Detailed Project Proposal: Project ref 15/170/02

1. Full title of project

Qualitative video-stimulated recall study to explore cardiovascular disease risk communication in NHS Health Checks using QRISK2 10-year risk and JBS3 lifetime risk calculators

2. Summary of Research:

Aim: To explore clinician and patient perception of CVD risk when using the JBS3 lifetime risk calculator or the QRISK2 10-year risk calculator, the associated advice or treatment offered by the clinician and the response of the patient.

Design: A qualitative study that will use analysis of video-recorded Health Check consultations, Video Stimulated Recall (VSR) and case study analysis.

Setting: A minimum of 12 general practices will be recruited from the West Midlands, stratified by deprivation, practice size and ethnic profile of the practice population (for generalisability).

Target population / inclusion criteria:
- Patient population - those eligible for NHS Health Checks based on national criteria (1) (adults (40-74 years; without chronic disease diagnosis or statin prescription).
- Clinician population - staff delivering NHS Health Checks (e.g., practice nurse, health care worker).
- Practices - those that deliver NHS Health Checks and use the QRISK2 risk calculator.

Health Technology: The health technology being assessed is the new JBS3 CVD risk calculator (12). This focuses on lifetime risk and has additional functionality in terms of displaying the effects of risk factor modification, providing other metrics (e.g., Heart Age) and using a range of visual displays.
JBS3 will be compared with QRISK2, with uses a percentage 10-year risk score and is used in most general practices.

Method and procedures:
Participating general practices will be randomly assigned to either use QRISK2 (usual practice) or use JBS3 to communicate CVD risk within Health Check consultations. The patient pathways will be largely unchanged for either group, with patients being invited to attend routine Health Check clinics through usual practice processes. The only difference between the experiences of patients in the two groups as a result of this study will be the risk calculator that is used within their consultation to discuss CVD risk.

Data Collection

Data will be collected in using three methods.

- Routine Health Check clinics will be video-recorded in each practice over approximately four weeks (or until 20 consultations are recorded); 12 recordings per practice will be selected for qualitative analysis (excluding those lacking relevant content, which will be subject to quantitative analysis). This will provide a valuable, objective record of verbal and non-verbal communication around CVD risk (2,33,34). The audio-record will be transcribed verbatim for analysis, using the visual information as context.

- Video-stimulated recall (VSR) interviews will be conducted with patients and clinicians (<2 weeks post-consultation). After each clinic, recordings of Health Checks will be screened to identify/extract relevant sections of the consultation (e.g., discussion of CVD risk). Excerpts will then be used in semi-structured, one-to-one VSR interviews with patients and clinicians. During interviews, participants will be shown the excerpts of the Health Check and asked a series of open questions. VSR offers a powerful and novel way to facilitate recall and reflection on CVD risk communication, individual perceptions and understanding, and subsequent advice/treatment, and related patient intentions and behaviour (3,20). Audio recorded VSR interviews will be transcribed for analysis.

- Medical records of participating patients would be reviewed (at minimum 12 weeks post-Health Check) using specific searches to identify possible outcomes as a result of the Health Check (e.g., GP appointment, lifestyle referral, statin prescription).

Data analysis

Qualitative data will be analysed using NVivo 11, taking a Thematic Analysis (TA) (5) approach (see Data Analysis section). Briefly:

- Health Check consultations will be analysed using deductive TA and described quantitatively (e.g., number of mentions of CVD risk; time spent discussing risk). Data will be compared for QRISK2 and JBS3 groups.
- VSR interviews (patient and clinician) will be analysed using inductive TA, and thematic maps compared for QRISK2 and JBS3 groups.
- Case study analysis will be used in a subsample combining deductive TA (qualitative data from consultation, and patient and clinician VSR interviews), with quantitative data on Health Check content and patient record review.
- Data from record reviews would be summarised and compared QRISK2 and JBS3 groups to provide an overview of the respective follow-up action following Health Checks in each group.

