful with their bodies, by keeping fit and healthy or cutting down on their bad habits such as smoking or drinking, would help them to continue to have a good quality of life as they got older.

A participant of South Asian ethnicity felt that as he got older it was likely that he would get diabetes because of his family history and ethnicity. His reason for exercising was not to be more certain of a good quality of life in old age but to help delay the onset of disease:

"Not really, my dad has got type 2 diabetes so I am actually, although I haven't got it yet, but I think I might be going to get it someday. It's not if, it's going to be when, kinda thing, I think. So by doing exercise and having my diet balanced I might delay that, that's what I was thinking." CM11, male

The NHS Health Check was not generally perceived to have made participants future likelihood of suffering from cardiovascular diseases more predictable. Most participants of this study did not talk about the NHS Health Check in terms of helping to prevent or reduce their risk of 'cardiovascular disease', 'stroke' 'heart attack', 'diabetes', or 'chronic kidney disease' without prompting. Participants most frequently talked about the NHS Health Check in terms of what they felt their results told them about their general health. For many the NHS Health Check programme was reassuring but even those who had found out they needed medication didn't think their future was much more certain or predictable. Fatalistic language was still used in relation to future health:

“Then yes, I take them and it gives me a bit more confidence, the fact that I’m fetching the cholesterol down, hopefully, well I haven’t heard anything from the doctors, and I’ll live as long as life allows me to live.” OC3, female.

This participant pointed out that if she had not attended the NHS Health Check she would not have known to worry about her cholesterol, she was pleased she had found out but she felt that her ignorance had not caused her emotional harm. She knew that she would have to die one way or another and was reminded every day when she thought of her son, who had died tragically, that coping with risk was part of living.

Participants felt that they could improve their future quality of life immediately through practices of self-regulation and/or medicine consumption; however, participants acknowledged that they would have less incentive to continue to self-regulate behaviour if the benefits of doing this were to be less important to them. CM4 spoke of how she would continue to believe that the health benefits of self-regulating her food choices would outweigh the appeal of sweet foods until she was about 80 or if her husband died, after that she would just eat what she liked. This participant thought that eighty was a good age to live until so she felt that past eighty she would put pleasure before health:

“As I said once I hit 80, hopefully I will, I think I might be one of these that have a bar of chocolate every day, just do it. [Laughs]. As I say it’s inevitable, but I’m lucky while I’ve got my husband and we’re together. I suppose one of us will go first and if it happens to be my husband I probably won’t care anymore. But that’s nothing really to do with my health, that’s my mental state. I think at 80, I’ve never really thought about it before, but I think if I hit 80 I’ll be happy, not that I think about it much to be honest. But if I had to say that yes.” CM4, female

Fatalistic views about the inevitability of decline, disease, or death were, generally, not perceived to limit participants’ current ability and choice to lead a healthy lifestyle. The relatively affluent participants of this study believed that they could live long, healthy lives and so were incentivised to keep fit and healthy. There

is a relationship here between aspirations about longevity and health choices. A future study could determine whether this relationship has a negative impact on the aims of the NHS Health Check programme in communities with very poor life expectancies, where people might have lower aspirations for their old age.

CHAPTER SEVEN: PATIENT-CENTRED PROVISION OF NHS HEALTH CHECKS: CONCLUSIONS AND IMPLICATIONS

7.1 Patients' Experiences of and Responses to NHS Health Checks

This research revealed the mindful bodies each with their personal stories who participate in NHS Health Checks. Attending the surgery for an NHS Health Check was described in just as a relational, emotional, and thoughtful way as any other part of each of my participant's lives. This research presents patients as active in shaping their encounter with the NHS Health Check. Participants were not passive recipients of the check; their experience of the check was shaped by individual opinion, viewpoints and personality, human interaction, perception of body and health, and their interpretations of the feedback about their bodies, and the health ideas and health ideals that the NHS Health Check had presented to them.

Participants' judgements relied on their biological abilities and were culturally situated: their accounts drew on sensory and intuitive knowledge of their bodies and their relationships with other beings and objects. Participants saw the NHS Health Check within the context of their socio-cultural knowledge of the world around them; responses to the check can be seen in the context of cultural expectations for quality of life and 'old age', the social life of diet, body shape, and taste, the place of the state and the family in social support, and a 'risk society' where all aspects of life are uncertain and the public feel unable to blindly trust in health authorities, political decision-making, and health care practitioners.

The NHS Health Check had limited and bounded influence on individual opinions about health risks, health aspirations and health behaviours. Participants of this study commonly drew on the health categories applied to them during their participation in the NHS Health Check programme to thoughtfully reconsider their perception of their health and their lifestyle choices. They tended to situate the medical evidence that emerged about their health within the context of their lives. The NHS Health Check did not operate in a vacuum. Some participants said that they had lost weight, adjusted their diet, joined the gym, or joined a diet group since

their NHS Health Check. In certain cases the NHS Health Check could be described as the catalyst for these behaviours, but family and social pressures were also described as having an influence:

“It’s all embedded over a period of time but the Health Check was kind of a turning point if you like.” CM11, male

Resistance to the categories used to describe health was not a philosophical state; it was not often formulated by patients asking political or critical questions about the nature of medical knowledge or the power of authorities. Resistance to these health categories resulted from the difficulties participants' faced when looking to align their habits and their perception of individual health with the information and advice provided to them at their NHS Health Check. Some participants of the NHS Health Check questioned or disputed the medical approach to understanding their bodies. Participants often thought of their bodies as more individual than the general health guidelines could recognise. They had more faith in knowledge about their individual health that had basis in their wider life experiences.

The following three examples show how participants contended the results they received when they did not conform to their health expectations, and previous and current experience of living as an able and healthy person.

*“When I saw doctor *** he said I’m within the borderline and I tend to dispute that at times because I don’t do what a lot of the people that are doing that do have these heart attacks and strokes, their lifestyle is totally different to mine and I’m thinking well I know my age bracket, I’m going on 74. But my age bracket and I’m thinking well my father was ninety and I’m living my life just exactly how he did.”* OC2, male

“I can’t see, I’m not saying what else can I do, because as far as I’m concerned I’ve been doing, still doing, all the right things... When I came back and I said I’ve got high cholesterol to my daughter and said I have to do this, I have to do that, she said you’re doing all the right things now, you can’t do anymore, can you [laughs]. So I’m happy with what I’m doing and how I’m doing it and if it’s anymore what can I do.” CM5, female

“Yeah, if I go down to 80kg according to the chart it looks perfect but if I go down to 80kg I know I was ill I was down to 80kg I was feeble and not fit so I ask how truthful all these things are sometimes, I mean 85kg I was trying to 85kg but if I get down to 85kg will I be healthy? So perhaps 90kg is the right weight for me I don't know. Sometimes all being well we'll all look up to the research and nice diagram drawn but in reality, in practical wise, I think I'm classified as overweight but has it been fair I don't know.” CM11, male

The three examples above show how participants at times struggled to relate to the ways the NHS Health Check assessed their bodies. They talked about their belief that a medical assessment of their body was just one perspective and could be quite limited. People drew on wider knowledge, beliefs, and experiences when thinking about their health status.

Participants' experiences did not point towards an interpretation of NHS Health Check results based around medical power or lack of power in predicting future health but to an embodied perception of results, which drew widely on sensory and communal knowledge and experiences. Participants' responses to the readings of their bodies, made at the NHS Health Check, showed that patients did not live the health identities medical professionals created for them. Patients could contest the measures used to categorise and define their bodies and health identity. Participants of NHS Health Checks carried lived, changing, and personal perceptions of their health status. Their health identities were forged from their physical and social experiences of daily life, including but not exclusive to their experiences of the NHS Health Check. This study frames patients as having independence outside the health care system over their health identities. In an environment where the health care system has limited authority over patients' identities and lives, health care services have to engage with patients' health identities and be patient-centred to be useful.

7.2 Patient-Centred Provision of NHS Health Checks

I analysed patients' satisfaction with the NHS Health Check and their expectations about the models and types of care their GP surgery should provide. The research finds that patients were generally positive about their NHS Health Check and for some individuals the check fulfilled all their expectations. This analysis did, however, identify five aspects of the design and delivery of NHS Health Checks which did not meet patients' expectations:

1. The NHS Health Check did not meet patients' expectations for a general health check which would provide empathy and support for all of their health priorities and concerns.
2. Patients felt that eligibility to attend an NHS Health Check should be based on patients' opinions about when they need or want to have a health check and that access to NHS Health Checks should not be restricted, through age-based criteria.
3. During the NHS Health Check, health was measured in ways that caused some patients discomfort, stress, or anxiety.
4. Patients did not think that all the measures of health used to define their bodies were relevant to their lives. Patients did not necessarily agree with, support, or believe in these definitions of their health.
5. Reliance on general advice about self-help, specifically with the letter of results, did not effectively support all patients to improve their future health outcomes. Some patients found the general advice did not apply to their individual circumstances.

The current format of an NHS Health Check does not adapt well to patients' needs and preferences as individuals and the particular health measures and health outcomes which they think are most important. Improved patient-centred provision of NHS Health Checks may help to improve patient satisfaction.

I found patients' subjective experiences of and responses to NHS Health Checks were, to some extent, influenced by both definitive and idiosyncratic aspects of the structure of the policy and methods of implementation. For example, patient-care provider relationships seemed to be too idiosyncratic to guarantee they will

always be positive, specifically in terms of their personality dynamics. However, changes to the approach of the programme, specifically in terms of provisioning more patient-centred NHS Health Checks, may improve patients' experiences of these relationships.

In general, the NHS Health Check provides a one-size-fits-all health assessment. The face-to-face health advice is individualised, but often the follow-up advice in the post is too generalised and failed to tell patients exactly what they, as individuals, could do. The tests to measure health could be declined, but the check was designed to deliver the same tests for everyone, regardless of patients' feelings of comfort, distress, or disaffection. A patient-centred approach would argue that measures of health that some patients are uncomfortable with or that do not deliver all patients value should not be a universal component of the check.

Patients, however, do recognise that they can feel uncomfortable with tests that do have great potential to improve their health outcomes. A patient-centred approach is currently favoured in general practice, but doing what patients want and working in patients' best interests can at times prompt two different approaches. This study does not want to join debates over which approach is 'right'. It does assert that there is potential to give patients more choice over and input in their route through the NHS Health Check without compromising on health outcomes. In order to create a more engaging NHS Health Check it is important that those delivering the programme can support patients as individuals to manage the risks that concern them and to achieve the health outcomes they value.

This research found that as many patients get older they want to be able to continue with behaviour they think enhances their well-being and health. They are also concerned about their embodied risks of being unable to work or participate in activities they enjoy and becoming burdensome to their loved ones, due to deterioration of their health. The NHS Health Check programme has the scope to support patients with these hopes and risks. However, as it currently stands, some patients do not feel that the focus of the NHS Health Check programme on managing risk of cardiovascular disease and categorising the body fully engages with their need for support to enhance and maintain their quality of life and experiences of fulfilment.

7.3 Implications

This case study of experiences of and responses to the NHS Health Check programme contributes to broader areas of interest in socio-cultural research. This study adds to knowledge related to health identities, embodiment of risk, managing health information in daily lives, trust and doubt about medical readings of the body, beliefs about disease prevention and predicting future health and well-being. This research specifically addresses the need for research into patients' experiences of the NHS Health Check programme in one local area. This study provides two GP surgeries with the information about their patients' health concerns and priorities so they may provision a popular model of care, care that is patient-centred. The methodology used in this study also promotes the general use of socio-cultural qualitative approaches to highlight patients' priorities for health care services.

Health professionals working for NHS Darlington and more widely across England may benefit from the findings of the study. This thesis will be made available to staff and patients at the two general practices involved in the research and it will be made available online via Durham University's digital repository service. The NHS Health Check resource library may also be interested in publishing this thesis, the online library helps to facilitate the exchanging of ideas and results from the implementation and development of the NHS Health Check programme in different areas of the country (NHS Improvement Programme 2008).

This study provides information to help policy makers make the NHS Health Check programme more inclusive and patient-centred. It provides them with more awareness of how well patients feel their health needs, expectations, concerns, and priorities are met by NHS Health Checks. The opportunities to use these findings for the purposes of improving patient-centred care are, however, likely to be limited. A combined explanatory model shows that health service managers and health practitioners cannot control all influences on patient satisfaction (Atkinson and Medeiros 2009: 2090). Some factors determining patient satisfaction are "beyond the remit or control of the health system" (Atkinson and Medeiros 2009: 2090). The

limitations of health practitioners' scope should be identified before they are set unachievable targets and goals for patient-centred provision (Ibid.). Further work should prioritise identifying the factors likely to limit GP practitioners and health service managers impacting on the patient-centeredness of NHS Health Checks.

The implications of the research findings and conclusions for NHS Health Check policy and its practical workings are open to debate. The findings of this study may be utilised for political, economic or social purposes. The development of patient-centred health care provision is and will continue to be a story with a political, economic and social context and this thesis can be situated within this story. The opportunities for patients to challenge the interests and priorities of political and health authorities will always be available, and the ways in which these challenges manifest themselves will be diverse, from individual acts of resistance to social movements about health. In this light, I see patient-centred care as a projection of the debate about how health care service provision can represent the concerns and priorities of all interested parties. Patient-centred care is a powerful political concept in our democratic, developed society because it claims that the individuals who believe they fund the system and cast the votes are being valued and prioritised. Within this system, it is likely that in the future NHS Health Checks will become more patient-centred because general practices are expected to provide patient-centred care and this model of care is valued by patients.

Certain aspects of this study might directly inspire further, more in-depth research. For example, the question of whether or not the NHS Health Check in general practice reaches those most at risk of cardiovascular disease, chronic kidney disease, or type 2 diabetes was mostly outside the scope of this study. Participants of this research add a contribution to our understanding of the reasons why some groups might not have an NHS Health Check but this still leaves a lot to be explored. Participants both imply and explicitly suggest reasons for not attending an NHS Health Check such as: *"I think a hell of a lot of people won't go because they're terrified of what it might highlight."* (OC1, male). Similar to this study, reasons for non-attendance at the NHS Health Check could be explored with a patient-centred outlook. This would facilitate understanding of how the health concerns and priorities of 'hard to reach' groups are both similar and different to the contemporary

health priorities of government.

7.4 Reflexive Thoughts about my Analysis and Interpretation

I recognise that the thesis could have taken many different turns; I could have chosen a different set of my participants' opinions to include and exclude. However, this project asserts that, despite the fluidity of qualitative analysis, this approach can most effectively bring together patients' voices and highlight some of the more marginal experiences as well as the mainstream views. I have presented participant viewpoints, as far as I am aware, in the context which highlights their intended meaning. When choosing which example quotations to use I tried to present the range of opinions about each topic, as a result, less common views were at times given the same space on the page as the mainstream viewpoints. I have picked particular examples and have not referred to a wider agreement when one or only two examples of a particular response appeared in all of the interviews.

It is important to also remember the role of my participants in creating and defining the research pathway. I present, in my participants' own words, their perceptions of their lives and their health priorities, as well as, possibly, how some participants wanted to present their lives. Considering this, it is worth reflecting on the reasons why most of the participants of this study described themselves as being health conscious. Perhaps the type of person who agreed to participate in this study was more likely to be someone who already viewed health as a priority. There is also the possibility that participants felt social pressure to say they were health conscious and led healthy lifestyles, even if they did not.

Participants of this study were a self-selecting group. When asked their reasons for taking part in the research, the majority of participants pointed to their interest in health and health care. Some felt positive about contributing to a project which might improve NHS Health Checks and/or the service provided by their GP:

"I wanted to take part in the research because it can only better a surgery. If there are faults found then it can only be bettered for the surgery itself." OC4,

male

"You'd like to hope that eventually it might make some sort of difference."

CM7, male

Others had formed an opinion about NHS Health Checks and felt they could add something specific to the study:

"Erm, just, (pause) if it makes the system better and easier for patients and medical people that's fine because I have some, lets say not issues, but ideas / whatever what happened to me which I think could possibly, you know, help the process." OC1, male

A few participants joined the research to find out some more information about their health or health care services:

"Oh I don't know. Probably want to know more about healthcare and what the surgery's like" CM5, female

"Inquisitive, just to find out what it meant to take part in this, like. Because I felt if it's to my advantage and it's something to do about my health and maybe wonder if I am a bit unhealthy and I might know the reason why." OC2, male

Not all participants pointed exclusively to their interest in health or health care as a reason for participating in the study. Others said they agreed to take part because they were parents and could empathise with the issues students face gaining experience:

"Just that I think you've all got to learn somehow, you've all got to have the experience, so that was the reason why." CM4, female

"Just to help out. I think University students need, if nobody helps then they're not going to get anywhere. It's just because you're a University student and it was to help you gather information." CM10, female

When reading this work it is vital to remember that it was created by its author in collaboration with the participants who chose to come forward to become an agent in the research. My research diary (see appendix H) provides some information

about my impressions of the participants of this study. Most were home-owners and, although I did not ask, I think that nearly half of my participants were educated to degree level. Although the theory generated by the study applies particularly to this cohort, and more widely to the patients of two surgeries in Darlington, it is likely that their experiences of the NHS Health Check will be shared by others. This study is not definitive, its scope was not to speak for all of society, but those who did make a contribution are likely to partially represent the range of experiences of participating in an NHS Health Check.

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APPENDIX A: LETTER OF INVITATION FOR PATIENTS FROM CARMEL MEDICAL PRACTICE

**DR GJG METCALFE
DR A FUAT
DR BF PENNEY
DR E MOORE**



**CARMEL MEDICAL PRACTICE
NUNNERY LANE
DARLINGTON
CO DURHAM
DL3 8SQ**

**Telephone: 0844 477 8758
Facsimile: (01325) 381834**

Dear

Experiences of the NHS Health Check programme in Darlington – Making your views count

We would like to invite you to take part in a research study where you will have the opportunity to give your views about the NHS Health Check you recently attended, and your feelings about the results you received. Your views, whatever they may be, will provide us with invaluable feedback which may help us improve the service we offer our patients. The research will be conducted by a postgraduate student at Durham University.

I enclose an information sheet that explains more about the research. If you would like to be involved then please complete the reply slip and return it in the stamped addressed envelope provided. The researcher will then contact you to arrange a convenient time to meet. We look forward to receiving your reply.

Yours sincerely,

Dr Ahmet Fuat
(General Practitioner)

If you have problems reading this letter please call Carmel Medical Practice on 0844 477 8758.

REPLY SLIP - Experiences of an NHS Health Check programme

I am willing to take part in this research and agree to be contacted by the postgraduate researcher, Ms Elizabeth Strutt.

Date: _____ Name: _____

Address: _____ Contact Number: _____

Version A (1.1) 27/04/2010

**APPENDIX B: LETTER OF INVITATION FOR PATIENTS FROM
ORCHARD COURT SURGERY**

**Dr. R. S. CHARLTON
Dr. D. RUSSELL
Dr. R. STEVENS
Dr. S. STONE**

**Orchard Court, Orchard Road, Darlington
Co. Durham DL3 6HZ
Telephone (01325) 465285
Fax (01325) 284034**

Dear

Experiences of the NHS Health Check programme in Darlington – Making your views count

We would like to invite you to take part in a research study where you will have the opportunity to give your views about the NHS Health Check you recently attended, and your feelings about the results you received. Your views, whatever they may be, will provide us with invaluable feedback which may help us improve the service we offer our patients. The research will be conducted by a postgraduate student at Durham University.

We enclose an information sheet that explains more about the research. If you would like to be involved then please complete the reply slip and return it in the stamped addressed envelope provided. The researcher will then contact you to arrange a convenient time to meet. We look forward to receiving your reply.

Yours sincerely,

Dr David Russell
(General Practitioner)

If you have problems reading this letter please call Orchard Court Surgery on 01325 465285.

REPLY SLIP - Experiences of an NHS Health Check programme

I am willing to take part in this research and agree to be contacted by the postgraduate researcher, Ms Elizabeth Strutt.

Date: _____ Name: _____

Address: _____ Contact Number: _____

APPENDIX C: INFORMATION BOOKLET FOR PATIENTS FROM CARMEL MEDICAL PRACTICE

Designed in Microsoft Publisher, printed as a three panel leaflet

INFORMATION

SHEET

Revealing and experiencing an 'at risk' diagnosis: implementing the NHS Health Check programme in general practice

CONTACT DETAILS:

DR A FUAT,
CARMEL MEDICAL PRACTICE,
NUNNERY LANE, DARLINGTON,
CO. DURHAM. DL3 8SQ
Telephone: 0844 477 8758

Ms E STRUTT,

DEPT. OF GEOGRAPHY,
DURHAM UNIVERSITY,
SOUTH ROAD, DURHAM.
DH1 3LE.

Email: elizabeth.strutt@dur.ac.uk

Telephone: 0191 384 4567

Use these contact details if you have any queries before, during, or after your involvement in this study.



This information sheet is provided to help you make up your mind about whether or not to take part in this study. Version A (4.1) 20/05/10

Will my taking part be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. You will not be identified in any spoken or written material that results from this study.

The researcher, Ms E Strutt, is responsible for the safeguarding of the information collected from you. The audio recordings will only be accessed and listened to by Ms E Strutt, so that she can produce a typed copy (transcription) of your viewpoints. This copy of the interview will not contain any personal information that could identify you. The copy may be looked at by others involved in the study. The transcriptions of our interview may be directly quoted from when the results of the study are written.

The voice recordings and typed transcriptions will be kept securely in digital form within Durham University. The transcriptions will be kept for up to five years after the study ends, in case they are needed for future publications. The voice recordings will be securely destroyed soon after the end of the study. All other personal information on paper will be kept in a locked cabinet at Durham University during the study, and will be destroyed in the same way. You have the right to check the accuracy of data held about you and correct any errors.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, (the Research Ethics Committee) who are there to protect your interests. This study has been reviewed and given favourable opinion by County Durham and Tees Valley NHS Research Ethics Committee.

What if there is a problem?

You can make an appointment with Dr Fuat if you have any issues about the research. Your practice also has a complaints procedure which you can access if required. The practice manager, Karen Crook is the complaints contact. She can be contacted via your practice's usual contact number.

If you would like to speak to someone outside your GP surgery then you can contact Mr Richard Errington at the NHS Research Management and Governance Unit. Tel: 0191 374 4211 Address: John Snow House, University Science Park, Durham, DH1 3YG.

If you would like to take part in this study then please complete the slip attached to the covering letter and return it in the stamped addressed envelope provided.

Summary of the research

The study will be conducted by Ms Elizabeth Strutt, a researcher at Durham University who is studying for a research degree.

What is the purpose of the study?

The purpose of the study is to help those working in the NHS find out what patients think and feel about their health check. It will also look into why some people decline their health check invitation. The information we collect will be used to try to improve the programme for future service users.

Why have I been invited?

You have been selected to take part in this study by a member of the practice staff at Carmel Medical Practice. You have been invited to join the research because you recently attended your practice for an NHS Health Check and have now received your results.

Do I have to take part?

It is up to you to decide to join the study. Your choice will not affect your relationship with your medical practice. No information about your taking part in this study will be added to your medical notes. No one outside your medical practice care team will have access to your medical notes.

What will happen to me if I take part?

If you decide you would like to take part then please return the reply slip. After this the researcher will telephone you to arrange to meet in person. This meeting will last about one hour. It will be arranged on a time and date to suit you and could take place in your home in Darlington. If you would prefer to meet in a public place in Darlington centre this could also be arranged.

At the meeting the researcher will spend the first five to ten minutes discussing the study with you and answering any of your questions. She will then take your consent to take part. You will be asked to agree to the recording of your responses. It is helpful to have recordings so that the researcher can look back on what you said, as she won't remember everything. The questions asked during this interview will be mainly very broad so that you can speak about whatever you feel is relevant. There are no right or wrong answers and we would like to find out exactly how you feel. After this meeting you will not be contacted again about the study, unless you have asked for feedback.

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive from your medical practice. If you decide not to take part in the research we will destroy any information you have given to the study.

What are the benefits and the possible disadvantages of taking part?

We cannot promise the study will help you but the information we get from this study may help improve the way health checks are delivered in the future.

A disadvantage of being involved is that you will have to give up about one hour of your time. In the unlikely event that you become distressed or worried at any time you will be referred to your GP surgery's usual recommended support mechanisms. In the event of poor practice being identified then appropriate local NHS policies will be adhered to.

What will happen to the results of the research?

We intend to report the results of the study in a number of different forms: both on paper and as spoken presentations. You can choose to receive a summary of the results of the study. The researcher will speak to you about the feedback she can provide at the meeting.

Who is organising and funding the research?

County Durham and Darlington Primary Care Trust is acting as sponsor of the study. Ms E Strutt is the main organiser of the study. To complete this study Ms Strutt will be funded by two studentships. No one else involved in the study is receiving financial benefit.

APPENDIX D: INFORMATION BOOKLET FOR PATIENTS FROM ORCHARD COURT SURGERY

Designed in Microsoft Publisher, printed as a three panel leaflet

INFORMATION

SHEET

Revealing and experiencing an 'at risk' diagnosis: implementing the NHS Health Check programme in general practice

CONTACT DETAILS:

**DR D RUSSELL,
ORCHARD COURT SURGERY,
ORCHARD ROAD, DARLINGTON,
CO. DURHAM, DL3 6HZ**
Telephone: 01325 465285

Ms E STRUTT,

**DEPT. OF GEOGRAPHY,
DURHAM UNIVERSITY,
SOUTH ROAD, DURHAM,
DH1 3LE.**

Email: elizabeth.strutt@dur.ac.uk

Telephone: 0191 384 4567

Use these contact details if you have any queries before, during, or after your involvement in this study.



This information sheet is provided to help you make up your mind about whether or not to take part in this study. Version A (4.2) 20/05/10

Will my taking part be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. You will not be identified in any spoken or written material that results from this study.

The researcher, Ms E Strutt, is responsible for the safeguarding of the information collected from you. The audio recordings will only be accessed and listened to by Ms E Strutt, so that she can produce a typed copy (transcription) of your viewpoints. This copy of the interview will not contain any personal information that could identify you. The copy may be looked at by others involved in the study. The transcriptions of our interview may be directly quoted from when the results of the study are written.

The voice recordings and typed transcriptions will be kept securely in digital form within Durham University. The transcriptions will be kept for up to five years after the study ends, in case they are needed for future publications. The voice recordings will be securely destroyed soon after the end of the study. All other personal information on paper will be kept in a locked cabinet at Durham University during the study, and will be destroyed in the same way. You have the right to check the accuracy of data held about you and correct any errors.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, (the Research Ethics Committee) who are there to protect your interests. This study has been reviewed and given favourable opinion by County Durham and Tees Valley NHS Research Ethics Committee.

What if there is a problem?

You can make an appointment with Dr Russell if you have any issues about the research. Your practice also has a complaints procedure which you can access if required. The practice manager, Karen Fuat is the complaints contact. She can be contacted via your practice's usual contact number.

If you would like to speak to someone outside your GP surgery then you can contact Mr Richard Errington at the NHS Research Management and Governance Unit. Tel: 0191 374 4211 Address: John Snow House, University Science Park, Durham, DH1 3YG .

If you would like to take part in this study then please complete the slip attached to the covering letter and return it in the stamped addressed envelope provided.

Summary of the research

The study will be conducted by Ms Elizabeth Strutt, a researcher at Durham University, who is studying for a research degree.

What is the purpose of the study?

The purpose of the study is to help those working in the NHS find out what patients think and feel about their health check. It will also look into why some people decline their health check invitation. The information we collect will be used to try to improve the programme for future service users.

Why have I been invited?

You have been selected to take part in this study by a member of the practice staff at Orchard Court Surgery. You have been invited to join the research because you recently attended your practice for an NHS Health Check and have now received your results.

Do I have to take part?

It is up to you to decide to join the study. Your choice will not affect your relationship with your medical practice. No information about your taking part in this study will be added to your medical notes. No one outside your medical practice care team will have access to your medical notes.

What will happen to me if I take part?

If you decide you would like to take part then please return the reply slip. After this the researcher will telephone you to arrange to meet in person. This meeting will last about one hour. It will be arranged on a time and date to suit you and could take place in your home in Darlington. If you would prefer to meet in a public place in Darlington centre this could also be arranged.

At the meeting the researcher will spend the first five to ten minutes discussing the study with you and answering any of your questions. She will then take your consent to take part. You will be asked to agree to the recording of your responses. It is helpful to have recordings so that the researcher can look back on what you said, as she won't remember everything. The questions asked during this interview will be mainly very broad so that you can speak about whatever you feel is relevant. There are no right or wrong answers and we would like to find out exactly how you feel. After this meeting you will not be contacted again about the study, unless you have asked for feedback.

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive from your medical practice. If you decide not to take part in the research we will destroy any information you have given to the study.

What are the benefits and the possible disadvantages of taking part?

We cannot promise the study will help you but the information we get from this study may help improve the way health checks are delivered in the future. A disadvantage of being involved is that you will have to give up about one hour of your time. In the unlikely event that you become distressed or worried at any time you will be referred to your GP surgery's usual recommended support mechanisms. In the event of poor practice being identified then appropriate local NHS policies will be adhered to.

What will happen to the results of the research?

We intend to report the results of the study in a number of different forms: both on paper and as spoken presentations. You can choose to receive a summary of the results of the study. The researcher will speak to you about the feedback she can provide at the meeting.

Who is organising and funding the research?

County Durham and Darlington Primary Care Trust is acting as sponsor of the study. Ms E Strutt is the main organiser of the study. To complete this study Ms Strutt will be funded by two studentships. No one else involved in the study is receiving financial benefit.

APPENDIX E: CONSENT FORM FOR PARTICIPANTS OF CARMEL MEDICAL PRACTICE

**DR GJG METCALFE
DR A FUAT
DR BF PENNEY
DR E MOORE**



**CARMEL MEDICAL PRACTICE
NUNNERY LANE
DARLINGTON
CO DURHAM
DL3 8SQ**

**Telephone: 0844 477 8758
Facsimile: (01325) 381834**

CONSENT FORM: To be completed by the Carmel Practice health check attendee participants.

Study Title: Revealing and experiencing an 'at risk' diagnosis: implementing the NHS Health Check programme in general practice

Name of Researcher: Ms Elizabeth Strutt

*Please cross out as appropriate
and initial inside each box*

- | | | |
|---|----------|--------------------------|
| 1. I confirm that I have read and I understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | YES / NO | <input type="checkbox"/> |
| 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. | YES / NO | <input type="checkbox"/> |
| 3. I understand and am happy with how the researcher will protect my right to confidentiality and anonymity. | YES / NO | <input type="checkbox"/> |
| 4. I agree that sound recordings can be made of the interview. | YES / NO | <input type="checkbox"/> |
| 5. I understand that the storage of data and purpose for which the material will be used will comply with the Data Protection Act and Durham University guidelines. | YES / NO | <input type="checkbox"/> |
| 6. I agree to the possible use of my responses for word for word quotation. | YES / NO | <input type="checkbox"/> |
| 7. I understand that in the event of poor practice being identified or risk of harm then appropriate local NHS policies will be adhered to. | YES / NO | <input type="checkbox"/> |
| 8. I agree to take part in the above study. | YES / NO | <input type="checkbox"/> |

Name of participant:

Signature Date.....

I confirm that I have taken informed consent:

Signature Date

(When completed: 1 for participant; 1 for researcher files.)

Version E (1.1) 27/4/2010

APPENDIX F: CONSENT FORM FOR PARTICIPANTS OF ORCHARD COURT SURGERY

Dr. R. S. CHARLTON
Dr. D. RUSSELL
Dr. R. STEVENS
Dr. S. STONE

Orchard Court, Orchard Road, Darlington
Co. Durham DL3 6HZ
Telephone (01325) 465285
Fax (01325) 284034

CONSENT FORM: To be completed by the Orchard Court health check attendee participants.

Study Title: Revealing and experiencing an 'at risk' diagnosis: implementing the NHS Health Check programme in general practice

Name of Researcher: Ms Elizabeth Strutt

*Please cross out as appropriate
and initial inside each box*

- | | | |
|---|----------|--------------------------|
| 1. I confirm that I have read and I understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | YES / NO | <input type="checkbox"/> |
| 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. | YES / NO | <input type="checkbox"/> |
| 3. I understand and am happy with how the researcher will protect my right to confidentiality and anonymity. | YES / NO | <input type="checkbox"/> |
| 4. I agree that sound recordings can be made of the interview. | YES / NO | <input type="checkbox"/> |
| 5. I understand that the storage of data and purpose for which the material will be used will comply with the Data Protection Act and Durham University guidelines. | YES / NO | <input type="checkbox"/> |
| 6. I agree to the possible use of my responses for word for word quotation. | YES / NO | <input type="checkbox"/> |
| 7. I understand that in the event of poor practice being identified or risk of harm then appropriate local NHS policies will be adhered to. | YES / NO | <input type="checkbox"/> |
| 8. I agree to take part in the above study. | YES / NO | <input type="checkbox"/> |

Name of participant:

Signature Date.....

I confirm that I have taken informed consent:

Signature Date

(When completed: 1 for participant; 1 for researcher files.)

Version E (1.2) 27/4/2010

APPENDIX G: INTERVIEW SCHEDULE

Participants invited to talk about their responses to and experiences of an NHS Health Check

- Introductions
- Explain the research by going through the participant information sheet
- Give the participant an opportunity to ask questions, or tape can I call you by name or a different name.
- Complete consent form
- Explain the next part of the meeting
- Start the audio-recording

Prompts for interview – to be treated as a guide so that participants can take the research in different directions

40 questions –

STAGE ONE - Practical – what happened, how was it done etc...

As you read in the letter participating in the study was voluntary so first of all I'd like to say thank you and ask if there was anything that particularly encouraged you to take part? Or do you have a viewpoint that you particularly wanted to share?

I know you've been given information about the health check from your practice, but can you tell me in your own words, as though you were telling a friend, why you were given a health check and what it was for?

Did you have any knowledge or experience of any cardiovascular diseases, such as stroke, diabetes, heart attack, coronary heart disease, before being invited to the health check? (E.g. Know people, told by your doctor, or seen on TV or in newspapers.)

What was your understanding of these cardiovascular diseases? (Mild, serious, worrying etc.)

Can you describe how you were invited to a health check appointment?

Did you feel you had enough information in a way you could understand to decide whether to attend? Are there any ways you may have preferred to be invited? (E.g. in person or by letter)

Thinking back to when you received the invitation to screening what were your initial feelings? (Surprised/expected; pleased/worried)

Did you feel that you'd benefit from the health check, and if so, how?

How did you decide whether or not to attend? (any encouragement or discouragement from others friends, family, health workers - what did they tell you?)

Did your previous experience of NHS health care or your GP surgery inform your decision? (Good/bad experiences, trust in health care, waiting times, nervousness etc)

Did you have to prepare any information before attending your appointment? (a form about your current lifestyle, family history?) What did this involve? Did any of your answers make you worry about your risk/health?

Did you in any way change your behaviour, for example the amount you ate, drank, exercised, before your health check?

What were your thoughts about some of the things that were assessed at the health check? What were your thoughts about the way the practice staff conducted the health check?

Tell me about the way you were given your screening results? (Letter, phone, called the practice or they called you. How long after? Who told you?) Were you pleased, dissatisfied, not bothered about the way you got your results?

I know these are quite sensitive issues, are you happy to discuss the results you were given after your health check? What did you think of your results? (worrying, nothing new, didn't think it would affect you etc) Did you expect the result you got?

Do you agree with the assessment made of your health and your risk category? Given your personal experience of what you're able to do or not able to do? Eg can do everything I want to do, or I do get out of breathe etc.

Did you ever think you could be at risk before the health check?

Did your views about your health change in any way after your risk assessment? – in what way - less healthy/more healthy or no different..? What are your views now and what were they before you had your health check?

Have you discussed your results with others?

STAGE TWO - Background to the person – feelings about health, being healthy, personal responsibility for health, the future and aging. How they have taken what they have been told at screening and brought it into their theorising on life and explanations of life and the future.

How do you feel about your risk of developing a cardiovascular disease in the future?

What do you expect from your health in the future?

Is this the type of future you would like?

Can you see yourself trying to prevent poor health?

How do you feel about trying to maximise health, keeping in mind the natural ageing process?

Was anything being asked of you by the health check programme in terms of individual responsibility for disease prevention?

What do you think about trying to prevent any cardiovascular health problems in the future? (Can it be achieved, is it worth it, or is it something you want to do?)

Have you done anything in response to your result? (What – change exercise, diet, habits etc.?) What do you hope this will achieve in the short term and the long term?

How confident are you of success?

What motivates you to change? Or what puts you off making changes? (Long-term and short-term disadvantages – such as lots of effort and what you have to give up)

Do you feel that others can help you reduce your risk or improve your health? E.g. family members or your doctor and how?

How much did the lifestyle advice at your health check influence your thinking about changing your behaviour?

What did you think of the advice provided with the health check, was it practical given your personal situation? (mobility, lifestyle, routine etc) What types of information could you use - examples? Anything not so helpful?

Did you prefer being told advice face-to-face, or on paper? e.g. didn't read the information or forgot what I was told.

Do you find any other sources of information provide you with useful advice about being healthy? Such as the TV, newspapers, magazines, friends and family or adverts for health foods.

STAGE THREE - OVERALL VIEWPOINT ABOUT THE PROGRAMME

Overall, how did you find the programme and going along for a health check? Was it useful or not? What would you say was the main thing that came out of the health check programme for you?

Did your experience of a health check correspond with or differ from your previous experiences of NHS health care or your GP surgery?

As a consequence of your involvement in the health check programme has there been any affect on your home life, social life or work?

What would you advise others if they were also asked to attend a health check?

Do you feel you could benefit from more information, education, or support?

Would you like to mention anything else that we haven't covered?

If ethnic minority

Would you say there are any issues to do with health care services, cardiovascular disease, the invitation, or the screening that might have an influence on whether people from minority ethnic communities attend a health check?

How might these issues be overcome or what could be done to improve uptake given these issues?

- Turn off recording
- How have you found the meeting?
- Any comments/questions?
- Say thank you and ask if she/he would like to receive a summary of results at the end of my project

APPENDIX H: RESEARCH DIARY

Orchard Court participant one – male – aged about forty-five to fifty.