Sample size

- A minimum of 12 practices, stratified by deprivation, size and ethnic profile of the practice population (half randomly allocated to use QRISK2 and half to use JBS3 in Health Check consultations)
- 240 consultations will be video-recorded (20 per practice), and screened to select 144 (12 per practice) for qualitative analysis (72 per group); all 240 will be quantitatively analysed
- 48 patient VSR interviews (24 per group) would be purposely sampled from the 144, stratified by patient age (40-54/55-64/65-74 yr), gender (m/f) and CVD risk (low/medium-high)
- 18-24 clinician VSR interviews (1-2 per practice)

This sample size is comparable size to studies using recorded consultations (1) and VSR (2) to provide data from a range of patients, allowing for dropout (~50%) and exclusion of consultations lacking discussion of CVD risk (3).

Outcomes

The outcomes of this approach will be insight specific to the stated objectives:

1. How clinicians use QRISK2 and JBS3 to communicate CVD risk in Health Checks
2. How patients respond to the risk information communicated in the consultation
3. How QRISK2 and JBS3 promote patient and clinician understanding and perceptions of CVD risk
4. How QRISK2 and JBS3 influence patient intentions regarding health-protective behaviours
5. Mechanisms by which intentions for health-protective behaviours are elicited.

Project timetable

- Practice recruitment/training (month 1-6)
- Ethics (month 1-6)
- Qualitative data collection (month 6-20)
- Patient record review (month 15-22)
- Qualitative and quantitative data analysis (month 9-26)
- Final report and dissemination (month 28-30).

Team Expertise

Collectively, the team have a wealth of research and clinical expertise that covers: qualitative and quantitative NHS Health Check research (25,24,23,21,22,27), including an ongoing RCT (HEalth Check TRial, HECTR) comparing different methods of invitation to promote uptake (CG, NE, DC, DCC); qualitative research methods to understand clinician and/or patient experiences (DC, SG, NE) (23,28–30); using VSR (ZP) in primary care consultations (3,4); general practice and clinical expertise (RC, EC, MK); commissioning and policy context (RC, MK); statistical expertise (DCC).

3. Background and Rationale

NHS Health Checks

Cardiovascular disease (CVD) is the leading cause of death, accounting for 27% of all UK deaths (6). NHS Health Check (7) is a strategically important national CVD risk assessment programme for adults in England

aged 40-74 without a chronic condition. It has been running since 2009 and represents a considerable public investment, with over 1 million checks completed in 2015 (http://www.healthcheck.nhs.uk/commissioners_and_providers/data/). Yet use of such health checks to reduce population CVD or CVD risk is much contested (8,37–41). In addition to a relative dearth of evidence to support the longer-term clinical value of general health checks, or specifically relating to NHS Health Checks, there is a lack of information on the nature of Health Check consultations. Consultations should involve a clinician (usually a nurse or health care worker) communicating the patient's CVD risk to them, with appropriate advice and action, which could range from basic lifestyle advice to a referral back to the GP for medication, or referral to specialist services (e.g., smoking cessation). But our only insight into this to date is through retrospective qualitative data (see below).

CVD risk communication

Clinician-patient interactions are complex (9) and communicating risk is challenging (10). For Health Checks to promote health-protective behaviours that reduce CVD risk, risk information must be effectively communicated and understood, such that the patient leaves the consultation with the knowledge and intention to act.

A review of 70 risk scoring methods concluded that there is no single 'correct' approach. As above, it depends on individual preferences and understanding, which differs with education, numeracy, and personality traits, such as optimism (11). The emotional response to the communication of risk, how and by whom the information is conveyed, presentation of risk and the influence on health behaviour, differs greatly between patients (42–45). Poor communication of risk can cause patients anxiety and reduce confidence in health professionals that use risk communication techniques (46). However, if risk communication is delivered effectively it can enhance knowledge, decision making about treatment, can empower and create autonomy (47). Wells et al. (16) assessed whether an electronic CVD risk visualisation tool facilitated explaining CVD risk to primary care patients. They found that watching a video about the communication of risk increased practitioner confidence and understanding which led to greater efficiency. More recent research has suggested that GPs have different communication strategies when addressing CVD risk, dependent on the patient's perception of risk, motivation and anxiety (48). They concluded that providing alternative ways of explaining absolute risk, in order to achieve different communication aims, may improve their use of absolute CVD risk assessment in practice.