I got on well with this man. I could emphasise with him and I found that he did a lot of talking but covered a lot of what I wanted to bring up without me having to ask the questions directly from the sheet. It was a very free-flowing interview. He had a spacious house, with children, and seemed to be from a fairly affluent background.

Orchard Court participant two – male – aged about seventy plus.

I didn't seem to get on so well with this man. He found it hard to talk about his own feelings and kept on referring to the general and going off topic. It was difficult to get him back on topic and I felt he'd misunderstood what the research was about and just wanted a bit of a chat. In retrospect, looking back at the tapes, he did make lots of good points and emphasised that he wasn't worried about his health but was worried about the younger generation. He lived in a poorer area, a terraced house.

Orchard Court participant three – female – aged 65

She was a nice lady. She was from a poorer background and maybe a less educated background. I got on well with her, although she seemed a little nervous to start with. It seemed to be a good, well focused interview though.

Orchard Court participant four – male – aged 50s

He was friendly and we got on fine, he was from a poorer background than some who I've spoken to as he lived in a council-style bungalow. He liked the way that risk was presented to him using smiley and sad faces – see www.nntonline.com

Carmel Medical Practice participant one- female – aged 50

She had decided to help out with the research because she liked Dr Fuat and wanted to help him out. She said she found it difficult to talk with the tape going, once the interview was over. It was a very short interview – I found it difficult to question her and in her answers she provided few leads for further questions. It seemed a bit of a disaster at the time. She hadn't read the information sheet before signing up so didn't

spend any time thinking about what she would say before I arrived. I think she demonstrated that for some people their health check is really quite insignificant and they have little to say about it. This lady seemed well off and lived in a spacious house. I didn't find out if she had any other family members living with her.

Carmel Medical Practice participant two – male – aged 50

I got on well with this man; he was focused on the health check, his responses, and wider views and attitudes. I thought that this was a very productive interview. He seemed well educated, thoughtful and inquisitive and fairly affluent. He lived in a very spacious house with children.

Carmel Medical Practice participant three – female – aged 60

She was well educated and fairly affluent. She lived in a spacious and well appointed house, and answered my questions directly and to the point. Perhaps, she wasn't as open or as talkative as I might have liked!

Carmel Medical Practice participant four – female – aged 65

I felt very comfortable in her presence. She was very helpful and showed me the letter she'd been sent from the practice with information about cardiovascular disease risk (from patient.co.uk), which didn't seem very relevant as the letter didn't mention cardiovascular disease risk. She lived in a detached house in a leafy part of Darlington. <http://www.patient.co.uk/health/Preventing-Cardiovascular-Diseases.htm>

Carmel Medical Practice participant five – female – aged 72

Her husband also sat in on the interview and contributed. It was a chatty interview and this couple were very friendly to me. She had been worried that I'd ask difficult questions but was pleased that I didn't in the end. She showed me her letter with the six page information sheet about cholesterol from patient.co.uk which she felt was a little too long and the information she most wanted, the lifestyle advice, was hidden on page 5: <http://www.patient.co.uk/health/Cholesterol.htm>. She came from an ordinary household and lived in an old-fashioned (decoration-wise) council-type Semi. After the tape was stopped she mentioned Moorlands surgery and how

difficult it was to get an appointment there compared to Carmel, where it was easy to get an appointment.

Carmel Medical Practice participant six – male – aged 66

I got on really well with him; because he reminded me of my dad (he was a retired self-employed roofer who liked fishing). He had attended retinal screening so we discussed this and the support he was getting despite not being eligible for a health check because of his diabetes. He lived in a terraced house, he wasn't rich, but I didn't think he was struggling too much either.

Carmel Medical Practice participant seven – male - aged 45ish

He was keen to help me and it felt like we had a good discussion. He was well educated raised some interesting points. I liked him. He had an aspirational detached house, with an older child staying with him who normally worked in the South.

Carmel Medical Practice participant eight – male – aged 60ish

He was visually impaired and I was unprepared for that, in terms of the practicalities of the consent form, but we made it work because I read the points out to him. He was happy to help me again, if I needed to get in touch about the cholesterol check follow-up he was due to have, because of ethics I couldn't take up his offer, but it showed willing. After the tape stopped Moorlands surgery was mentioned, in terms of how hard it was to get an appointment and having long waiting times, sometimes an hour. Carmel Practice, compared favourable, he thought it was easy to get an appointment and they did not make you wait. When he visited he often went straight in to see a doctor, even when he arrived early. Carmel was thought to be very well run compared to Moorlands and also they had complaints about the personality of a particular doctor at the Memorial Hospital. The wife had been with Moorlands all her life and for them a Medical Practice was something thought to be given, that you didn't change (so they hadn't even thought about seeing if she could go to Carmel). He did not seem too chatty; his wife was much more so. His wife had a terrible ordeal and I felt as though I had finally come face-to-face with just how severe diabetes could be as it has caused her a severe disability. He still went out to work. They lived in a poor area, with Union flags hanging from some houses, probably a

sign of support for the BNP.

Carmel Medical Practice participant nine – male – aged 40ish

He was business-like and short with his answers. I saw him at work in a meeting room, if that made a difference. It seemed less friendly perhaps, than it the home environment, but I also found him to be not a very talkative person in general. Although I was happy with what he did tell me.

Carmel Medical Practice participant ten – Female – aged 50

She lived with her older children in a nice semi-detached house. She wasn't poor and wasn't rich either. I got on well with her as she was friendly, helpful, and somewhat motherly towards me.

Carmel Medical Practice participant eleven – male – aged about 45

He was of Indian origin. He had a busy work life and a family. I met him at his work and he was very talkative and helpful.

Carmel Medical Practice participant twelve – male – aged about 50

He was from the Middle-East but had lived here since he was a child. He was happy to help me with this research and we got on well. He lived in his own semi-detached house.

Carmel Medical Practice participant thirteen – female – aged about 40-45

She was of Indian origin. She wasn't too chatty and gave me quite limited responses. I felt that she was quite wary. She lived in a spacious 70s build and her husband was a doctor.

APPENDIX I: LIST OF NVIVO NODE CODINGS

Free Nodes			
	Name	Sources ▾	References
	Feelings about invitation	16	24
	Feelings about results	15	57
	Outcome of checks	15	41
	Cardiovascular disease	15	25
	Viewpoints about health	14	55
	Following advice	14	53
	Fat or diet	14	65
	Exercise	14	38
	Health check content or conduct	14	45
	Usefulness of tests	13	20
	Explanation of risk	13	21
	Heredity	13	22
	Reason for health check	12	22
	Relationship with medical practice	12	31
	Age	12	37
	Future	12	40
	Family	12	24
	Prevention	12	22
	Self responsibility	11	27
	Participant motivation	10	11
	(in)Convenience of appointments	10	18
	Feelings about risk	10	20
	Previous lifestyle	10	24
	Follow-up	9	17

Free Nodes		
Name	Sources	References
changes to lifestyle	9	25
Wider information	9	15
Drinking habits	9	26
Explanation of results	8	24
Non attendee type explanations	8	12
literature	8	14
Feelings about BP measurement	7	8
Waiting for results	6	12
Information from GP	6	6
Feelings about the doctor's	5	11
Conflicting advice or info	5	11
Medication	5	17
Expectation of test	5	6
Embedded in lifestyle	5	9
Smoking	5	14
Viewpoint of NHS	4	5
Belief in medical measuring	4	4
Financial considerations	4	8
Wider support for change	4	4
causes of result	4	10
Attitude about tests	3	4
Personal experiences	3	15
Discipline and health	3	7
Government and health	3	3
Communication issue	2	8
Self reported information	2	3
Loneliness	2	2
Background or Culture	2	3
Genes	1	2
Holistic medical care	1	2
Blame for problems	1	3
Uptake	1	1
Prostate prevention	1	1
Health check programme	1	1

APPENDIX J: RESEARCH ETHICS AND DATA PROTECTION MONITORING FORM

Research Ethics and Data Protection Monitoring Form

Research involving humans and environmental impacts by all academic and related staff and students in the department is subject to University requirements for ethics and data protection review. The Department's Research Ethics and Data Protection Peer Review Group will assess research against the guidelines given by the British Sociological Society Association and the Natural Environment Research Council.

It is a requirement that prior to the commencement of all research that this form be completed and submitted to the Department's Research Ethics and Data Protection Peer Review Group. The Peer Review Group will be responsible for issuing certification that the research meets acceptable ethical standards and will, if necessary, require changes to the research methodology or reporting strategy.

YES, a copy of the research proposal detailing methods and reporting strategies is attached

Name of principal investigator or main applicant: ELIZABETH STRUTT

Title of research project: "Revealing and experiencing the 'at risk' body: implementing the National Vascular Screening Programme"

Main subject area: Interdisciplinary – Human Geography/Anthropology

Questionnaire

		YES	NO	
1.	Does your research involve living human subjects?	YES		
2.	Does your research involve only the analysis of large, secondary and anonymised datasheets?		NO	
3a.	Will you give your informants a written summary of your research and its uses?	YES		If NO, please provide further details and go to 3b
3b.	Will you give your informants a verbal summary of your research and its uses?	YES		If NO, please provide further details
4.	Does your research involve contemporary covert surveillance (for example, participant observation)?		NO	I will openly ask to watch my participants' medical appointments.
5a.	Will your information <i>automatically</i> be anonymised in your research?	YES		If NO, please provide further details and go to 5b
5b.	IF NO Will you explicitly give <i>all</i> your informants the right to remain anonymous?			If NO, why not?
6.	Will monitoring devices be used openly and only with the permission of informants?	YES		If NO, why not?
7.	Will your informants be provided with a summary of your research findings?	YES		Yes – given the option to request the summary of findings.
8.	Will your research be available to informants and the general public without authorities restrictions placed by sponsoring authorities?	YES		If NO, please provide further details
9.	Have you considered the implications of your research intervention on your informants?	YES		See next page for details
10.	Are there any other ethical issues arising from your research?	YES		Seeking NHS ethics permission

Further details (please include any potential risks to the environment from your research and the steps taken to address the consequent ethical issues):

Implications of your research intervention on your informants: I have considered the implications in line with the NHS Ethics advice and have submitted an application for NHS ethical review.

Risks and benefits:

In line with NHS ethical advice, Dr Fuat, a supervisor who also works at my field site, will monitor the risks throughout the project and make necessary changes to further minimise them.

An inconvenience of the study to participants is that they will have to give up an hour to invite the researcher to their homes or meet with the researcher in their preferred public location for an 'interview', which sounds quite formal and could cause worry. In participant information literature the term 'interview' will be avoided, instead it will be described as a meeting lasting about one hour where participants will be asked about their impressions of the 'health check' they have recently attended. They could also feel inconvenienced when replying to the initial invitation letter, although it will be reminded to them that taking part in the study is optional. The participants will be told before they agree to take part in the study what the study involves; they can also change their minds about being involved at any time.

Participants might become upset during the interview because of the topic of discussion about their risk of vascular disease. If this occurs the participant will not be pressured to continue and will be reminded that they can leave the study at any time without any cause for concern about their relationship with the medical practice or the research team. They will be referred back to the medical practice or a helpline if there is any upsetting issue they would like to further discuss.

The risks of misunderstanding the person/ misinterpretation of their opinions will be dealt with by reiterating answers during interviews or asking for further elaboration.

There is also potential for breach of confidentiality, through identifiable published material and a breach of data security. Code names will always be used and only limited individual case details will ever be discussed or published so that we will never reveal enough information for anyone to guess a participant's identity. All comments from participants used in written or conference materials will be checked through many times to make sure that they contain no identifiable information. Data will be held securely on a research drive/locked filing cabinet on university premises for only as long as is necessary for this study. Then data will be destroyed using appropriate data destruction software.

Continuation sheet NO

Declaration

I have read the Departmental Guidance on Research Ethics and Data Protection and believe that, where appropriate, the research proposal complies fully with the requirements of the documents listed (Appendices B-F) and The Durham University Principles for Data Protection (http://www.dur.ac.uk/data.protection/dp_principles/). I will not deviate from the methodology or reporting strategy without further permission from the Department's Research Ethics and Data Protection Peer Review Group.

Signed..... Date.....18/01/10

Signed (Supervisor)..... Date.....

Submissions without a copy of the research proposal (see below) will not be considered.

Summary of Research Proposal

To be completed by Department of Geography Postgraduates in consultation with their supervisors and to accompany the 'Research Ethics and Data Protection Monitoring Form'

This 1 page summary research proposal should be submitted along with your completed 'Research Ethics and Data Protection Monitoring Form'. The summary should not exceed 1 page in length and should demonstrate that you have thought carefully about the ethical issues to do with your research. Please read the notes provided for each section and then delete them before completing the form yourself.

Name of Student: Elizabeth Strutt

Please provide a brief summary of your proposed research under the following headings:

(1) Context and Research Questions

Health prevention policies in the UK are increasingly directed at complex, chronic diseases, with a recent emphasis on screening and identification of those at high risk. The aim of this project is to interrogate the experiences and responses of individuals to a new screening programme for chronic disease. It will ask how people interpret an invitation to screening, the process of screening, and the results of a screening programme. This will be done using a case study of responses to screening for vascular disease at two general practices in Darlington, which is being conducted as part of the new National Vascular Screening Programme. The current literature demonstrates the problematic nature of organising a successful screening programme, in terms of patients' perceptions of the screening process and their results. Thus, it is important to investigate how the design and implementation of a new screening programme impacts upon individuals' responses to screening and their risk diagnosis. Other studies have explored how people merge health information with other information sources, beliefs, and attitudes so it is important to consider the implications of this process for the implementation of the screening programme. It remains unclear exactly why people choose not to attend for a 'health check' after receiving an invitation, and so facilitators would also like to find out more from the perspectives of the patients who do not attend in order to further develop their inclusion strategies.

The principal research question is how do participants of risk assessment screening for vascular disease interpret, experience and respond to their invitation to screening, the screening procedures, and the health information they are given?

The secondary question being asked is how do medical knowledges and healthcare agents reveal a body at risk of vascular disease?

(2) Proposed Methods

Recorded interviews (n=50) and overt non-participant observations of medical appointments (n=30). Field sites: Carmel Medical Practice and Orchard Court Surgery, Darlington for the observation stage. (NHS ethical permission sought). Potential interview participants will be identified by healthcare staff at these practices and invited by letter of invitation to take part in an interview in their own homes.

(3) Communication of Research Findings

At the end of the study those participants who have requested to see a summary of the final report will be sent one in the post or by email. A summary of findings will be posted on the medical practice notice-board for visitors to read. Participants will also be able to access an electronic copy of the thesis through the Durham University website. Analyses/reports will be made to keep the medical practice staff, funders, and the supervision team informed of the progress of the research and the results of the study. NHS County Durham and NHS Darlington will also be sent details of the results of the study and their implications for the future implementation of their screening programme. These results will also be shared with other people involved in vascular screening programmes around the United Kingdom via the 'NHS Health Check Resource Library' provided by the NHS Improvement Programme. Other communication of research findings may include academic publications and conference presentations. The final report will discuss the findings and their implications, as well as issues of researcher bias and it aims to be reflexive about the researcher's involvement in shaping the design, implementation, and outcomes of the research.

In all written work resulting from the research, participants will be given code names and will not be identifiable from any other information mentioned about their case histories. Publication of direct quotations, or other information provided by participants will be anonymised and care will be taken to ensure that no other information published allows participants to be identified, such as the combination of gender, age, ethnicity, and location. The researcher will maintain the confidentiality of individual participants and will only reveal anonymised information to other interested parties.

APPENDIX K: SITE SPECIFIC RISK ASSESSMENT FORM



Site Specific Risk Assessment - Department of Geography, Durham University

Name of Fieldworker / Leader (Module): ELIZABETH STRUTT
 Fieldwork Location: Darlington town centre, Co. Durham

Dates of fieldwork: April 2010 to January 2011
 Grid Reference/Map Sheet: N/A

Hazard category	Hazard	Who might be harmed?	Precautions (Risk Control Measures)
Physical – violence	Assault	Fieldworker	Ensure wherever possible to get an introduction from an experienced local contact to a particular area. In this case the introduction will be made by Dr A. Fuat who works at the practice where I'll be observing medical appointments. Avoid fieldwork at night unless absolute necessary, and if so with a local 'escort' if possible, and carry a phone and/or alarm. Try to carry out as much fieldwork outside the area (e.g. collection of statistics can usually be done through a central administrative authority). Always back off and leave the area immediately if threatened. Report regularly to a third party who is aware of your location, especially when finished.
Physical - traffic	Motor vehicles	Fieldworker	Stay aware of traffic in urban areas. Take care on roads and act responsibly.
Physical - violence	Assault/abduction	Fieldworker	Will be conducting interviews in participants homes (to facilitate openness) or in a public place such as a coffee shop (if the person requests) – I will ensure that my location is known by a third party local contact other than the interviewee.
Physical – fire or similar	Fire or major incident	Fieldworker	Field worker will familiarise themselves with local fire regulations and emergency procedures
Lone working	Isolation	Fieldworker	Robust communications procedure (carry mobile phone), ensure location and movements are known
Physical: Weather	Sunstroke/ Dehydration	Fieldworker	Wear appropriate clothing, carry water.
Physical: Terrain	Slips, trips and falls	Fieldworker	Wear suitable footwear.
Mobile telephone contact number and nearest landline telephone	Mobile (on person): 07922 585895 Landlines will vary as conducting interviews at participants' homes – will provide landline information on the daily itinerary that I give to my key contact.	07922 585895	Source of local weather forecast (e.g. TV, phone service, etc.)
Nearest doctor / local surgery (with contact details)	Dr A Fuat, Carmel Medical Practice, Nunnery Lane Darlington County Durham DL3 8SQ		Communication Procedure (Means of alerting another party in event of a change of plan, incident or emergency- include key contact details) Carry mobile phone and change for landline. Will communicate by text message to next of kin. Will text message any changes of plan, and when enter and exit a participant's home. Home base contact will be given a detailed



	Tel: 0844 477 8758
Nearest hospital (with contact details)	Darlington Memorial Hospital Hollyhurst Road, Darlington, County Durham, DL3 6HX Tel: 01325 380100
Landowner	Varying landowners as I will be conducting interviews in participants' homes.
Is permission required for access?	Yes, permission gained via reply slip on letter of invitation to take part in the research.
daily itinerary so that my whereabouts are known and I will keep in touch during the day. I will also return to home base every day. 	Emergency Procedure (Protocol used in an emergency – include key contact details)
	Key contact details (see next of kin above). In an emergency I will contact the person named above/ the local medical surgery/hospital. If I do not send a text message to my next of kin two hours after entering an interview, which should last approx. one hour he will contact me by mobile phone or the landline of the person I was visiting to check I'm okay. If still cannot gain contact, dependent on situation, he will notify the emergency services/drive to find me. If there is a major incident then I will notify the emergency services directly.

Notes:

The form can be filled-in electronically, OR printed-out and filled-in manually.
This form is to be used for Student Fieldwork and Field Trips; Postgraduate Fieldwork; and Staff Fieldwork.
The Form (hardcopy or e-mail attachment) is to be returned to Departmental Health & Safety Co-ordinator (HSC). In absence of HSC, form should go to Chair of BoS
Direct queries to Dr Jerry Lloyd (Department of Geography HSC, J.M.Lloyd@durham.ac.uk).