CVD risk communication in Health Checks

To date, there is insufficient evidence to suggest that CVD risk communication NHS Health Checks is consistently well delivered. The CVD risk score used in most Health Checks is QRISK2, a percentage risk of CVD in the next 10 years, which is automatically generated in general practice software. QRISK2 has two main limitations. First, as a short-term risk estimate, the score depends heavily on age and gender (underestimating risk in younger adults/women) and cannot account for risk from other diseases as effectively as long-term estimates (12). Second, retrospective interview data show limited clinician/patient understanding of percentage CVD risk (13,14) and that patients often have unanswered questions about risk following Health Checks (15). There is evidence that practitioners find it difficult to explain CVD risk using percentage risk formats (43,49–51). A number of studies have shown that representing percentage risk over the next 10 years (absolute risk) can be falsely reassuring (52,53). This is particularly problematic for individuals with low to moderate CVD risk who have a number of modifiable risk factors, e.g. smokers, obese, high blood pressure (54). These limitations have sparked interest in alternative metrics, such as heart age (8,16–18) and lifetime risk (12), and use of multiple visual displays to present them (10).

JBS3 is a new risk calculator with a primary focus on lifetime risk (12). It has additional functionality in terms of displaying the effects of risk factor modification (e.g., smoking cessation) on risk trajectory, and includes various visual displays, and other metrics (e.g., Heart Age). This allows patients to visualise the likely impact of their behaviour change and see that their risk is amenable to change. JBS3 has been designed to help clinicians to support patients to make appropriate decisions about their lifestyle and drug treatments based on a better understanding of their personal CVD risks. Through having multiple ways of presenting risk across the life span, JBS3 aims to help clinicians address three key questions for their patients: Why should I start CVD risk reduction? When should I start? What should I do? (12). The potential advantages of JBS3 over QRISK2 include:

(i) lifetime risk is less dependent on age and gender (younger subjects/women will not be overlooked)
(ii) lifetime risk takes into account both risk from CVD and competing diseases, such as cancer

(iii) visual displays should accommodate the needs of a greater range of patients (10) and are designed to facilitate an informed discussion between clinician and a range of patients regarding decisions about lifestyle changes and, where indicated, pharmacological therapy
(iv) heart age combines absolute risk and relative CVD risk in a way that is easily communicated (55) and easier to understand than percentage CVD risk (8).

So, by reducing the chance of underestimating risk and accommodating a range of patient preferences for receiving risk information, JBS3 aims to early intervention which can decrease or slow down CVD and thereby the risk of future CVD events.

We currently lack evidence on how risk is communicated in Health Checks. However, we do understand the limitations of percentage risk scores, like QRISK2 (13,14) and can see the potential benefit of using more flexible and interactive JBS3.

Contribution to NHS practice and policy
NHS Health Check is one of only three mandatory functions included in the 2012 Health and Social Care Act and has political backing as evidenced by inclusion in *Living Well for Longer: A call to action to reduce avoidable premature mortality* (56). Local authorities are now responsible for commissioning the programme in accordance with the Department of Health and Public Health England's NHS Health Check Best Practice Guidance (1). Yet there remains a debate on their effectiveness and a review of the supporting evidence is now planned. Nevertheless, the NHS Health Check programme remains part of the health delivery infrastructure in England and regardless of whether the programme continues in the long term, the need to effectively communicate CVD risk and prompt positive behaviour change to protect against future disease, will always remain a key component of primary care. As detailed below, the proposed study is an in-depth exploration of current practice (QRISK2) and the potential advantages of JBS3, which will produce recommendations for which should be endorsed for Health Checks and how clinical could make best use of them. We envisage that the findings from all studies funded under this HTA call would contribute towards evidence future syntheses and recommendations, updating of previous NICE guidance (57) and PHE best practice guide.