APPENDIX L: NHS ETHICS RESPONSE TO REQUEST FOR FURTHER INFORMATION

Dear Dr John Drury

Re: 10/H0908/20 - response to request for further information

Thank you for your feedback from my ethics application. Set out below are my responses to your numbered requests for further clarification (as outlined in your letter dated 20th April 2010) and enclosed are the amended documents which you requested.

- 1) Dr D Russell is the appointed GP lead at Orchard Court Surgery, Darlington. His CV is enclosed and has been submitted to the local RM&G office.
- 2) The option of a private room being made available in the GP surgeries for conducting interviews has been investigated and was found to be unfeasible. Instead we have incorporated more stringent safety safeguards, as per your advice. A) The researcher will strictly adhere to the University Lone Worker Policy and the Practice policy. B) The researcher will only conduct research during daylight and not at night. C) The researcher will only enter the interviewee's home when the person whom she will be interviewing has been seen. D) The practice staff at the two surgeries responsible for selecting and inviting participants to join the study will screen patient records and exclude those patients from invitation to the study if they have or have had mental health problems which could pose a danger to the researcher.
- 3) This will be monitored by the local RM&G office via the R&D database for Darlington PCT.
- 4) Evidence of practice indemnity (medical protection arrangements) for the two GP surgeries involved in the study is enclosed.
- 5) The observational arm of the study will just be a learning process. I will use my observations to find out what happens in a health check in order to better understand interview responses. I will not discuss any details about the patients that I have observed in any research reports. Consent will be taken

for observations using the red/green ticket system. The ticket system will be used twice for participants who are observed attending both their health check appointment and follow-up consultation. Your feedback suggested that if the observations were just a learning process then written consent would not be required. So, I will no longer be giving out any information sheets or consent forms to patient participants for the observational arm of the study. I have amended and enclosed the protocol and have highlighted the change to the observational arm of the study. The GP lead at each practice will arrange with those who conduct the health checks some suitable dates for me to observe.

- 6) We will be recruiting between 6 and 10 staff participants, half at each GP surgery. These numbers break down as follows: two staff members who have conducted the health checks, two to four office staff members responsible for inviting patients to health checks, and two to four GPs who have spoken to patients at the follow-up consultation stage of the health checks and have overseen their GP surgery's implementation of the NHS Health Check programme.
- 7) Mrs Karen Fuat, named on page 22 of the application, is the Practice Manager at Orchard Court Surgery. She will take charge of coordinating the recruitment of appropriate participants at Orchard Court Surgery. Dr Russell is GP Lead at Orchard Court (see point 1). Dr A Fuat remains GP lead at Carmel Medical Practice. The appointed practice collaborators will not be conducting any data collection. Their role is to ensure that the research, at each of their research sites, is being conducted to the specification set out in the documents which have been approved (subject to approval) by the NHS Ethics committee.
- 8) – 12) Amended and additional letters/sheets/consents enclosed as suggested in letter, changes are highlighted and version numbers and dates have been adjusted. See list of enclosures.

If you have any queries for the two lead GPs their contact details are: Dr A Fuat, Carmel Medical Practice, Nunnery Lane Darlington County Durham DL39SQ Phone: 0844 477 8758 and Dr D Russell, Orchard Court Surgery, Orchard Road,

Darlington, County Durham, DL3 6HZ Phone: 01325 465285.

Yours sincerely

Ms Elizabeth Strutt

Postgraduate researcher

List of enclosures:

Document	Version	Date
Carmel Medical Practice Indemnity (3 pages)	GMC Status MDDUS Membership Employer's Liability	Nov 09 2009-2010 2010-2011
Lone Worker Policy	(2 pages)	2009-2010
CV for Dr David Russell	MDDUS no: R/7/1044/SK.AK	
Protocol	1.1	20/05/2010
FOR CARMEL PRACTICE		
Interview invitation to attendees	A (1.1)	27/04/2010
Interview invitation to non-attendees	B (1.1)	27/04/2010
Interview information sheet attendees	A (4.1)	20/05/2010
Interview information sheet non-attendees	B (4.1)	20/05/2010
Interview information sheet staff	C (2.1)	20/05/2010
Interview consent attendee participants	E (1.1)	27/04/2010
Interview consent non-attendee participants	I (1.1)	27/04/2010
Interview consent staff participants	H (1.1)	27/04/2010
FOR ORCHARD SURGERY		

Interview invitation to attendees	A (1.2)	27/04/2010
Interview invitation to non-attendees	B (1.2)	27/04/2010
Interview information sheet attendees	A (4.2)	20/05/2010
Interview information sheet non-attendees	B (4.2)	20/05/2010
Interview information sheet staff	C (2.2)	20/05/2010
Interview consent attendee participants	E (1.2)	27/04/2010
Interview consent non-attendee participants	I (1.2)	27/04/2010
Interview consent staff participants	H (1.2)	27/04/2010

APPENDIX M: NHS ETHICS FORMS

Published in pdf format, turn over to view the main NHS Ethics forms completed for this project: includes 1x NHS REC form, 1x NHS R&D form, 2x NHS SSI forms.

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Revealing and experiencing an at risk diagnosis: NHS Health Checks v.1

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial or clinical investigation
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples, other human biological samples and/or data (*specific project only*)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located? (*Tick all that apply*)

- England
- Scotland
- Wales
- Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
- Scotland

- Wales
 Northern Ireland
 This study does not involve the NHS

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
 Social Care Research Ethics Committee
 Research Ethics Committee
 National Information Governance Board for Health and Social Care (NIGB)
 Ministry of Justice (MoJ)

5. Will any research sites in this study be NHS organisations?

- Yes No

5a. Do you want your application to be processed through the NIHR Coordinated System for gaining NHS Permission?

- Yes No

If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

6. Do you plan to include any participants who are children?

- Yes No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? *The guidance notes explain how an adult is defined for this purpose.*

- Yes No

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?

- Yes No

9. Is the study, or any part of the study, being undertaken as an educational project?

- Yes No

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

- Yes No

10. Is this project financially supported by the United States Department for Health and Human Services?

- Yes No

11. Will identifiable patient data be accessed outside the clinical care team without prior consent at any stage of the project (including identification of potential participants)?

- Yes No



Integrated Research Application System
Application Form for Research involving qualitative methods only


National Patient Safety Agency

National Research Ethics Service

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting [Help](#).

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
 Revealing and experiencing an at risk diagnosis: NHS Health Checks v.1

Please complete these details after you have booked the REC application for review.

REC Name:

County Durham & Tees Valley 2 REC

REC Reference Number:

10/H0908/20

Submission date:

16/03/2010

PART A: Core study information
1. ADMINISTRATIVE DETAILS
A1. Full title of the research:

Revealing and experiencing an 'at risk' diagnosis: implementing the National Health Service Health Check programme in general practice (v.1)

A2-1. Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:

Doctor of Philosophy (PhD)

Name of educational establishment:

Durham University

Name and contact details of academic supervisor:

	Title	Forename/Initials	Surname
	Dr	Sarah	Atkinson
Address	Durham University Department of Geo Science Laboratories South Road, Durham		
Post Code	DH13LE		

E-mail s.j.atkinson@durham.ac.uk
 Telephone 01913341871
 Fax 01913341801

Name and contact details of student:

	Title	Forename/Initials	Surname
	Ms	Elizabeth	Strutt
Address	20 Bainbridge Street Carrville Durham		
Post Code	DH1 1NA		
E-mail	elizabeth.strutt@durham.ac.uk		
Telephone	07922585895		
Fax			

A copy of a current CV for the student (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- Student
 Academic supervisor
 Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Ms	Elizabeth	Strutt
Post	Research Postgraduate (PhD)		
Qualifications	BA (Hons) Dunelm		
Employer	Student		
Work Address	Department of Geography Durham University South Road, Durham		
Post Code	DH13LE		
Work E-mail	elizabeth.strutt@durham.ac.uk		
* Personal E-mail			
Work Telephone	01913844567		
* Personal Telephone/Mobile	07922585895		
Fax	01913341801		

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?

This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mr	Richard	Errington

Address NHS County Durham and Darlington
John Snow House
Durham University Science Park

Post Code DH1 3YG

E-mail richard.errington@nhs.net

Telephone 01913744211

Fax

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available): N/A

Sponsor's/protocol number: RE-704ES

Protocol Version: N/A

Protocol Date:

Funder's reference number: N/A

International Standard Randomised Controlled Trial Number (ISRCTN): N/A

ClinicalTrials.gov Identifier (NCT number): N/A

European Clinical Trials Database (EudraCT) number: N/A

Project website: N/A

Ref.Number	Description	Reference Number
------------	-------------	------------------

A5-2. Is this application linked to a previous study or another current application?

Yes No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. This summary will be published on the website of the National Research Ethics Service following the ethical review.*

Revealing and experiencing an 'at risk' diagnosis: implementing the NHS Health Check programme

The research question is: how do participants of risk assessment screening for vascular disease interpret, experience and respond to their invitation to screening, the screening procedures, and the health information they are given? It is important to conduct this research because it gives patients and healthcare staff the chance to give their opinion. It will raise more awareness useful to those implementing health checks about why some people do not attend and how other patients receive and explain the screening procedure and health advice in light of their wider lives and everyday experiences. This has great potential to benefit patients in the future by leading to more targeted health interventions.

The study will be recruiting adult participants from two medical practices, in Darlington, who have been routinely invited to have a 'health check' and a results appointment. The study comprises observation of approximately thirty of these appointments. Fifty participants will also be recruited to take part in an informal interview lasting one hour in each of their homes. Twenty interview participants will have been given a high risk diagnosis and twenty a lesser risk diagnosis. Ten participants will be interviewed who declined the screening invitation. We intend to recruit an equal mix of male and female participants, of European and South Asian origin. Healthcare staff will also be interviewed. The final contact each participant will have with the researcher is at their observation or interview, unless the participant

wishes to be contacted at the end of the study to receive information about the findings.

The study is part of a PhD programme which runs from October 2009 to September 2012 and is funded by ONE North East and Durham University. Fieldwork will be completed from April 2010 to January 2011.

A6-2. Summary of main issues. *Please summarise the main ethical and design issues arising from the study and say how you have addressed them.*

Purpose and design

The research has three main purposes. One (a): to provide more insight into the experiences and responses to cardiovascular disease risk assessment screening and diagnosis in participants who have been medically identified as at risk of cardiovascular disease, in comparison to those who are identified at lesser risk. One (b): to explore how medical professionals identify, explain, approach and treat the varying risk factors which put different patients at high risk or at lesser risk. This aspect explores why and how medical practices reveal an 'at risk' diagnosis and links with purpose one (a) to consider how the medical framing of risk factors are perceived by participants. Two: to provide information on the factors affecting the uptake of screening, from the perspective of those who decline the invitation to be screened and those who attend. Three: to identify the ways in which the information provided at screening is interpreted and becomes merged into a person's sense of self and their wider theories on life and expectations for the future. The project will assess the implications of all these findings for the practical implementation of the screening programme.

The ways these three purposes will be achieved will involve:

1) Observations -

People aged 40 to 74 will be invited to the practice routinely to take part in the NHS Health Check programme, which involves a 'health check' and a follow-up/results consultation. The study comprises observation of approximately thirty of these routine appointments, the people observed could belong to any of the risk groups. This aspect of the study looks at how the screenings are conducted and the results are presented. It will analyse the space in which the health interventions take place, the meanings of equipment used, the reasoning behind procedures, the decisions taken by healthcare workers, and the negotiation of knowledge and power in interactions between patient and health professionals. It provides information for purpose one (b).

2) Interviews -

The first criteria for recruitment to interviews will target ten people, both men and women, who have declined an invitation to screening, approximately five of South Asian origin and five of European origin. This is in order to provide information on the factors affecting screening uptake, considering the cultural and gender dimensions to reasoning. These interviews will provide information to answer purpose two.

The second criteria for recruitment to interviews will target forty people, both men and women of South Asian and European origin who have attended screening and been given their results. Twenty of these participants will be selected from the high risk group. The remaining twenty participants will be selected from the lesser risk groups. These interviews aim to provide more insight into the experiences and responses, to an NHS Health Check, of those who have been screened and given a risk diagnosis. It provides information directly for purposes one (a), two, and three.

The third criteria for recruitment to interviews will target members of the healthcare team involved in the 'health checks' at Carmel Medical Practice and Orchard Court Surgery in Darlington. It will provide information for purpose one (b). Members of the healthcare team will be asked to describe what they do as part of the 'Health Check' programme, why this is done, their viewpoints about the programme, and we will find out what the healthcare team would like to know about patient experiences of the screening programme.

In developing the proposal the postgraduate student and chief investigator of the study, Elizabeth Strutt, has drawn contributions from Dr A. Fuat, Dr T. Pollard, and Dr S. Atkinson. Dr A. Fuat is a General Practitioner (cardiology specialist) and Clinical Senior Lecturer in the Centre for Integrated Health Care Research, Durham University. Dr T. Pollard is a Senior Lecturer in the Department of Anthropology, at Durham University, whose main research interest is in working to explain why some groups of people, especially those of South Asian origin living in the UK, have very high rates of metabolic diseases. Her specialism in looking to improve understanding of health and lifestyle behaviours is of particular relevance to the study. Dr S. Atkinson, a Reader in the Department of Geography at Durham University, has also contributed to the design of the study, her interest in health policy discourse and practice at local and global scales has also helped in the design of the study.

Recruitment

Letters inviting participation in the study will be given to potential participants while attending their practice for a 'health check' or sent out by post. Members of staff working at the two medical practices involved in the study will identify participants meeting the criteria and provide them with the letter of invitation to join the study. Healthcare staff will be handed their letter of invitation and information sheet by the student researcher, whilst she is visiting the practice where they work. No personal information about those invited will be available to the researcher and the researcher will at no stage have access to medical records. The person invited will be asked to return a reply slip if they are happy to take

part in the study, once the reply slip is returned the researcher will be given the name, address, and telephone number of the recruited participant. The recruitment material will make no therapeutic promises and it will be emphasised to participants that the student is not a member of the practice and is not able to offer any advice. Participants who raise questions will be referred back to the practice team. Recruitment of participants who are happy for their medical appointment to be observed will also be done through their medical practice. When patients arrive for their appointment their consent for the student to observe will be sought.

Inclusion / exclusion

Only those individuals who have been invited for screening and have received their results in the last three months will be invited to take part in the study (n=40). Men and women of South Asian ethnicity and of European origin will be invited to take part in the study, from both the high risk and lesser risk groups. Also a small number of those who have been invited for screening and sent reminder letters but still have not attended approximately three months later will be invited to take part (n=10). Letters inviting participation in the study will not be sent to vulnerable individuals. These individuals will be excluded from the study because gaining their consent would be problematic and the interview methodology requires that participants can represent their own interests.

Consent

Research will be conducted with full consents. A letter of invitation, information sheet, and stamped addressed reply envelope will be sent to potential participants at their home addresses or handed to them whilst attending the practice for an NHS Health Check appointment. This invitation 'pack' will give them the information they need to decide if they would like to take part. They will be told that their involvement in the research is optional and that their decision will not affect their relationship with the practice. Information about the purpose and the nature of the research and what it involves will be included in the letter. If potential participants would like to be involved they can return a reply slip to the student researcher in the stamped addressed envelope. At interview, participants' consent will be sought before the interview begins and consent will be asked to record what is spoken. Patients will be asked for consent before the student observes any consultations, using a card system. They will be given an information sheet before their appointment so they can be fully informed about the purpose of the research before making a decision. Consent for observation of appointments will also be sought from healthcare staff conducting the health checks and results consultations. Healthcare workers will be provided with an information sheet explaining how the appointment observations will be used in the research and they will be given the opportunity to ask the researcher questions. The researcher will let them know that anonymity in written material cannot be guaranteed because the research will only include a small number of health check facilitators.

Risks, burdens and benefits

A benefit of the study is that participants will be helping to further understanding about individual responses and experiences of vascular screening and reasons for acceptance or non-acceptance of a screening invitation. Another benefit of the study is that it gives participants the opportunity to talk about their experiences of the screening process, which is often neglected due to time pressures and conflicts of interest in healthcare settings.

A burden to participants is that they will have give up an hour of their time to invite the researcher to their homes or meet with the researcher in their preferred public location for an 'interview', which sounds quite formal.

Confidentiality

No identifiable data will be included in any of the written material resulting from the research. In writing up the study participants will be given code names and true identities will not be revealed by the student to anyone else, including the supervisory team. The audio-recordings of the interviews will be kept on a password-protected research drive and will not be accessible to anyone other than the student.

If a person is found to be at serious risk and the researcher decides that confidentiality needs to be broken the interviewee will be informed why it is important to break confidentiality, what needs to be revealed and who will be told, for example in a case of abuse the police would need to be informed if specifics were revealed, such as names and dates. Before these specifics were revealed the researcher would, if possible, inform the participant that if any more information is said confidentially would need to be broken. This situation is very unlikely, given the topic of enquiry.

Conflict of interest

The research will be conducted by a non-healthcare professional so conflict of interests between being a researcher and the duties of a healthcare professional are not relevant.

At the end of the study those participants who have requested to see a summary of the final report will be sent one in the post or by email. They will be able to access an electronic copy of the thesis through the Durham University website.

A10. What is the principal research question/objective? Please put this in language comprehensible to a lay person.

The principal research question is: how do participants of risk assessment screening for cardiovascular disease interpret, experience and respond to their invitation to screening, the screening procedures, and the health information they are given?

A11. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.

The secondary question being asked is how is an 'at risk' diagnosis revealed, justified, and explained to participants of the NHS Health Check programme?

A12. What is the scientific justification for the research? Please put this in language comprehensible to a lay person.

The research context of the study

Screening for slow-onset 'lifestyle' diseases raises new questions about understandings of risk. For example, one study of diabetes screening showed that patients who received a diagnosis of diabetes expressed low levels of concern about its implications for their future health, and those who did not receive a diagnosis interpreted this as meaning that they were 'in the clear' (Eborall et al., 2007). Thus, neither group expressed the intention to modify behaviour. These findings were supported by another study of diabetes screening which concluded that a new diagnosis of diabetes was not, in general, experienced as a cause for concern (Adriaanse, et al. 2002). Both these studies demonstrate the problematic nature of organising a successful screening programme, a positive outcome of these programmes were that they generally found participants' sense of wellbeing not to be harmed by their diagnosis, yet this seemed to tie together with negative implications for effecting change in participants' lifestyles. This study will report to facilitators of this screening programme information from patients' perspectives about how their sense of wellbeing has been affected by their diagnosis and whether the scheme has effectively communicated the seriousness of the need for them to change their health-related activities. It is recognised that "The psychological impact of screening reflects, in part, the way that a screening programme is conducted." (Marteau et al., 1996: 581). Thus, it is important to investigate how the design and implementation of this programme affects individuals' interpretation of the screening invitation, responses to screening and their risk diagnosis in both high risk and lesser risk cases.

A number of studies have considered how the choice of words used by health professionals influences patients' interpretations of a diagnosis and health advice in screening scenarios. Marteau et al. (2001) found that choice of words when providing a 'normal' smear test result led to false reassurance, these findings were not supported when a completely different scenario was examined by Paddison et al. (2009), who found no evidence of false reassurance. It will be important to know how healthcare professionals' explanations are perceived and responded to in this screening programme. Participant interpretations of health explanations will be framed by the perspective used in a study about MMR vaccination choices (Poltorak et al., 2005). This study considered how health information was integrated into participants other everyday viewpoints and experiences of life (Ibid.). The research project proposed here draws on this work to examine how what people are told at their 'health check' and follow-up consultation then becomes mingled with their other influences, theories of life and everyday experiences. The implications of these finding for the NHS Health Check programme will then be discussed.

How best to deal with those at high risk of cardiovascular disease was recognised at a consultation seminar for the screening programme as one of the biggest issues facing the implementers of cardiovascular risk assessments (House of Commons, 25 June 2008). Previous work with people of South Asian origin has identified socio-cultural barriers towards effecting change in health-related behaviour, including views on the hereditary nature of heart disease and 'fate' (Netto et al., 2007). However, another study suggested that perceived susceptibility to poor health was not a significant aspect of South Asians' or white Europeans' reasons to not participate in health-related behaviours (Beishon and Nazroo, 1997: 50). Thus, it is important to find out about the responses to the programme from those sub-groups identified at high risk.

It is important for this research to consider how the risk of high risk groups and lesser risk groups is framed by medical practices and how people belonging to these risk groups perceive their risk and views of the future given the medical explanations of their risk factors. For example, how does attributing their risk to genetic, physiological, inherited, or lifestyle causes in the health information provided by the programme affect participants' responses to their diagnosis? Also, how do participants interpret the reasons for asking about family history and lifestyle choices at screening and the measurements taken at screening and how do these interpretations affect their responses to their diagnosis?

In addition, investigating why some people decide not to attend screening is another aspect of the enquiry which might be connected to those at high risk; one study found that those least likely to attend an established screening programme were those most at risk (Leese et al., 2008). A pilot scheme which informed the policy-makers for this vascular screening programme considered screening uptake and found that the people who attended a GP practice infrequently were the least likely to answer an invitation to screening (Goyder, Carlisle et al. 2008: 9). It remains unclear

exactly why people choose not to attend for a 'health check', and so facilitators would like to find out more from the perspectives of the patients who do not attend.

Educational Justifications

This project has an educational and training value. It will provide qualitative research training for a PhD student who wishes to specialise in health research within the social sciences. The study is interdisciplinary as it draws on the boundaries of anthropology, human geography and primary care research to consider the experience of vascular disease risk screening. It draws on work in the medical humanities by considering the ways that the health sciences impart their situated knowledge of disease risk and will consider how disease risk is measured and revealed to patients. The student receives training in all aspects of being a postgraduate researcher through the Durham University Doctoral Training Programme, university events, departmental assessments, and research groups. This research project will give the researcher the chance to put these skills into practice. She has attended courses in using interviews as a research methodology and in ethics to refresh her first degree training in qualitative methodology.

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- Goyder, E., J. Carlisle, et al. (2008). *National Evaluation of DHDS Diabetes Screening Pilot Programme - Final Report*. Sheffield, University of Sheffield.
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- Poltorak, M., M. Leach, et al. (2005). "'MMR talk' and vaccination choices: An ethnographic study in Brighton." *Social Science & Medicine* 61(3): 709-719.

A13. Please give a full summary of your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Participants will be interviewed about their responses to the 'health check' programme and the advice and medical diagnosis they have received as a consequence of the screening process. Participants who are facilitators of the NHS Health Check programme will be interviewed about their viewpoints of the programme and their role within the programme. Each participant will be interviewed once; this interview will last for approximately one hour. Interviews will be undertaken in participants' homes to facilitate openness, with appropriate measures taken to ensure the interviewer's safety. If a participant requests not to be interviewed at home they may suggest a preferred public meeting place. Interviews with healthcare staff may also take place at their workplace. Interviews are a selected aspect of the methodology because the study is looking to find in-depth explanations of experiences and perspectives of the screening programme in which participants have been involved. Rather than testing a hypothesis, interviews will be analysed deductively and inductively. In other words, the researcher will look to the interview responses to answer the already prescribed research questions but what participants say will strongly guide the research themes and research outcomes. During interviews, the interviewer will confirm that her understanding of the points made by participants have not been misinterpreted/ misunderstood.

Observations of appointments will also be undertaken so the researcher can understand how the healthcare staff identify different 'at risk' sub-groups, and how they treat these differences, for example those with a family history of cardiovascular disease or those of South Asian origin. Observations will also provide the researcher with an understanding of what happens during the screening process: such as how it is conducted, what information is given, what instruments are used, and how patients and healthcare workers interact with each other.

All participants will have the choice about whether they would like to be sent a summary of the conclusions from the study, once the thesis has been prepared.

Preliminary Timetable

- Literature review, refine methodology, seek ethics permissions – October 2009 to April 2010
- Observations of consultations – April 2010 to November 2010.
- Interviews will be conducted and transcribed and letters of invitation will be sent out during this period until the required numbers of participants are recruited - April 2010 to January 2011.
- Transcription will continue, interpretation and analysis of findings – January 2011 to August 2011.
- Preparation of thesis – September 2011 to September 2012

Interim analyses/reports will be made to keep the medical practice, funders, and the supervision team informed of the progress of the research. Other interim analyses may include academic publications and conference presentations. The final report will discuss issues of researcher bias and aims to be reflexive about the researcher's involvement in shaping the design, implementation, and outcomes of the research.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

Give details of involvement, or if none please justify the absence of involvement.

We are committed to involving others in different areas of the research. Ways to achieve involvement will become more clear once the researcher is in the field.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Interviews will be held with forty NHS patients who have been screened in the last three months for cardiovascular disease risk and have their results: approximately half of whom will have been given a high risk diagnosis and half a lesser risk diagnosis. Participants will also be recruited on the basis of their ethnic origin: with half being of European origin and half of South Asian origin. Within each ethnic group we will recruit approximately equal numbers of male and female participants. These inclusion criteria apply to assess the role of gender and ethnic identity in interpretations of screening. We also plan to interview ten patients who were invited to be screened but did not take up the invitation, at approximately three months after receiving their first letter inviting them to attend for a health check. Interviews will also be held with health professionals who have facilitated the screenings and the dissemination of screening results. Observations will take place of the routine health checks and/or follow-up appointments of thirty participants who have not yet been assigned a risk category (at the 'health check' stage) or are in any risk category (normally follow-up appointments would only be made for those at high risk).

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Those who have not been invited to screening will be excluded from the study. Vulnerable adults will not be invited to take part because gaining their informed consent would be problematic and the interview methodology requires participants to be able to represent their own interests.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Seeking consent.	1- 2	0	N/A	Healthcare staff at Carmel Medical Practice and Orchard Court Surgery, Darlington will identify participants and send letters of invitation in the post or give the letters to potential participants face-to-face. The letters asking for consent to take part in the study will be written by the chief investigator, but she will not have access to potential participants' addresses until they have given their consent. If there is no reply to the letter the practice staff may have time to make a follow-up telephone call to confirm that potential participants do not want to be involved in the study: it has been previously found that some participants may respond better to the telephone than to letters.
Interviews - these will be recorded (subject to consent) and the recordings will be held securely.	1	0	1hr	Interviews will be conducted by the chief investigator, they will take place at participants' homes. Interviews with practice staff will be conducted at the practice or their homes.
Non-participant observations of the initial health checks with the health care assistant or practice nurse and the follow-up consultations with a GP or nurse.	1/2	All	20mins	Non-participant observations of the appointments taking place as part of the NHS Health Check programme at the two GP practices involved in the study. Permissions for the chief investigator to observe will be sought by the practice staff before the patient starts their appointment.

A21. How long do you expect each participant to be in the study in total?

For all participants whose medical appointment will be observed and/or will be interviewed they would expect their last contact with the research team to be at the end of their appointment/ the interview, unless they request to see the overall results of the research, which will be sent once the PhD thesis has been prepared.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Dr Fuat will monitor the risks throughout the project and make necessary changes to further minimise them.

Participants might become upset during the interview because of the topic of discussion. If this occurs the participant will not be pressured to continue and will be reminded that they can leave the study at any time without any cause for concern about their relationship with the medical practice or the research team. They will be referred back to the medical practice if there is any upsetting issue they would like to further discuss.

The risks of misunderstanding the person/ misinterpretation of their opinions will be dealt with by reiterating answers during interviews or asking for further elaboration.

There is also potential for breach of confidentiality, through identifiable published material and a breach of data security. Code names will always be used and only limited individual case details will ever be discussed or published so that we will never reveal enough information for anyone to guess a participant's identity. All comments from participants used in written or conference materials will be checked to make sure that they contain no identifiable

information. Data will be held securely for only as long as is necessary for this study. Then data will be destroyed using appropriate data destruction software.

An inconvenience of the study to participants is that they will have to give up an hour to invite the researcher to their homes or meet with the researcher in their preferred public location for an 'interview', which sounds quite formal and could cause worry. In participant information literature the term 'interview' will be avoided, instead it will be described as a meeting lasting about one hour where participants will be asked about their impressions of the 'health check' they have recently attended. They could also feel inconvenienced when replying to the initial invitation letter, although it will be reminded to them that taking part in the study is optional. The participants will be told before they agree to take part in the study what the study involves, they can also change their minds about being involved at any time.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

Yes No

If Yes, please give details of procedures in place to deal with these issues:

Participants might become upset during the interview because of the topic of discussion. If this occurs the participant will not be pressured to continue and will be reminded that they can leave the study at any time without any cause for concern about their relationship with the medical practice or the research team. They will be referred back to the medical practice if there is an upsetting issue they would like to further discuss.

Criminal or other disclosures requiring action are unlikely to occur during the study.

A24. What is the potential for benefit to research participants?

There are no therapeutic benefits to this research. Although it could be argued that talking through their feelings and viewpoints with someone may help participants make more sense of their diagnosis. By taking part participants may benefit others in the future who are invited to a cardiovascular disease risk assessment. They will be sincerely thanked for helping the researcher and it is hoped that they will feel valued.

A26. What are the potential risks for the researchers themselves? (if any)

There is a risk to the researcher visiting participants' homes on her own. The researcher's next of kin will always be informed before the interview when interviews will occur or if arrangements change. A text message will be sent before the researcher enters the house and as she leaves so that her next of kin knows that she is safe. A risk assessment has been completed for the Department of Geography, Durham University and has been approved by the Risk Assessment Officer.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).

Potential participants will be reminded in their initial letter of invitation that the researcher is not a member of the NHS and that no aspects of their participation or non-participation in the research will affect their relationship with their GP practice. They will be informed that no information they provide the researcher will be revealed to or identifiable to healthcare staff at the practice. However, they will be told that if they want to raise any issues about the research with Dr Fuat, the GP supervising the conduct of the research, they can contact him by telephone, email or face-to-face at the practice.

Recruitment to the study will be conducted by the two medical practices involved in the study, which will identify participants meeting the criteria. No personal information about those invited will be available to the researcher and the researcher will at no stage have access to medical records. The recruitment material will make no therapeutic promises and it will be emphasised to participants that the student is not a member of the practice and is not able to offer any advice. Participants who raise questions will be referred back to the practice team. Recruitment of participants who are happy for their medical appointment to be observed will also be done through the practice. When patients

arrive for their appointment their consent for the student to observe will be sought.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

Yes No

Please give details below:

Only a member of the patient's existing healthcare team will have access to the patient medical records stored at the practice that are to be used to recruit participants meeting the set criteria.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

Yes No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

Yes No

A29. How and by whom will potential participants first be approached?

Letters inviting participation in the study, which will include the participant information sheet and a stamped addressed reply envelope will be sent by post to potential participants by the medical practice. These letters will also be handed to patients by practice staff while they are attending the practice for the NHS Health Check scheme. A member of the healthcare team will identify participants meeting the criteria. Healthcare staff will be recruited directly by the student researcher, who will give them an invitation 'pack', containing a letter, information sheet, and envelope.

A30-1. Will you obtain informed consent from or on behalf of research participants?

Yes No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Consent from adult participants will be required. This will be recorded on the consent form before the interview commences and after the researcher has verbally summarised the research and participants have been given the chance to ask the researcher questions. Participants will receive details about what the study involves when they receive their invitation to the study. This will give them the opportunity to see exactly what being involved in the study entails and will allow them time to think about whether or not they want to take part.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

Yes No

A31. How long will you allow potential participants to decide whether or not to take part?

For participants invited to interview: after they receive an initial letter they will be given three weeks to respond before it might be possible for a member of their healthcare team at the medical practice to make a follow-up telephone call.

The telephone call will simply ask whether or not the potential participant would like to be involved so as not to coerce participants into something they do not want to do. This telephone call is designed to give those who do not respond to letters a second opportunity to take part in the research.

When the student observes consultations, it is only felt necessary to ask participants when they arrive for their appointments because no personal information from these appointments will be used in the research and no recordings will be made. The main purpose of the observations are to reflect on the work of the medical team, the setting, ways of thinking, decision-making, procedures, communication, and instruments; not the individual cases. These participants will be given a short information sheet while they wait for their appointment so they know why the student wants to observe their consultation and can make an informed decision about whether or not they would like to take part in this stage of the research. These participants will not be coerced into being interviewed, but if they give permission for the student to observe they will be given the invitation to interview by healthcare staff.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)

In some cases it will be necessary for interviews to take place in a South Asian language and in these cases an interpreter/translator will be employed. However, most of the South Asian members of the practice do understand written and spoken English.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

- The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?(Tick as appropriate)

- Access to medical records by those outside the direct healthcare team
- Electronic transfer by magnetic or optical media, email or computer networks
- Sharing of personal data with other organisations
- Export of personal data outside the EEA
- Use of personal addresses, postcodes, faxes, emails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:
- Manual files including X-rays
- NHS computers

- Home or other personal computers
- University computers
- Private company computers
- Laptop computers

Further details:

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Overall, ethical issues concerning anonymity of participants and confidentiality of information divulged will be handled in accordance with the British Sociological Association guidelines and the NHS Confidentiality guidelines. Transcriptions will be done by the chief investigator in a private setting wearing ear-phones. In all cases true identities will not be revealed by the student to anyone else, including the supervisory team. In all written work resulting from the research, participants will be given code names and will not be identifiable from any other information mentioned about their case histories. Publication of direct quotations, or other information provided by participants will be anonymised and care will be taken to ensure that no other information published allows participants to be identified, such as the combination of gender, age, ethnicity, and location.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The chief investigator will be the only person with access to the audio recordings and other personal data generated as part of the research. She will transcribe these, give participants code names and delete any other identifiable information before other members of the supervisory team are able to help with coding by reading and commenting on transcriptions. Participants will be asked to give their consent for the recording and transcription to occur before their interview.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months
- 3 – 6 months
- 6 – 12 months
- 12 months – 3 years
- Over 3 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

- Yes No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

- Yes No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

Yes No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

Yes No

Please give details, or justify if not registering the research.

The protocol will be published in the NHS health check resource library.

A51. How do you intend to report and disseminate the results of the study? Tick as appropriate:

- Peer reviewed scientific journals
- Internal report
- Conference presentation
- Publication on website
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- No plans to report or disseminate the results
- Other (please specify)

A53. Will you inform participants of the results?

Yes No

Please give details of how you will inform participants or justify if not doing so.

Participants will be asked if they would like to be on the mailing list to be sent a summary of results by post or email. Participants will also be informed that there will be online access to the final thesis through the Durham University website. NHS County Durham and NHS Darlington will also be sent details of the results of the study and their implications for future implementation of their screening programme. These results will also be shared with other people involved in cardiovascular screening programmes around the United Kingdom via the 'NHS Health Check Resource Library' provided by the NHS Improvement Programme.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? Tick as appropriate:

- Independent external review

- Review within a company
- Review within a multi-centre research group
- Review within the Chief Investigator's institution or host organisation
- Review within the research team
- Review by educational supervisor
- Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

Three academic supervisors from three different fields: geography, anthropology, and medicine have contributed to the design and review of the study to ensure that the proposal has identified a valid research question and is suitably designed, taking into account the limitations of time and resources.

The project has also been reviewed by the Economic and Social Research Council as part of a funding application, please see documentary evidence of the feedback from this review.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 80
 Total international sample size (including UK): 0
 Total in European Economic Area: 0

Further details:

Approximately fifty participants will be interviewed.
 Approximately thirty participants will take part in the screening/consultation observations stage of research.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

It was decided that fifty interviews and thirty observations would be a feasible number for the researcher to undertake in the timescale given for the PhD. The number is deemed to be sufficient to achieve worthwhile results without involving unnecessary recruitment and burdens for participants. After consulting other researchers and considering other qualitative studies it was also decided that this number would provide a good range of opinions and viewpoints without responses being repeated too much.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The themes and categories will be found using both deductive and inductive approaches: this means that themes will be informed by both the research questions and participants' interview responses. The research will involve concurrent data collection and analysis, together with systematic efforts to check and refine categories of data. The student will meet regularly with the supervisory team in order to discuss and agree these categories. Interviews will be digitally recorded and transcribed, and NVIVO, a qualitative indexing package, will be used to help with data coding and retrieval.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

Title Forename/Initials Surname
Dr Sarah Atkinson

Post Reader in the Department of Geography

Qualifications BA Anthropology (Dunelm)
MSc Human Nutrition (LSHTM, London)
PhD Anthropology (Dunelm)

Employer Durham University

Work Address Durham University Department of Geo
Science Laboratories
South Road, Durham

Post Code DH13LE

Telephone 01913341871

Fax 01913341801

Mobile

Work Email s.j.atkinson@durham.ac.uk

Title Forename/Initials Surname
Dr Tessa M. Pollard

Post Senior Lecturer in the Department of Anthropology

Qualifications BA Human Sciences (Oxford)
MSc Human Biology (Oxford)
PhD Anthropology (Oxford)

Employer Durham University

Work Address Department of Anthropology Durham U
Dawson Building
South Road, Durham

Post Code DH1 3LE

Telephone 01913341623

Fax 01913341615

Mobile

Work Email t.m.pollard@durham.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

- Status: NHS or HSC care organisation
 Academic
 Pharmaceutical industry
 Medical device industry
 Local Authority
 Other social care provider (including voluntary sector or private organisation)
 Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation Research Management & Governance Unit
 Given name Richard
 Family name Errington
 Address NHS County Durham and Darlington
 Town/city John Snow House
 Post code DH1 3YG
 Country UNITED KINGDOM
 Telephone 01913744211
 Fax
 E-mail richard.errington@nhs.net

Is the sponsor based outside the UK?

Yes No

Where the lead sponsor is not established within the UK, a legal representative in the UK may need to be appointed. Please consult the guidance notes.

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

Yes No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Mr	Richard	Errington
Organisation	County Durham Primary Care Trust		
Address	John Snow House University Science Park Durham		
Post Code	DH13YG		
Work Email	richard.errington@nhs.net		
Telephone	01913744211		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>

A69-1. How long do you expect the study to last in the UK?

Planned start date: 05/10/2009

Planned end date: 28/09/2012

Total duration:

Years: 3 Months: 0 Days: 0

A71-1. Is this study?