4. Evidence explaining why this research is needed now:

Relevance
There is a lack of evidence on how risk is communicated by clinicians, and understood and used by patients in NHS Health Checks. However, we do understand the limitations of percentage risk scores, like QRISK2 (13,14), and can see the potential for conveying risk information of more the flexible and interactive JBS3. This research is an opportunity to investigate: how clinicians use QRISK2 and JBS3 to communicate CVD risk in Health Checks; how JBS3 could be used to improve practice; their relative merits in terms of clinician and patient perceptions and understanding of risk; subsequent advice and patient response, and potential translation into health-protective action. Given the scale and reach of the programme, this is important to optimise the opportunity that Health Checks afford; to initiate CVD risk-reducing behaviours in a large proportion of 40-74 year olds in England.

Timing
NHS Health Check programme has been in operation since 2009 and is under growing scrutiny. Throughout this time, the QRISK2 (or similar) percentage risk score has been used as it is routinely generated by general practice software. Based on theories of behaviour change JBS3, which was launched in 2014, has the potential to offer a better solution to CVD risk (as detailed above), but decisions around integrating JBS3 into primary care software system for routine use must be evidence-based.

5. Aims and objectives

Aim:
To explore clinician and patient perception of CVD risk when using the JBS3 lifetime risk calculator or the QRISK2 10-year risk calculator, the associated advice or treatment offered by the clinician and the response of the patient.

Objectives:
1. Explore how clinicians use QRISK2 and JBS3 to communicate CVD risk in the consultation

2. Explore how patients respond to the risk information communicated in the consultation
3. Explore how QRISK2 and JBS3 promote patient and clinician understanding and perception of CVD risk
4. Explore patient intentions with respect to health-protective behaviours
5. Explore mechanisms by which intentions for health-protective behaviours are elicited
6. Make recommendations regarding use of QRISK2 or JBS3 in Health Checks.

To meet these objectives, we propose a qualitative study using VSR, whereby Health Check consultations will be video-recorded and analysed, and recordings then used within post-consultation interviews with patients and clinicians to facilitate recall and reflection. This approach has advantages over solely quantitative or retrospective qualitative methods. First, video recorded Health Check consultations can be analysed in terms of both verbal and non-verbal communication, providing comprehensive, subtle and sensitive information (33). Capturing nonverbal behaviour can convey additional emotional information that is important in the study of clinician-patient relationships (35). Second, in addition to the greater sensitivity for *qualitative* analysis of consultations and patient/clinician recall and reflections, the video-recordings provide an objective record for *quantitative* description of consultations; for example, consultations will be characterised in terms of time spent discussing CVD risk, the number of times risk score is mentioned, and the number of patient questions (see Detailed Project Proposal). Third, using excerpts of video-recorded consultations in post-consultation interviews will enhance participant recall of thoughts, perceptions and emotions during the consultation, and allow a considered reflection on their related intentions and actions (3).

6. Research Plan

This will be a qualitative study, with quantitative data to provide context and to be used as part of case study analysis. Detail on procedures for sampling, data collection and so on are detailed below, and summarised here.

Methods of data collection
Video recording of Health Checks: Within participating general practices, half of which will use QRISK2 (usual practice) and half will use JBS3. Up to 240 Health Check consultations will be video-recorded to obtain 144 recordings for qualitative analysis and 240 for quantitative analysis (see Sampling). Health Checks, which typically last 20-30 minutes and are run in specific clinics on one or two half days each week, will be video-recorded over approximately four weeks (or until 20 recordings are obtained).

Video-stimulated recall (VSR) is central to this study. After each clinic, the recordings will be screened to identify sections of the consultation relevant to the study objectives (e.g., discussion of CVD risk, the risk score, clinician advice, recommended intervention, patient response to both risk information and advice). These excerpts will then be used within post-consultation semi-structured interviews with patients (subsample, n = 48) and clinicians (n = 18-24). During interviews, participants will be shown the excerpts of the Health Check and then be asked a series of open questions. This Video-Simulated Recall (VSR) approach is designed to facilitate recall and reflection on CVD risk communication, individual perceptions and understanding, and subsequent advice/treatment, and related patient intentions and behaviour. The audio recording of the Health Checks and the VSR interviews will be transcribed, providing three sources of qualitative data for analysis: objective record of Health Check consultations – transcript will provide the verbal data, with contextual richness provided by the video to allow analysis that considers both verbal and non-verbal behaviour; patient VSR interviews; clinician VSR interviews.