- Single centre
 Multicentre

A71-2. Where will the research take place? (Tick as appropriate)

- England
 Scotland
 Wales
 Northern Ireland
 Other countries in European Economic Area

Total UK sites in study 2

Does this trial involve countries outside the EU?

- Yes No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:

- NHS organisations in England
 NHS organisations in Wales
 NHS organisations in Scotland
 HSC organisations in Northern Ireland
 GP practices in England 2
 GP practices in Wales
 GP practices in Scotland
 GP practices in Northern Ireland
 Social care organisations
 Phase 1 trial units
 Prison establishments
 Probation areas
 Independent hospitals
 Educational establishments
 Independent research units
 Other (give details)

Total UK sites in study: 2

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? Please tick box(es) as applicable.

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (NHS sponsors only)
- Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- Other insurance or indemnity arrangements will apply (give details below)

See copy of Durham University's insurance certificate showing employer's liability for the University protocol authors. Durham University has in force a Policy providing legal liability cover and the activities here are included within that coverage.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

Research site		Investigator/ Collaborator/ Contact	
Institution name	Durham and Darlington PCT	Title	Dr
Department name	Carmel Medical Practice	First name/ Initials	Ahmet
Street address	Nunnery Lane	Surname	Fuat
Town/city	Darlington		
Post Code	DL38SQ		

Institution name Durham and Darlington PCT
Department name Orchard Court Surgery
Street address Orchard Road
Town/city Darlington
Post Code DL36HZ

Title Mrs
First name/
Initials Karen
Surname Fuat

PART D: Declarations**D1. Declaration by Chief Investigator**

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
 - Will be held by the main REC or the GTAC (as applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
 - May be disclosed to the operational managers of review bodies, or the appointing authority for the main REC, in order to check that the application has been processed correctly or to investigate any complaint.
 - May be seen by auditors appointed to undertake accreditation of RECs.
 - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- Chief Investigator
 Sponsor
 Study co-ordinator

- Student
- Other – please give details
- None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature:

Print Name: ELIZABETH STRUTT

Date: 12/03/2010 (dd/mm/yyyy)

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

This section was signed electronically by Richard Errington on 12/03/2010 01:22.

Job Title/Post: Research Governance Lead
Organisation: NHS County Durham and Darlington
Email: richard.errington@nhs.net

D3. Declaration for student projects by academic supervisor

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.
2. I undertake to fulfil the responsibilities of the Chief Investigator and the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.
3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.
4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Signature:

Print Name: DR. SARAH ATKINSON

Post: READER IN HUMAN GEOGRAPHY

Organisation: DURHAM UNIVERSITY

Date: 12/03/2010 (dd/mm/yyyy)

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)

Revealing and experiencing an at risk diagnosis: NHS Health Checks v.1

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial or clinical investigation
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples, other human biological samples and/or data (*specific project only*)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located? (*Tick all that apply*)

- England
- Scotland
- Wales
- Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
- Scotland

- Wales
 Northern Ireland
 This study does not involve the NHS

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
 Social Care Research Ethics Committee
 Research Ethics Committee
 National Information Governance Board for Health and Social Care (NIGB)
 Ministry of Justice (MoJ)

5. Will any research sites in this study be NHS organisations?

- Yes No

5a. Do you want your application to be processed through the NIHR Coordinated System for gaining NHS Permission?

- Yes No

If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

6. Do you plan to include any participants who are children?

- Yes No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? The guidance notes explain how an adult is defined for this purpose.

- Yes No

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?

- Yes No

9. Is the study, or any part of the study, being undertaken as an educational project?

- Yes No

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

- Yes No

10. Is this project financially supported by the United States Department for Health and Human Services?

- Yes No

11. Will identifiable patient data be accessed outside the clinical care team without prior consent at any stage of the project (including identification of potential participants)?

- Yes No

Integrated Research Application System

Application Form for Research involving qualitative methods only

NHS/HSC R&D Form (project information)

Please refer to the *Submission and Checklist* tabs for instructions on submitting R&D applications.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting [Help](#).

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Revealing and experiencing an at risk diagnosis: NHS Health Checks v.1

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Revealing and experiencing an 'at risk' diagnosis: implementing the National Health Service Health Check programme in general practice (v.1)

A2-1. Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctor of Philosophy (PhD)

Name of educational establishment:
Durham University

Name and contact details of academic supervisor:

	Title	Forename/Initials	Surname
	Dr	Sarah	Atkinson
Address	Durham University Department of Geo Science Laboratories South Road, Durham		
Post Code	DH13LE		
E-mail	s.j.atkinson@durham.ac.uk		
Telephone	01913341871		
Fax	01913341801		

Name and contact details of student:

	Title	Forename/Initials	Surname
	Ms	Elizabeth	Strutt
Address	20 Bainbridge Street Carrville Durham		

Post Code	DH1 1NA
E-mail	elizabeth.strutt@durham.ac.uk
Telephone	07922585895
Fax	

A copy of a current CV for the student (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- Student
 Academic supervisor
 Other

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Ms Elizabeth Strutt
Post	Research Postgraduate (PhD)
Qualifications	BA (Hons) Dunelm
Employer	Student
Work Address	Department of Geography Durham University South Road, Durham
Post Code	DH13LE
Work E-mail	elizabeth.strutt@durham.ac.uk
* Personal E-mail	
Work Telephone	01913844567
* Personal Telephone/Mobile	07922585895
Fax	01913341801

* This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?

This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title Forename/Initials Surname
	Dr Ahmet Fuat
Address	Carmel Medical Practice Nunnery Lane Darlington, Co. Durham
Post Code	DL3 8SQ
E-mail	ahmetfuat@nhs.net
Telephone	01325341411
Fax	01325381834

A5-1. Research reference numbers. Please give any relevant references for your study:

Applicant's/organisation's own reference number, e.g. R & D (if available): N/A
 Sponsor's/protocol number: N/A
 Protocol Version: N/A
 Protocol Date:
 Funder's reference number: N/A
 International Standard Randomised Controlled Trial Number (ISRCTN): N/A
 ClinicalTrials.gov Identifier (NCT number): N/A
 European Clinical Trials Database (EudraCT) number: N/A
 Project website: N/A

Ref.Number	Description	Reference Number
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A5-2. Is this application linked to a previous study or another current application?

Yes No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. This summary will be published on the website of the National Research Ethics Service following the ethical review.*

Revealing and experiencing an 'at risk' diagnosis: implementing the NHS Health Check programme

The research question is: how do participants of risk assessment screening for vascular disease interpret, experience and respond to their invitation to screening, the screening procedures, and the health information they are given? It is important to conduct this research because it gives patients and healthcare staff the chance to give their opinion. It will raise more awareness useful to those implementing health checks about why some people do not attend and how other patients receive and explain the screening procedure and health advice in light of their wider lives and everyday experiences. This has great potential to benefit patients in the future by leading to more targeted health interventions.

The study will be recruiting adult participants from two medical practices, in Darlington, who have been routinely invited to have a 'health check' and a results appointment. The study comprises observation of approximately thirty of these appointments. Fifty participants will also be recruited to take part in an informal interview lasting one hour in each of their homes. Twenty interview participants will have been given a high risk diagnosis and twenty a lesser risk diagnosis. Ten participants will be interviewed who declined the screening invitation. We intend to recruit an equal mix of male and female participants, of European and South Asian origin. Healthcare staff will also be interviewed. The final contact each participant will have with the researcher is at their observation or interview, unless the participant wishes to be contacted at the end of the study to receive information about the findings.

The study is part of a PhD programme which runs from October 2009 to September 2012 and is funded by ONE North East and Durham University. Fieldwork will be completed from April 2010 to January 2011.

A6-2. Summary of main issues. *Please summarise the main ethical and design issues arising from the study and say how you have addressed them.*

Purpose and design

The research has three main purposes. One (a): to provide more insight into the experiences and responses to cardiovascular disease risk assessment screening and diagnosis in participants who have been medically identified as at risk of cardiovascular disease, in comparison to those who are identified at lesser risk. One (b): to explore how

medical professionals identify, explain, approach and treat the varying risk factors which put different patients at high risk or at lesser risk. This aspect explores why and how medical practices reveal an 'at risk' diagnosis and links with purpose one (a) to consider how the medical framing of risk factors are perceived by participants. Two: to provide information on the factors affecting the uptake of screening, from the perspective of those who decline the invitation to be screened and those who attend. Three: to identify the ways in which the information provided at screening is interpreted and becomes merged into a person's sense of self and their wider theories on life and expectations for the future. The project will assess the implications of all these findings for the practical implementation of the screening programme.

The ways these three purposes will be achieved will involve:

1) Observations -

People aged 40 to 74 will be invited to the practice routinely to take part in the NHS Health Check programme, which involves a 'health check' and a follow-up/results consultation. The study comprises observation of approximately thirty of these routine appointments, the people observed could belong to any of the risk groups. This aspect of the study looks at how the screenings are conducted and the results are presented. It will analyse the space in which the health interventions take place, the meanings of equipment used, the reasoning behind procedures, the decisions taken by healthcare workers, and the negotiation of knowledge and power in interactions between patient and health professionals. It provides information for purpose one (b).

2) Interviews -

The first criteria for recruitment to interviews will target ten people, both men and women, who have declined an invitation to screening, approximately five of South Asian origin and five of European origin. This is in order to provide information on the factors affecting screening uptake, considering the cultural and gender dimensions to reasoning. These interviews will provide information to answer purpose two.

The second criteria for recruitment to interviews will target forty people, both men and women of South Asian and European origin who have attended screening and been given their results. Twenty of these participants will be selected from the high risk group. The remaining twenty participants will be selected from the lesser risk groups. These interviews aim to provide more insight into the experiences and responses, to an NHS Health Check, of those who have been screened and given a risk diagnosis. It provides information directly for purposes one (a), two, and three.

The third criteria for recruitment to interviews will target members of the healthcare team involved in the 'health checks' at Carmel Medical Practice and Orchard Court Surgery in Darlington. It will provide information for purpose one (b). Members of the healthcare team will be asked to describe what they do as part of the 'Health Check' programme, why this is done, their viewpoints about the programme, and we will find out what the healthcare team would like to know about patient experiences of the screening programme.

In developing the proposal the postgraduate student and chief investigator of the study, Elizabeth Strutt, has drawn contributions from Dr A. Fuat, Dr T. Pollard, and Dr S. Atkinson. Dr A. Fuat is a General Practitioner (cardiology specialist) and Clinical Senior Lecturer in the Centre for Integrated Health Care Research, Durham University. Dr T. Pollard is a Senior Lecturer in the Department of Anthropology, at Durham University, whose main research interest is in working to explain why some groups of people, especially those of South Asian origin living in the UK, have very high rates of metabolic diseases. Her specialism in looking to improve understanding of health and lifestyle behaviours is of particular relevance to the study. Dr S. Atkinson, a Reader in the Department of Geography at Durham University, has also contributed to the design of the study, her interest in health policy discourse and practice at local and global scales has also helped in the design of the study.

Recruitment

Letters inviting participation in the study will be given to potential participants while attending their practice for a 'health check' or sent out by post. Members of staff working at the two medical practices involved in the study will identify participants meeting the criteria and provide them with the letter of invitation to join the study. Healthcare staff will be handed their letter of invitation and information sheet by the student researcher, whilst she is visiting the practice where they work. No personal information about those invited will be available to the researcher and the researcher will at no stage have access to medical records. The person invited will be asked to return a reply slip if they are happy to take part in the study, once the reply slip is returned the researcher will be given the name, address, and telephone number of the recruited participant. The recruitment material will make no therapeutic promises and it will be emphasised to participants that the student is not a member of the practice and is not able to offer any advice. Participants who raise questions will be referred back to the practice team. Recruitment of participants who are happy for their medical appointment to be observed will also be done through their medical practice. When patients arrive for their appointment their consent for the student to observe will be sought.

Inclusion / exclusion

Only those individuals who have been invited for screening and have received their results in the last three months will be invited to take part in the study (n=40). Men and women of South Asian ethnicity and of European origin will be invited to take part in the study, from both the high risk and lesser risk groups. Also a small number of those who have been invited for screening and sent reminder letters but still have not attended approximately three months later will be invited to take part (n=10). Letters inviting participation in the study will not be sent to vulnerable individuals. These

individuals will be excluded from the study because gaining their consent would be problematic and the interview methodology requires that participants can represent their own interests.

Consent

Research will be conducted with full consents. A letter of invitation, information sheet, and stamped addressed reply envelope will be sent to potential participants at their home addresses or handed to them whilst attending the practice for an NHS Health Check appointment. This invitation 'pack' will give them the information they need to decide if they would like to take part. They will be told that their involvement in the research is optional and that their decision will not affect their relationship with the practice. Information about the purpose and the nature of the research and what it involves will be included in the letter. If potential participants would like to be involved they can return a reply slip to the student researcher in the stamped addressed envelope. At interview, participants' consent will be sought before the interview begins and consent will be asked to record what is spoken. Patients will be asked for consent before the student observes any consultations, using a card system. They will be given an information sheet before their appointment so they can be fully informed about the purpose of the research before making a decision.

Consent for observation of appointments will also be sought from healthcare staff conducting the health checks and results consultations. Healthcare workers will be provided with an information sheet explaining how the appointment observations will be used in the research and they will be given the opportunity to ask the researcher questions. The researcher will let them know that anonymity in written material cannot be guaranteed because the research will only include a small number of health check facilitators.

Risks, burdens and benefits

A benefit of the study is that participants will be helping to further understanding about individual responses and experiences of vascular screening and reasons for acceptance or non-acceptance of a screening invitation. Another benefit of the study is that it gives participants the opportunity to talk about their experiences of the screening process, which is often neglected due to time pressures and conflicts of interest in healthcare settings.

A burden to participants is that they will have give up an hour of their time to invite the researcher to their homes or meet with the researcher in their preferred public location for an 'interview', which sounds quite formal.

Confidentiality

No identifiable data will be included in any of the written material resulting from the research. In writing up the study participants will be given code names and true identities will not be revealed by the student to anyone else, including the supervisory team. The audio-recordings of the interviews will be kept on a password-protected research drive and will not be accessible to anyone other than the student.

If a person is found to be at serious risk and the researcher decides that confidentiality needs to be broken the interviewee will be informed why it is important to break confidentiality, what needs to be revealed and who will be told, for example in a case of abuse the police would need to be informed if specifics were revealed, such as names and dates. Before these specifics were revealed the researcher would, if possible, inform the participant that if any more information is said confidentially would need to be broken. This situation is very unlikely, given the topic of enquiry.

Conflict of interest

The research will be conducted by a non-healthcare professional so conflict of interests between being a researcher and the duties of a healthcare professional are not relevant.

At the end of the study those participants who have requested to see a summary of the final report will be sent one in the post or by email. They will be able to access an electronic copy of the thesis through the Durham University website.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. Please tick all that apply:

- Case series/ case note review
- Case control
- Cohort observation
- Controlled trial without randomisation
- Cross-sectional study
- Database analysis
- Epidemiology

- Feasibility/ pilot study
- Laboratory study
- Metanalysis
- Qualitative research
- Questionnaire, interview or observation study
- Randomised controlled trial
- Other (please specify)

A10. What is the principal research question/objective? Please put this in language comprehensible to a lay person.

The principal research question is: how do participants of risk assessment screening for cardiovascular disease interpret, experience and respond to their invitation to screening, the screening procedures, and the health information they are given?

A11. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.

The secondary question being asked is how is an 'at risk' diagnosis revealed, justified, and explained to participants of the NHS Health Check programme?

A12. What is the scientific justification for the research? Please put this in language comprehensible to a lay person.

The research context of the study

Screening for slow-onset 'lifestyle' diseases raises new questions about understandings of risk. For example, one study of diabetes screening showed that patients who received a diagnosis of diabetes expressed low levels of concern about its implications for their future health, and those who did not receive a diagnosis interpreted this as meaning that they were 'in the clear' (Eborall et al., 2007). Thus, neither group expressed the intention to modify behaviour. These findings were supported by another study of diabetes screening which concluded that a new diagnosis of diabetes was not, in general, experienced as a cause for concern (Adriaanse, et al. 2002). Both these studies demonstrate the problematic nature of organising a successful screening programme, a positive outcome of these programmes were that they generally found participants' sense of wellbeing not to be harmed by their diagnosis, yet this seemed to tie together with negative implications for effecting change in participants' lifestyles. This study will report to facilitators of this screening programme information from patients' perspectives about how their sense of wellbeing has been affected by their diagnosis and whether the scheme has effectively communicated the seriousness of the need for them to change their health-related activities. It is recognised that "The psychological impact of screening reflects, in part, the way that a screening programme is conducted." (Marteau et al., 1996: 581). Thus, it is important to investigate how the design and implementation of this programme affects individuals' interpretation of the screening invitation, responses to screening and their risk diagnosis in both high risk and lesser risk cases.

A number of studies have considered how the choice of words used by health professionals influences patients' interpretations of a diagnosis and health advice in screening scenarios. Marteau et al. (2001) found that choice of words when providing a 'normal' smear test result led to false reassurance, these findings were not supported when a completely different scenario was examined by Paddison et al. (2009), who found no evidence of false reassurance. It will be important to know how healthcare professionals' explanations are perceived and responded to in this screening programme. Participant interpretations of health explanations will be framed by the perspective used in a study about MMR vaccination choices (Poltorak et al., 2005). This study considered how health information was integrated into participants other everyday viewpoints and experiences of life (Ibid.). The research project proposed here draws on this work to examine how what people are told at their 'health check' and follow-up consultation then becomes mingled with their other influences, theories of life and everyday experiences. The implications of these finding for the NHS Health Check programme will then be discussed.

How best to deal with those at high risk of cardiovascular disease was recognised at a consultation seminar for the screening programme as one of the biggest issues facing the implementers of cardiovascular risk assessments (House of Commons, 25 June 2008). Previous work with people of South Asian origin has identified socio-cultural barriers towards effecting change in health-related behaviour, including views on the hereditary nature of heart disease and 'fate' (Netto et al., 2007). However, another study suggested that perceived susceptibility to poor health was not a significant aspect of South Asians' or white Europeans' reasons to not participate in health-related behaviours (Beishon and Nazroo, 1997: 50). Thus, it is important to find out about the responses to the programme from those sub-groups identified at high risk.

It is important for this research to consider how the risk of high risk groups and lesser risk groups is framed by medical practices and how people belonging to these risk groups perceive their risk and views of the future given the medical explanations of their risk factors. For example, how does attributing their risk to genetic, physiological, inherited, or lifestyle causes in the health information provided by the programme affect participants' responses to their diagnosis? Also, how do participants interpret the reasons for asking about family history and lifestyle choices at screening and the measurements taken at screening and how do these interpretations affect their responses to their diagnosis?

In addition, investigating why some people decide not to attend screening is another aspect of the enquiry which might be connected to those at high risk; one study found that those least likely to attend an established screening programme were those most at risk (Leese et al., 2008). A pilot scheme which informed the policy-makers for this vascular screening programme considered screening uptake and found that the people who attended a GP practice infrequently were the least likely to answer an invitation to screening (Goyder, Carlisle et al. 2008: 9). It remains unclear exactly why people choose not to attend for a 'health check', and so facilitators would like to find out more from the perspectives of the patients who do not attend.

Educational Justifications

This project has an educational and training value. It will provide qualitative research training for a PhD student who wishes to specialise in health research within the social sciences. The study is interdisciplinary as it draws on the boundaries of anthropology, human geography and primary care research to consider the experience of vascular disease risk screening. It draws on work in the medical humanities by considering the ways that the health sciences impart their situated knowledge of disease risk and will consider how disease risk is measured and revealed to patients. The student receives training in all aspects of being a postgraduate researcher through the Durham University Doctoral Training Programme, university events, departmental assessments, and research groups. This research project will give the researcher the chance to put these skills into practice. She has attended courses in using interviews as a research methodology and in ethics to refresh her first degree training in qualitative methodology.

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A13. Please give a full summary of your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Participants will be interviewed about their responses to the 'health check' programme and the advice and medical diagnosis they have received as a consequence of the screening process. Participants who are facilitators of the NHS Health Check programme will be interviewed about their viewpoints of the programme and their role within the programme. Each participant will be interviewed once; this interview will last for approximately one hour. Interviews will be undertaken in participants' homes to facilitate openness, with appropriate measures taken to ensure the interviewer's safety. If a participant requests not to be interviewed at home they may suggest a preferred public meeting place. Interviews with healthcare staff may also take place at their workplace. Interviews are a selected aspect of the

methodology because the study is looking to find in-depth explanations of experiences and perspectives of the screening programme in which participants have been involved. Rather than testing a hypothesis, interviews will be analysed deductively and inductively. In other words, the researcher will look to the interview responses to answer the already prescribed research questions but what participants say will strongly guide the research themes and research outcomes. During interviews, the interviewer will confirm that her understanding of the points made by participants have not been misinterpreted/ misunderstood.

Observations of appointments will also be undertaken so the researcher can understand how the healthcare staff identify different 'at risk' sub-groups, and how they treat these differences, for example those with a family history of cardiovascular disease or those of South Asian origin. Observations will also provide the researcher with an understanding of what happens during the screening process: such as how it is conducted, what information is given, what instruments are used, and how patients and healthcare workers interact with each other.

All participants will have the choice about whether they would like to be sent a summary of the conclusions from the study, once the thesis has been prepared.

Preliminary Timetable

-Literature review, refine methodology, seek ethics permissions – October 2009 to April 2010

-Observations of consultations – April 2010 to November 2010.

-Interviews will be conducted and transcribed and letters of invitation will be sent out during this period until the required numbers of participants are recruited - April 2010 to January 2011.

-Transcription will continue, interpretation and analysis of findings – January 2011 to August 2011.

-Preparation of thesis – September 2011 to September 2012

Interim analyses/reports will be made to keep the medical practice, funders, and the supervision team informed of the progress of the research. Other interim analyses may include academic publications and conference presentations. The final report will discuss issues of researcher bias and aims to be reflexive about the researcher's involvement in shaping the design, implementation, and outcomes of the research.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

Give details of involvement, or if none please justify the absence of involvement.

We are committed to involving others in different areas of the research. Ways to achieve involvement will become more clear once the researcher is in the field.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- Blood
- Cancer
- Cardiovascular
- Congenital Disorders
- Dementias and Neurodegenerative Diseases

- Diabetes
-
- Eye
- Generic Health Relevance
- Infection
- Inflammatory and Immune System
- Injuries and Accidents
- Mental Health
- Metabolic and Endocrine
- Musculoskeletal
- Neurological
- Oral and Gastrointestinal
- Paediatrics
- Renal and Urogenital
- Reproductive Health and Childbirth
- Respiratory
- Skin
- Stroke

Gender: Male and female participants

Lower age limit: 40 Years

Upper age limit: 74 Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Interviews will be held with forty NHS patients who have been screened in the last three months for cardiovascular disease risk and have their results: approximately half of whom will have been given a high risk diagnosis and half a lesser risk diagnosis. Participants will also be recruited on the basis of their ethnic origin: with half being of European origin and half of South Asian origin. Within each ethnic group we will recruit approximately equal numbers of male and female participants. These inclusion criteria apply to assess the role of gender and ethnic identity in interpretations of screening. We also plan to interview ten patients who were invited to be screened but did not take up the invitation, at approximately three months after receiving their first letter inviting them to attend for a health check. Interviews will also be held with health professionals who have facilitated the screenings and the dissemination of screening results. Observations will take place of the routine health checks and/or follow-up appointments of thirty participants who have not yet been assigned a risk category (at the 'health check' stage) or are in any risk category (normally follow-up appointments would only be made for those at high risk).

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Those who have not been invited to screening will be excluded from the study. Vulnerable adults will not be invited to take part because gaining their informed consent would be problematic and the interview methodology requires participants to be able to represent their own interests.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?

3. Average time taken per intervention/procedure (minutes, hours or days)

4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Seeking consent.	1- 2	0	N/A	Healthcare staff at Carmel Medical Practice and Orchard Court Surgery, Darlington will identify participants and send letters of invitation in the post or give the letters to potential participants face-to-face. The letters asking for consent to take part in the study will be written by the chief investigator, but she will not have access to potential participants' addresses until they have given their consent. If there is no reply to the letter the practice staff may have time to make a follow-up telephone call to confirm that potential participants do not want to be involved in the study: it has been previously found that some participants may respond better to the telephone than to letters.
Interviews - these will be recorded (subject to consent) and the recordings will be held securely.	1	0	1hr	Interviews will be conducted by the chief investigator, they will take place at participants' homes. Interviews with practice staff will be conducted at the practice or their homes.
Non-participant observations of the initial health checks with the health care assistant or practice nurse and the follow-up consultations with a GP or nurse.	1/2	All	20mins	Non-participant observations of the appointments taking place as part of the NHS Health Check programme at the two GP practices involved in the study. Permissions for the chief investigator to observe will be sought by the practice staff before the patient starts their appointment.

A21. How long do you expect each participant to be in the study in total?

For all participants whose medical appointment will be observed and/or will be interviewed they would expect their last contact with the research team to be at the end of their appointment/ the interview, unless they request to see the overall results of the research, which will be sent once the PhD thesis has been prepared.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Dr Fuat will monitor the risks throughout the project and make necessary changes to further minimise them.

Participants might become upset during the interview because of the topic of discussion. If this occurs the participant will not be pressured to continue and will be reminded that they can leave the study at any time without any cause for concern about their relationship with the medical practice or the research team. They will be referred back to the medical practice if there is any upsetting issue they would like to further discuss.

The risks of misunderstanding the person/ misinterpretation of their opinions will be dealt with by reiterating answers during interviews or asking for further elaboration.

There is also potential for breach of confidentiality, through identifiable published material and a breach of data security. Code names will always be used and only limited individual case details will ever be discussed or published so that we will never reveal enough information for anyone to guess a participant's identity. All comments from participants used in written or conference materials will be checked to make sure that they contain no identifiable information. Data will be held securely for only as long as is necessary for this study. Then data will be destroyed using appropriate data destruction software.

An inconvenience of the study to participants is that they will have give up an hour to invite the researcher to their homes or meet with the researcher in their preferred public location for an 'interview', which sounds quite formal and could cause worry. In participant information literature the term 'interview' will be avoided, instead it will be described as a meeting lasting about one hour where participants will be asked about their impressions of the 'health check' they have recently attended. They could also feel inconvenienced when replying to the initial invitation letter, although it

will be reminded to them that taking part in the study is optional. The participants will be told before they agree to take part in the study what the study involves, they can also change their minds about being involved at any time.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

Yes No

If Yes, please give details of procedures in place to deal with these issues:

Participants might become upset during the interview because of the topic of discussion. If this occurs the participant will not be pressured to continue and will be reminded that they can leave the study at any time without any cause for concern about their relationship with the medical practice or the research team. They will be referred back to the medical practice if there is an upsetting issue they would like to further discuss.

Criminal or other disclosures requiring action are unlikely to occur during the study.

A24. What is the potential for benefit to research participants?

There are no therapeutic benefits to this research. Although it could be argued that talking through their feelings and viewpoints with someone may help participants make more sense of their diagnosis. By taking part participants may benefit others in the future who are invited to a cardiovascular disease risk assessment. They will be sincerely thanked for helping the researcher and it is hoped that they will feel valued.

A26. What are the potential risks for the researchers themselves? (if any)

There is a risk to the researcher visiting participants' homes on her own. The researcher's next of kin will always be informed before the interview when interviews will occur or if arrangements change. A text message will be sent before the researcher enters the house and as she leaves so that her next of kin knows that she is safe. A risk assessment has been completed for the Department of Geography, Durham University and has been approved by the Risk Assessment Officer.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).

Potential participants will be reminded in their initial letter of invitation that the researcher is not a member of the NHS and that no aspects of their participation or non-participation in the research will affect their relationship with their GP practice. They will be informed that no information they provide the researcher will be revealed to or identifiable to healthcare staff at the practice. However, they will be told that if they want to raise any issues about the research with Dr Fuat, the GP supervising the conduct of the research, they can contact him by telephone, email or face-to-face at the practice.

Recruitment to the study will be conducted by the two medical practices involved in the study, which will identify participants meeting the criteria. No personal information about those invited will be available to the researcher and the researcher will at no stage have access to medical records. The recruitment material will make no therapeutic promises and it will be emphasised to participants that the student is not a member of the practice and is not able to offer any advice. Participants who raise questions will be referred back to the practice team. Recruitment of participants who are happy for their medical appointment to be observed will also be done through the practice. When patients arrive for their appointment their consent for the student to observe will be sought.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

Yes No

Please give details below:

Only a member of the patient's existing healthcare team will have access to the patient medical records stored at the practice that are to be used to recruit participants meeting the set criteria.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants. Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.

There will be no breach of any duty of confidentiality as the researcher will only be provided with consenting participants' address details, the researcher will never have access to their medical records. The address details of participants will only be provided to the researcher once the participant has given their consent for the practice to pass on their address details and has agreed to take part in the research, by returning a reply slip.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

Yes No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

Yes No

A29. How and by whom will potential participants first be approached?

Letters inviting participation in the study, which will include the participant information sheet and a stamped addressed reply envelope will be sent by post to potential participants by the medical practice. These letters will also be handed to patients by practice staff while they are attending the practice for the NHS Health Check scheme. A member of the healthcare team will identify participants meeting the criteria. Healthcare staff will be recruited directly by the student researcher, who will give them an invitation 'pack', containing a letter, information sheet, and envelope.

A30-1. Will you obtain informed consent from or on behalf of research participants?

Yes No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Consent from adult participants will be required. This will be recorded on the consent form before the interview commences and after the researcher has verbally summarised the research and participants have been given the chance to ask the researcher questions. Participants will receive details about what the study involves when they receive their invitation to the study. This will give them the opportunity to see exactly what being involved in the study entails and will allow them time to think about whether or not they want to take part.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

Yes No

A31. How long will you allow potential participants to decide whether or not to take part?

For participants invited to interview: after they receive an initial letter they will be given three weeks to respond before it might be possible for a member of their healthcare team at the medical practice to make a follow-up telephone call. The telephone call will simply ask whether or not the potential participant would like to be involved so as not to coerce participants into something they do not want to do. This telephone call is designed to give those who do not respond to letters a second opportunity to take part in the research.

When the student observes consultations, it is only felt necessary to ask participants when they arrive for their appointments because no personal information from these appointments will be used in the research and no recordings will be made. The main purpose of the observations are to reflect on the work of the medical team, the setting, ways of thinking, decision-making, procedures, communication, and instruments; not the individual cases. These participants will be given a short information sheet while they wait for their appointment so they know why the student wants to observe their consultation and can make an informed decision about whether or not they would like to take part in this stage of the research. These participants will not be coerced into being interviewed, but if they give permission for the student to observe they will be given the invitation to interview by healthcare staff.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)

In some cases it will be necessary for interviews to take place in a South Asian language and in these cases an interpreter/translator will be employed. However, most of the South Asian members of the practice do understand written and spoken English.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

- The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study**A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?(Tick as appropriate)**

- Access to medical records by those outside the direct healthcare team
- Electronic transfer by magnetic or optical media, email or computer networks
- Sharing of personal data with other organisations
- Export of personal data outside the EEA
- Use of personal addresses, postcodes, faxes, emails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices

Storage of personal data on any of the following:

- Manual files including X-rays
- NHS computers
- Home or other personal computers
- University computers
- Private company computers
- Laptop computers

Further details:

A37. Please describe the physical security arrangements for storage of personal data during the study?

Data will be encrypted during all necessary electronic transfers, such as those from the audio-recording device onto a password-protected, secure research drive maintained by Durham University. This will be done within two days of the interview and after the data is transferred the recording will be appropriately deleted from the audio-recording device.

The personal contact details of participants will not be shared with any third party and will be held on the password protected secure University research drive. Paper copies of reply slips and the paper consent forms will be stored in a locked filing cabinet on University premises.

A38. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.

Overall, ethical issues concerning anonymity of participants and confidentiality of information divulged will be handled in accordance with the British Sociological Association guidelines and the NHS Confidentiality guidelines. Transcriptions will be done by the chief investigator in a private setting wearing ear-phones. In all cases true identities will not be revealed by the student to anyone else, including the supervisory team. In all written work resulting from the research, participants will be given code names and will not be identifiable from any other information mentioned about their case histories. Publication of direct quotations, or other information provided by participants will be anonymised and care will be taken to ensure that no other information published allows participants to be identified, such as the combination of gender, age, ethnicity, and location.

A40. Who will have access to participants' personal data during the study? Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.

The chief investigator will be the only person with access to the audio recordings and other personal data generated as part of the research. She will transcribe these, give participants code names and delete any other identifiable information before other members of the supervisory team are able to help with coding by reading and commenting on transcriptions. Participants will be asked to give their consent for the recording and transcription to occur before their interview.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

To ensure confidentiality of data, audio recordings of interviews will be stored on a secure research drive within Durham University. They will be transcribed by the chief investigator in a private setting, wearing ear-phones. Transcriptions which do not reveal the identities of participants will then be analysed by the chief investigator with help from her academic supervisors.

A42. Who will have control of and act as the custodian for the data generated by the study?

Title Forename/Initials Surname

	Ms Elizabeth Strutt
Post	Research Postgraduate (PhD)
Qualifications	BA (Hons) Dunelm
Work Address	Department of Geography Durham University South Road, Durham
Post Code	DH13LE
Work Email	elizabeth.strutt@dur.ac.uk
Work Telephone	07922585895
Fax	01913341801

A43. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months
 3 – 6 months
 6 – 12 months
 12 months – 3 years
 Over 3 years

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. Say where data will be stored, who will have access and the arrangements to ensure security.

Anonymised transcriptions of audio-recordings will kept once the study is over and will be stored on a secure research drive held within Durham University. The identifiable voice recordings will be securely destroyed after the study is completed and once the assessors of the PhD give their permission. Ms Elizabeth Strutt will have access to the transcriptions in order to produce follow-up reports and publications after the PhD thesis has been submitted.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

- Yes No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

- Yes No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

- Yes No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

Yes No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

Yes No

Please give details, or justify if not registering the research.

The protocol will be published in the NHS health check resource library.

A51. How do you intend to report and disseminate the results of the study? Tick as appropriate:

- Peer reviewed scientific journals
- Internal report
- Conference presentation
- Publication on website
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- No plans to report or disseminate the results
- Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

In writing up the study participants will be given code names and true identities will not be revealed by the student to anyone else, including the supervisory team. Care will be taken to ensure that details of individual participants, such as gender, ethnicity, and ages are sufficiently vague to maintain anonymity.

A53. Will you inform participants of the results?

Yes No

Please give details of how you will inform participants or justify if not doing so.

Participants will be asked if they would like to be on the mailing list to be sent a summary of results by post or email. Participants will also be informed that there will be online access to the final thesis through the Durham University website. NHS County Durham and NHS Darlington will also be sent details of the results of the study and their implications for future implementation of their screening programme. These results will also be shared with other people involved in cardiovascular screening programmes around the United Kingdom via the 'NHS Health Check Resource Library' provided by the NHS Improvement Programme.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? Tick as appropriate:

- Independent external review
- Review within a company
- Review within a multi-centre research group
- Review within the Chief Investigator's institution or host organisation
- Review within the research team
- Review by educational supervisor
- Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

Three academic supervisors from three different fields: geography, anthropology, and medicine have contributed to the design and review of the study to ensure that the proposal has identified a valid research question and is suitably designed, taking into account the limitations of time and resources.

The project has also been reviewed by the Economic and Social Research Council as part of a funding application, please see documentary evidence of the feedback from this review.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 80
 Total international sample size (including UK): 0
 Total in European Economic Area: 0

Further details:

Approximately fifty participants will be interviewed.

Approximatley thirty participants will take part in the screening/consultation observations stage of research.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

It was decided that fifty interviews and thirty observations would be a feasible number for the researcher to undertake in the timescale given for the PhD. The number is deemed to be sufficient to achieve worthwhile results without involving unnecessary recruitment and burdens for participants. After consulting other researchers and considering other qualitative studies it was also decided that this number would provide a good range of opinions and viewpoints without responses being repeated too much.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The themes and categories will be found using both deductive and inductive approaches: this means that themes will be informed by both the research questions and participants' interview responses. The research will involve concurrent data collection and analysis, together with systematic efforts to check and refine categories of data. The student will meet regularly with the supervisory team in order to discuss and agree these categories. Interviews will be digitally recorded and transcribed, and NVIVO, a qualitative indexing package, will be used to help with data coding and retrieval.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

Title Forename/Initials Surname
Dr Sarah Atkinson

Post Reader in the Department of Geography

Qualifications BA Anthropology (Dunelm)
MSc Human Nutrition (LSHTM, London)
PhD Anthropology (Dunelm)

Employer Durham University

Work Address Durham University Department of Geo
Science Laboratories
South Road, Durham

Post Code DH13LE

Telephone 01913341871

Fax 01913341801

Mobile

Work Email s.j.atkinson@durham.ac.uk

Title Forename/Initials Surname
Dr Tessa M. Pollard

Post Senior Lecturer in the Department of Anthropology

Qualifications BA Human Sciences (Oxford)
MSc Human Biology (Oxford)
PhD Anthropology (Oxford)

Employer Durham University

Work Address Department of Anthropology Durham U
Dawson Building
South Road, Durham

Post Code DH1 3LE

Telephone 01913341623

Fax 01913341615

Mobile

Work Email t.m.pollard@durham.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: NHS or HSC care organisation
 Academic
 Pharmaceutical industry
 Medical device industry
 Local Authority
 Other social care provider (including voluntary sector or private organisation)
 Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation Research Management & Governance Unit
 Given name Richard
 Family name Errington
 Address NHS County Durham and Darlington
 Town/city John Snow House
 Post code DH1 3YG
 Country UNITED KINGDOM
 Telephone 01913744211
 Fax
 E-mail richard.errington@nhs.net

Is the sponsor based outside the UK?

Yes No

Where the lead sponsor is not established within the UK, a legal representative in the UK may need to be appointed. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- Funding secured from one or more funders
 External funding application to one or more funders in progress
 No application for external funding will be made

Please give details of funding applications.

Organisation ONE North East Studentship
 Address Durham University
 University Office
 Old Elvet, Durham
 Post Code DH13HP
 Telephone 01913346485
 Fax
 Mobile
 Email chris.harrop@dur.ac.uk

Funding Application Status: Secured In progress

Amount: £16,680

Duration

Years: 1

Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

Funding for first year of PhD, for healthcare research, stipend plus fees.