Patient record reviews would be used to determine subsequent action. Searches would be designed by the CRN to identify possible outcomes with searchable read codes that occurred at minimum 12 weeks post-Health Check, such as GP appointment, lifestyle referrals, physiotherapy referral, lifestyle referral, smoking cessation referral, alcohol advice, or statin prescription. This list will be agreed between clinical experts within the team and the CRN.

Methods of data analysis
Qualitative data will be analysed using NVivo 11, taking a Thematic Analysis (TA) (5) approach (see Data Analysis section for detail). Briefly:

- Health Check consultations (n=144) will be analysed using deductive TA, where predetermined themes are applied to recorded discussions, to create a thematic map related to Protection Motivation Theory and risk communication literature. Consultations (n=240) will also be described quantitatively (e.g., number of

mentions of CVD risk; time spent discussing risk; in how many of the consultations the clinician manipulated the risk score to illustrate amenability of the risk to change). Data will be compared for QRISK2 and JBS3 groups.

- VSR interviews (patient and clinician) will be analysed using inductive TA, where coding is open and themes are generated from the data. Thematic maps will then be compared for QRISK2 and JBS3 groups.
- Case study analysis will be used in a subsample who demonstrate most positive intentions and/or behaviours to reduce CVD risk following the Health Check will be selected. Deductive TA would be used for analysis of qualitative data (from consultation, and patient and clinician VSR interviews), with quantitative data on Health Check content and patient records (i.e., subsequent actions) to add context.
- Data from record reviews would be summarised QRISK2 and JBS3 groups to provide an overview of the respective follow-up action following Health Checks in each group.

Overall, triangulating data from recorded consultations, VSR post-consultation interviews and additional data from patient record reviews will provide a level of insight into the relative influence of QRISK2 or JBS3 risk calculators on discussions around CVD risk (within Health Checks), associated perceptions and subsequent advice/treatment, that cannot be provided by solely quantitative or retrospective qualitative methods.

Setting/Organisations: The study will take place within a sample of general practices (in the West Midlands) that already deliver NHS Health Checks. Practice sampling will involve stratification to provide diversity in practice size, deprivation and ethnic profile of the practice population. Procedures for practice-level stratification will be conducted by the West Midlands CRN, and GP Practices identified through stratification procedures will be invited to take part in the study (also through the CRN).

Patient group: The patient sample will be those participants who are eligible to receive a Health Check, based on the national criteria (aged 40-74 years and without a diagnosed chronic condition, statin prescription and who have not attended a Health Check in the preceding five years) during the study period. Participants will receive a postal invitation to attend the Health Check and take part in the study. To minimise practice burden, the West Midlands CRN will facilitate the distribution of postal invitations at each practice.

Staff involved: NHS Health Checks are typically delivered by practice nurses or health care workers within the practice. These are the clinicians who will run the Health Check clinics that will be video-recorded and who will participate in VSR interviews. Other practice staff that will be involved include the Practice Manager, for whom we will need agreement (on behalf of the practice/partners). The West Midlands CRN will initially provide support for practice recruitment and carry out searches to enable practice-level stratified sampling. Within each practice, the CRN will conduct patient searches to ensure patient-level stratified sampling is achieved (for recruitment to the study and recruitment for VSR interviews) and will also facilitate the distribution of postal invitations to identified patients eligible for a Health Check. The study information posted to potential participants will require them, if interested in participating, to book their Health Check using a direct number to the CRN representative within the practice. The CRN representative will then gain their informed consent for the study over the telephone and book them into a clinic being video-recorded for the study. If the patient does not want to be involved in the study but still would like to receive a Health Check, they will be instructed to book via their usual method (e.g., telephoning the Practice reception, booking online etc.). On data collection days, the CRN representative will assist with gathering patient consent forms and gaining contact information for invitation to follow up VSR interviews (alongside the onsite researcher).

7. Health technologies being assessed

The JBS3 lifetime CVD risk calculator, a newer tool, will be compared with the QRISK2 risk calculator, which is equivalent to ‘usual practice’. QRISK2 uses patient demographic and clinical data to estimate the percentage risk of developing CVD in the next 10 years (%10-year risk). This is already embedded in general practice systems such that 10-year risk scores are generated from patient data (demographic and health). JBS3 uses similar patient data to estimate 10-year risk, but the main focus is on CVD risk over the lifetime. It offers a novel way of communicating risk to individuals in a clinical setting, such as a GP surgery, which is displayed using a range of visuals to accommodate individual preference. JBS3 also provides an opportunity to change CVD progression in an individual by earlier intervention on risk factors, which can be demonstrated by clinicians during the consultations (e.g., showing the change in lifetime risk if smoking status is changed from smoker to non-smoker). Within the protection motivation theory (PMT, described below) this demonstrates to a

patient the response efficacy. These new measures and communication tools aim to motivate patients to make positive lifestyle changes and decisions about drug treatments (an adaptive response) based on a better understanding of their personal cardiovascular disease (CVD) risks (which informs the individual's 'threat appraisal' within the PMT). This will help clinicians to address key issues with their patients: Why should I start CVD risk reduction? When should I start? What should I do? Clinicians will use the online JBS3 calculator, with simple manual entry of patient data to generate risk estimate outputs. Integration of JBS3 into the practice systems is not warranted for this study.

8. Design and theoretical/conceptual framework:

This qualitative study will use VSR to explore the relative merits of the QRISK2 and JBS3 in CVD risk communication in NHS Health Checks, in terms of the resulting understanding and perceptions of risk, and associated health-protective intentions and behaviours (an adaptive response). Given the complexity of clinician-patient interactions (3,20) and the translation of risk information into health-protective behaviour (19), it is useful to consider this within a theoretical framework. Multiple behavioural theories have been developed within health psychology to understand why people may or may not undertake health promoting behaviours (19). In general, they present engagement with health promoting behaviour as emerging as the net positive behaviour after consideration of the risk in question and the burdens of reducing the risk (19). An appropriate model for this study is the revised Protection Motivation Theory (PMT), as 'protection motivation' in the present context refers to the intention to undertake health protective behaviour (58) as a result of the risk communication (Figure 1).

Protection Motivation Theory was informed by fear-drive models, which recognised that behaviour change can be prompted by fear-inducing communications, in this context, highlighting CVD risk. This subsequently motivates patients to take action to reduce the perceived threat (or risk) (19,36). However, the relationship between fear and motivation to change behaviour (or facilitation) is more complex than a simple stimulus-response and this is recognised by PMT (36). In PMT, protection motivation (58) is the preceding step to behaviour change. It is influence by two cognitive appraisals.

1. Threat appraisal evaluates the maladaptive responses; i.e., not initiating behaviours in response to an elevated CVD risk. This considers the source of the threat (i.e., clinician/Health Check), intrinsic rewards (e.g., better health) and extrinsic rewards (e.g., social approval), and the perception of the threat (perceived severity and personal vulnerability).
2. Coping appraisal evaluates the adaptive response to cope with the threat (i.e., CVD risk), and considers the likelihood that positive behaviour change (adaptive response) will reduce their risk (response efficacy), ability to make the necessary changes (self-efficacy), and the burdens of, or barriers to, making the change (response costs) (19,58–60).

The threat and coping appraisals in PMT are influenced by both environmental aspects (e.g., persuasive communication and observational learning) and intrapersonal variables (e.g., personality and feedback from prior experience of both positive (adaptive) and negative (maladaptive) behaviours) (19). Thus the PMT underlines the key role that clinicians have in providing the information on CVD risk (vulnerability) and incorporating a patient's beliefs, priorities and experiences into strategies to reduce this risk so that patients feel they can achieve adaptive behaviours (3) and subsequent health outcomes.