What type of research project is this?

Standalone project

- Project that is part of a programme grant
 Project that is part of a fellowship/ personal award/ research training award
 Other

Other – please state:

Organisation Faculty of Social Sciences and Health
 Address Durham University
 University Office
 Old Elvet, Durham
 Post Code DH13HP
 Telephone 01913346485
 Fax
 Mobile
 Email chris.harrop@dur.ac.uk

Funding Application Status: Secured In progress

Amount: £16, 780

Duration

Years: 2

Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

Second and third years of PhD programme a stipend plus fees.

What type of research project is this?

- Standalone project
 Project that is part of a programme grant
 Project that is part of a fellowship/ personal award/ research training award
 Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? Please give details of subcontractors if applicable.

Yes No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

Yes No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68. Give details of the lead NHS R&D contact for this research:

Title Forename/Initials Surname

Mr Richard Errington
 Organisation County Durham Primary Care Trust
 Address John Snow House
 University Science Park
 Durham
 Post Code DH13YG
 Work Email richard.errington@cdpct.nhs.uk
 Telephone 01388452298
 Fax
 Mobile

Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>

A69-1. How long do you expect the study to last in the UK?

Planned start date: 05/10/2009

Planned end date: 28/09/2012

Total duration:

Years: 3 Months: 0 Days: 0

A71-1. Is this study?

- Single centre
 Multicentre

A71-2. Where will the research take place? (Tick as appropriate)

- England
 Scotland
 Wales
 Northern Ireland
 Other countries in European Economic Area

Total UK sites in study 2

Does this trial involve countries outside the EU?

- Yes No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:

- NHS organisations in England
 NHS organisations in Wales
 NHS organisations in Scotland
 HSC organisations in Northern Ireland
 GP practices in England 2
 GP practices in Wales
 GP practices in Scotland
 GP practices in Northern Ireland
 Social care organisations

- Phase 1 trial units
- Prison establishments
- Probation areas
- Independent hospitals
- Educational establishments
- Independent research units
- Other (give details)

Total UK sites in study: 2

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

Yes No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

Dr Fuat, a GP at the main research site will supervise the conduct of the research. Any negative or positive feedback a participant would like to provide about the conduct of the research will be audited by Dr Fuat.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? Please tick box(es) as applicable.

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (NHS sponsors only)
- Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

478. Could the research lead to the development of a new product/process or the generation of intellectual property?

- Yes
- No
- Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

Research site		Investigator/ Collaborator/ Contact	
Institution name	Durham and Darlington PCT	Title	Dr
Department name	Carmel Medical Practice	First name/ Initials	Ahmet
Street address	Nunnery Lane	Surname	Fuat
Town/city	Darlington		
Post Code	DL38SQ		
Institution name	Durham and Darlington PCT	Title	Mrs
Department name	Orchard Court Surgery	First name/ Initials	Karen
Street address	Orchard Road	Surname	Fuat
Town/city	Darlington		
Post Code	DL36HZ		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
 - Will be held by the main REC or the GTAC (as applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
 - May be disclosed to the operational managers of review bodies, or the appointing authority for the main REC, in order to check that the application has been processed correctly or to investigate any complaint.
 - May be seen by auditors appointed to undertake accreditation of RECs.
 - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- Chief Investigator
 Sponsor
 Study co-ordinator

- Student
 Other – please give details
 None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature:

Print Name: ELIZABETH STRUTT

Date: 05/03/2010 (dd/mm/yyyy)

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Signature:

Print Name: DR. AHMET FUAT

Post: GENERAL PRACTITIONER

Organisation: CARMEL MEDICAL PRACTICE, DARLINGTON

Date: 05/03/2010 (dd/mm/yyyy)

D3. Declaration for student projects by academic supervisor

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the Chief Investigator and the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Signature:

Print Name: DR. SARAH ATKINSON

Post: READER IN HUMAN GEOGRAPHY

Organisation: DURHAM UNIVERSITY

Date: 05/03/2010 (dd/mm/yyyy)

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Revealing and experiencing an at risk diagnosis: NHS Health Checks v.1

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial or clinical investigation
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples, other human biological samples and/or data (*specific project only*)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located? (*Tick all that apply*)

- England
- Scotland
- Wales
- Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
- Scotland

- Wales
- Northern Ireland
- This study does not involve the NHS

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
- Social Care Research Ethics Committee
- Research Ethics Committee
- National Information Governance Board for Health and Social Care (NIGB)
- Ministry of Justice (MoJ)

5. Will any research sites in this study be NHS organisations?

- Yes No

5a. Do you want your application to be processed through the NIHR Coordinated System for gaining NHS Permission?

- Yes No

If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

6. Do you plan to include any participants who are children?

- Yes No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? The guidance notes explain how an adult is defined for this purpose.

- Yes No

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?

- Yes No

9. Is the study, or any part of the study, being undertaken as an educational project?

- Yes No

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

- Yes No

10. Is this project financially supported by the United States Department for Health and Human Services?

- Yes No

11. Will identifiable patient data be accessed outside the clinical care team without prior consent at any stage of the project (including identification of potential participants)?

- Yes No



Site-Specific Information Form

Is the site hosting this research a NHS site or a non-NHS site? *NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.*

- NHS site
 Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.

The data in this box is populated from Part A:

Title of research:

Revealing and experiencing an 'at risk' diagnosis: implementing the National Health Service Health Check programme in general practice (v.1)

Short title: Revealing and experiencing an at risk diagnosis: NHS Health Checks v.1

Chief Investigator:

Title	Forename/Initials	Surname
Ms	Elizabeth	Strutt

Name of NHS Research Ethics Committee to which application for ethical review is being made:
 County Durham & Tees Valley 2 REC

Project reference number from above REC: 10/H0908/20

1-1. Give the name of the NHS organisation responsible for this research site

County Durham and Darlington Primary Care Trust

1-2. In which country is the research site located?

- England
 Wales
 Scotland
 Northern Ireland

1-3. Is the research site a GP practice or other Primary Care Organisation?

- Yes No

If Yes, please give the name of the research site:
 Carmel Medical Practice

2. Who is the Principal Investigator or Local Collaborator for this research at this site?

Select the appropriate title: Principal Investigator
 Local Collaborator

Title Forename/Initials Surname
 Dr Ahmet Fuat
 Post General Practitioner
 Qualifications PhD MBChB (Aberdeen 1982) MRCPG DRCOG DFFP Cert Med Ed
 Organisation Durham and Darlington PCT
 Work Address Carmel Medical Practice
 Nunnery Lane
 Darlington, Co. Durham
 PostCode DL3 8SQ
 Work E-mail ahmetfuat@nhs.net
 Work Telephone 01325341411
 Mobile
 Fax 01325381834

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
 n/a

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? Yes No

A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.

3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.

Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.

Location	Activity/facilities
1 Carmel Medical Practice	Observations of health checks with healthcare assistant or practice nurse. Observations of results consultation with GP. Recruitment of participants to interview. Interviews with healthcare staff.
2 Participants' homes	Interviews lasting one hour.

5. Please give details of all other members of the research team at this site.

1

Title Forename/Initials Surname
 Ms Elizabeth Strutt
 Work E-mail elizabeth.strutt@dur.ac.uk

Employing organisation: Student
 Post: Research Postgraduate (PhD)
 Qualifications: BA (Hons) Dunelm
 Role in research team: researcher

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalent (WTE).*
 N/A as honorary unpaid research contract - will sit in on approx 20 appointments at the site.

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? Yes No

A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.

6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No

7. What is the proposed local start and end date for the research at this site?

Start date: 28/04/2010
 End date: 31/01/2011
 Duration (Months): 9

8-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. (These include seeking consent, interviews, non-clinical observations and use of questionnaires.)

Columns 1-4 have been completed with information from A18 as below:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?
3. Average time taken per intervention (minutes, hours or days)
4. Details of who will conduct the procedure, and where it will take place

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
Seeking consent.	1-2	0	N/A	Healthcare staff at Carmel Medical Practice and Orchard Court Surgery, Darlington will identify participants and send letters of invitation in the post or give the letters to potential participants face-to-face. The letters asking for consent to take part in the study will be written by the chief investigator, but she will not have access to potential participants' addresses until they have given their consent. If there is no reply to the letter the practice staff may have time to make a follow-up telephone call to confirm that potential participants do not want to be involved in the study: it has been previously found	Reception staff or healthcare assistant/practice nurse

				that some participants may respond better to the telephone than to letters.	
Interviews - these will be recorded (subject to consent) and the recordings will be held securely.	1	0	1hr	Interviews will be conducted by the chief investigator, they will take place at participants' homes. Interviews with practice staff will be conducted at the practice or their homes.	Ms E Strutt, researcher
Non-participant observations of the initial health checks with the health care assistant or practice nurse and the follow-up consultations with a GP or nurse.	1/2	All	20mins	Non-participant observations of the appointments taking place as part of the NHS Health Check programme at the two GP practices involved in the study. Permissions for the chief investigator to observe will be sought by the practice staff before the patient starts their appointment.	Ms E Strutt, researcher

8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

Yes No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?

10. How many research participants/samples is it expected will be recruited/obtained from this site?

20 OBSERVATIONS
25-30 INTERVIEWS

11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.

They will be identified by the reception staff using their computer database or by the healthcare assistant/practice nurse when patients attend a health check appointment. They will provide the letters of invitation to participants.

12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

Name	Expertise/training
Ms E Strutt	Training in research methods/ interview methods and research ethics from Durham University

15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?

Generic info sheet covers local contact points for advice.

15-2. Is there a contact point where potential participants can seek further details about this specific research project?

These are included in the generic info sheet.

16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study? A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.

NO

Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).

17. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters etc.)

If required then an interpreter will be hired for those participants of South Asian origin who do not speak English, although this is unlikely to be necessary. If necessary translations of the forms will be provided in another language, although this appears unlikely at the outset of the research. The telephone number of the medical practice is provided on the letter of invitation in case the person has trouble reading the letter.

18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?

There is no need to inform the GP about this qualitative research study.

19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

Participants will be advised to speak to their GP if they are psychologically affected by the study, if they do then the GP will handle this meeting in accordance with his regular care practices.

20. What are the arrangements for the supervision of the conduct of the research at this site? Please give the name and contact details of any supervisor not already listed in the application.

See the details of Dr A Fuat.

21. What external funding will be provided for the research at this site?

- Funded by commercial sponsor
- Other funding
- No external funding

How will the costs of the research be covered?

Funding provided to CI, as discussed in previous form, the CI is the only researcher at the site.

23. Authorisations required prior to R&D approval

This section deals with authorisations by managers within the NHS organisation. It should be signed in accordance with the guidance provided by the NHS organisation. This may include authorisation by clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers, depending on the nature of the research. Managers completing this section should confirm in the text what the authorisation means, in accordance with the guidance provided by the NHS organisation.

This section may also be used by university employers or research support staff to provide authorisation to NHS organisations, in accordance with guidance from the university.

1. Type of authorisation:

	Title Forename/Initials Surname
	Mr Richard Errington
Post	Research Governance Lead

Qualifications
 Organisation Research Management & Governance Unit
 Work Address NHS County Durham and Darlington
 John Snow House
 Durham University Science Park
 PostCode DH1 3YG
 Work E-mail richard.errington@nhs.net
 Work Telephone 01913744211
 Mobile
 Fax

Signature:

Date:

Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.
12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

Signature of Principal Investigator
or Local Collaborator:

Print Name:

Date: 08/03/2010

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Revealing and experiencing an at risk diagnosis: NHS Health Checks v.1

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial or clinical investigation
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples, other human biological samples and/or data (*specific project only*)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located? (*Tick all that apply*)

- England
- Scotland
- Wales
- Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
- Scotland

- Wales
- Northern Ireland
- This study does not involve the NHS

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
- Social Care Research Ethics Committee
- Research Ethics Committee
- National Information Governance Board for Health and Social Care (NIGB)
- Ministry of Justice (MoJ)

5. Will any research sites in this study be NHS organisations?

- Yes No

5a. Do you want your application to be processed through the NIHR Coordinated System for gaining NHS Permission?

- Yes No

If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

6. Do you plan to include any participants who are children?

- Yes No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? The guidance notes explain how an adult is defined for this purpose.

- Yes No

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?

- Yes No

9. Is the study, or any part of the study, being undertaken as an educational project?

- Yes No

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

- Yes No

10. Is this project financially supported by the United States Department for Health and Human Services?

- Yes No

11. Will identifiable patient data be accessed outside the clinical care team without prior consent at any stage of the project (including identification of potential participants)?

- Yes No



Site-Specific Information Form

Is the site hosting this research a NHS site or a non-NHS site? *NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.*

- NHS site
 Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.

The data in this box is populated from Part A:

Title of research:

Revealing and experiencing an 'at risk' diagnosis: implementing the National Health Service Health Check programme in general practice (v.1)

Short title: Revealing and experiencing an at risk diagnosis: NHS Health Checks v.1

Chief Investigator:	Title	Forename/Initials	Surname
	Ms	Elizabeth	Strutt

Name of NHS Research Ethics Committee to which application for ethical review is being made:
 County Durham & Tees Valley 2 REC

Project reference number from above REC: 10/H0908/20

1-1. Give the name of the NHS organisation responsible for this research site

County Durham and Darlington Primary Care Trust

1-2. In which country is the research site located?

- England
 Wales
 Scotland
 Northern Ireland

1-3. Is the research site a GP practice or other Primary Care Organisation?

- Yes No

If Yes, please give the name of the research site:
 Orchard Court Surgery

2. Who is the Principal Investigator or Local Collaborator for this research at this site?

Select the appropriate title: Principal Investigator
 Local Collaborator

Title Forename/Initials Surname
 Mrs Karen Fuat
 Post Practice Manager
 Qualifications
 Organisation County Durham and Darlington Primary Care Trust
 Work Address Orchard Court Surgery
 Orchard Road
 Darlington, Co. Durham
 PostCode DL3 6HZ
 Work E-mail Karen.Fuat@GP-A83006.nhs.uk
 Work Telephone 01325465285
 Mobile
 Fax 01325284034

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
 N/A

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? Yes No

A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.

3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.

Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.

Location	Activity/facilities
1 Orchard Court Surgery	Observations of health checks with healthcare assistant or practice nurse. Observations of results consultations with clinical practitioners. Recruitment of participants to interview. Interviews with healthcare staff.
2 Participants' homes	Interviews lasting one hour.

5. Please give details of all other members of the research team at this site.

1
 Title Forename/Initials Surname
 Ms Elizabeth Strutt
 Work E-mail elizabeth.strutt@dur.ac.uk

Employing organisation: Student at Durham University
 Post: Research Postgraduate (PhD)
 Qualifications: BA (Hons) Dunelm
 Role in research team: researcher

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalent (WTE).*

N/A - on an honorary unpaid research contract. Will sit in on approx 10-15 appointments at the site.

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? Yes No

A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.

6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No

7. What is the proposed local start and end date for the research at this site?

Start date: 01/05/2010

End date: 31/01/2011

Duration (Months): 8

8-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. (These include seeking consent, interviews, non-clinical observations and use of questionnaires.)

Columns 1-4 have been completed with information from A18 as below:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?
3. Average time taken per intervention (minutes, hours or days)
4. Details of who will conduct the procedure, and where it will take place

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
Seeking consent.	1-2	0	N/A	Healthcare staff at Carmel Medical Practice and Orchard Court Surgery, Darlington will identify participants and send letters of invitation in the post or give the letters to potential participants face-to-face. The letters asking for consent to take part in the study will be written by the chief investigator, but she will not have access to potential participants' addresses until they have given their consent. If there is no reply to the letter the practice staff may have time to make a follow-up telephone call to confirm that potential participants do not want to be involved in the study: it has been previously found	Reception staff or healthcare assistant/practice nurse

				that some participants may respond better to the telephone than to letters.	
Interviews - these will be recorded (subject to consent) and the recordings will be held securely.	1	0	1hr	Interviews will be conducted by the chief investigator, they will take place at participants' homes. Interviews with practice staff will be conducted at the practice or their homes.	Ms E Strutt, researcher
Non-participant observations of the initial health checks with the health care assistant or practice nurse and the follow-up consultations with a GP or nurse.	1/2	All	20mins	Non-participant observations of the appointments taking place as part of the NHS Health Check programme at the two GP practices involved in the study. Permissions for the chief investigator to observe will be sought by the practice staff before the patient starts their appointment.	Ms E Strutt, researcher

8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

Yes No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?

10. How many research participants/samples is it expected will be recruited/obtained from this site?

10 - 15 OBSERVATIONS
20 - 25 INTERVIEWS

11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.

Participants will be identified by the reception staff using their computer database or by the healthcare assistant/practice nurse when patients attend a health check appointment. Practice staff will provide the letters of invitation to participants.

12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

Name	Expertise/training
Ms E Strutt	Training in research methods/interview methods and research ethics from Durham University

15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?

Generic info sheet covers local contact points for advice.

15-2. Is there a contact point where potential participants can seek further details about this specific research project?

These are included in the generic info sheet.

16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study? A substantial amendment may need to be discussed with the Chief Investigator and

submitted to the main REC.

NO

Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).

17. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters etc.)

If required then an interpreter will be hired for those participants of South Asian origin who do not speak English, although this is unlikely to be necessary. If necessary translations of the forms will be provided in another language, although this appears unlikely at the outset of the research. The telephone number of the medical practice is provided on the letter of invitation in case the potential participant has trouble reading the letter.

18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?

There is no need to inform the GP about participation in this qualitative research study.

19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

Participants will be advised to speak to their GP if they are psychologically affected by the study, if they do then the GP will handle this meeting in accordance with his or her regular care practices.

20. What are the arrangements for the supervision of the conduct of the research at this site? Please give the name and contact details of any supervisor not already listed in the application.

The local collaborator listed for this site will help to supervise the conduct of the research at this site. Dr A Fuat will remain a point of contact for participants from this research site because of his main supervisory role within the overall project.

21. What external funding will be provided for the research at this site?

- Funded by commercial sponsor
- Other funding
- No external funding

How will the costs of the research be covered?

Funding provided to CI, as discussed in the previous form, the CI will be the only researcher at this site.

23. Authorisations required prior to R&D approval

This section deals with authorisations by managers within the NHS organisation. It should be signed in accordance with the guidance provided by the NHS organisation. This may include authorisation by clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers, depending on the nature of the research. Managers completing this section should confirm in the text what the authorisation means, in accordance with the guidance provided by the NHS organisation.

This section may also be used by university employers or research support staff to provide authorisation to NHS organisations, in accordance with guidance from the university.

1. Type of authorisation:

	Title Forename/Initials Surname
	Mr Richard Errington
Post	Research Governance Lead
Qualifications	
Organisation	Research Management & Governance Unit
Work Address	NHS County Durham and Darlington
	John Snow House
	Durham University Science Park
PostCode	DH1 3YG
Work E-mail	richard.errington@nhs.net
Work Telephone	01913744211
Mobile	
Fax	
Signature:
Date:

Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.

- 12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
- 13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

Signature of Principal Investigator
or Local Collaborator:

Print Name:

Date: 08/03/2010