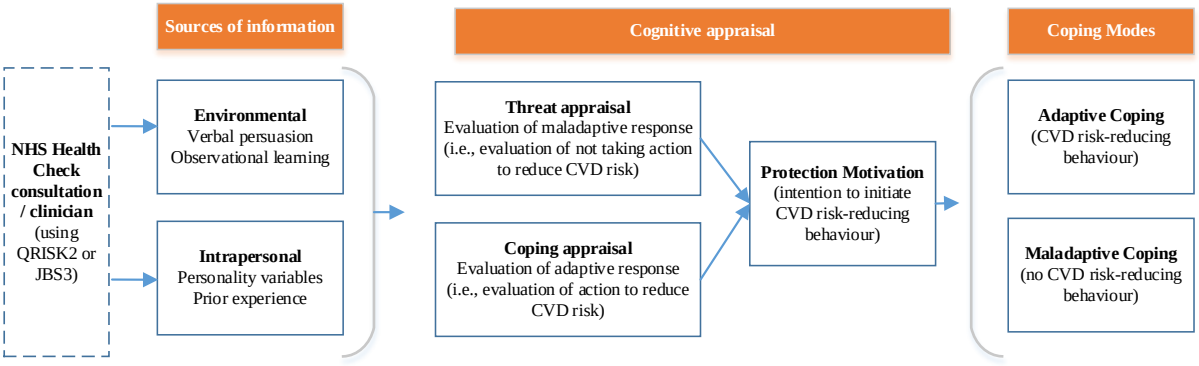

Figure 1. Protection Motivation Theory - overall model adapted to proposed study context (adapted from Floyd et al. (19))

Using PMT as a foundation to investigate the use of the two CVD risk assessment tools as proposed here will provide insight into their relative merits and mechanisms by which they might promote positive behaviour change, as:

- it was initially developed to examine intention to adopt behaviours relating to disease prevention (61)
- it does not assume rationality within behaviour choices (19,62)
- when examined in multiple settings (62), its components have been found to be associated with (intention for) behavioural change in relevant contexts (e.g., smoking cessation, exercise) (58,59)
- it is recognised as a "*viable model*" which "*provides an understanding of why attitudes and behaviour can change when people are confronted with threats*" (2).

9. Target population:

The patient population will be those eligible for NHS Health Checks based on national criteria (1) (adults (40-74 years; without chronic disease diagnosis or statin prescription).

The clinician population will be staff delivering NHS Health Checks (e.g., practice nurse, health care worker).

10. Inclusion/Exclusion Criteria:

General practices
Practices will be excluded from recruitment if they:

- Do not already deliver NHS Health Checks within the practice
- Do not use the QRISK2 percentage risk score
- Do not, or are not willing, to deliver Health Checks in specific clinics to facilitate data collection
- Be signed up to the 'incentive scheme' implemented by the CRN to ensure the GP practice is 'research ready'
- Provide necessary practice-level consent and Data Sharing Agreements

Within each practice all patients eligible for a NHS Health Check can be included in the study (a stratified sample will be drawn from this list of patients – see sampling below).

Patients
No exclusion criteria will be applied beyond those of the national Health Check programme (1) that are routinely used by practices to identify eligible patients. These are not specific to, or influenced by this study, but for information, they exclude adults diagnosed with an existing chronic condition (coronary heart disease; chronic kidney disease; diabetes; hypertension; atrial fibrillation; transient ischaemic attack; hypercholesterolemia; heart failure; peripheral arterial disease; stroke), people on statins, and people who have previously had a NHS Health Check in the last five years, or received a NHS Health Check (or similar) and been found to be at high risk (≥20% 10-year CVD risk score).

11. Setting/context:

The study will take place in a minimum of 12 general practices in the West Midlands.

12. Sampling:

Practice sampling
A minimum of 12 general practices will be purposively sampled from the West Midlands to ensure diversity in terms of deprivation level, practices and ethnic profile of the practice population. The CRN will facilitate practice sampling. Briefly, this will involve an initial email invitation to express interest, with follow-up discussions/meetings with practice managers and clinicians will be used to identify willing and eligible practices. Practice participation will be incentivised (£1000/practice).

As summarised in Table 1, stratification of the practice sample will involve:

- CRN providing a list of eligible practices (according to above criteria) and information on practice list size, postcode and ethnic composition of the practice population.
- Postcodes will be used to characterise practices by quartile of deprivation according to the Index of Multiple Deprivation (63) to provide a proxy measure of typical socio-economic status of the practice population.
- Information on ethnic profile of the practice population would be used to dichotomise practices based on the proportion of the practice population classified as White British (WBRI). For example, high diversity is <70% WBRI and low diversity is >70% WBRI. This threshold would be determined based on the ethnic profiles of eligible practices identified by the CRN.
- Purposive stratified sampling will be used to provide diversity in practice characteristics in both groups (Table 1)
- The practices will be randomly assigned to the QRISK2 or JBS3 risk calculator groups using a random number generator in MS Excel.

Table 1. Stratified sampling of at minimum six practices per group based on deprivation and list size

		IMD quartile	
		1-2 (most deprived 50%)	3-4 (least deprived 50%)
Practice list size	Small-Medium (<8000)	1 Low ethnic diversity 1 High ethnic diversity	1 Low ethnic diversity 1 High ethnic diversity
	Large (≥8000)	1 High ethnic diversity	1 High ethnic diversity

Patient sampling

To provide data from a range of patients (e.g., socio-demographic, health literacy, CVD risk), the target is to secure 48 consultations with completed patient VSR interviews (24 per group). Patients eligible for a Health Check during the study period will be invited to take part in the study via postal invitations facilitated by the CRN. Consent forms for the research will also be included with the invitation, to enable telephone consent to be sought by the CRN (see data collection below). Postal invitations are a method commonly used to invite patients for a Health Check and so this will help to ensure ecological validity. Consequently, this demands that a large number of Health Check consultations are recorded. It will allow stratified patient sampling across the study, provide a large volume of data to give confidence of reaching data saturation in qualitative analysis, and provide statistical power to detect between-group differences in the nature of consultations based on the quantitative characterisation (see Data Analysis).

There will be three levels of patient sampling.

1) For the 240 total sample:
To achieve the 144 recorded consultations suitable for qualitative analysis (12 per practice), Health Check clinics would be recorded for up to four weeks within each practice, or until 20 recordings per practice (240 total) have been achieved. This is based on the following:

- Health Checks are delivered in 1-2 dedicated clinics (or one dedicated day) per week;
- Each clinic could accommodate 6-9 Health Checks, but on average should result in 4-5 completed Health Checks (allowing for DNAs);
- The first recorded clinic could be used to habituate clinicians to video recording;
- Further 5 clinics would provide a total of 20 consultations per practice;
- Allowing for loss from exclusion of recordings where CVD risk is not discussed sufficiently for useful qualitative analysis,[1] patients subsequently declining the VSR interview (despite providing consent) and technical failure, we should obtain 144 recorded consultations (~12 per practice total) for stratified sampling of the 48 VSR interview participants (see below), and;
- 1-2 clinicians deliver Health Checks within a practice, providing approximately 18 clinician VSR interviews across 12 practices.

In each practice, the CRN will run a search to identify the cohort of patients who are eligible and due for a NHS Health check. This list will be stratified according to: age (40-54, 55-64, 65-74 years); gender (male, female); ethnicity (White British, Black, Asian and Minority Ethnic) to ensure appropriate representation from different demographic groups. The above age categories have been used to maintain consistency with work in this area (72,73). Table 2 shows an example of how this could be stratified to offer diversity in the sample. The proportion from each broad ethnicity category will be decided based on the local practice population; for example, in areas with high concentrations of South Asian populations, the relative proportions of WBRI to BAME would be adjusted to reflect this.

Table 2. Example of stratified sampling of the 20 patients per practice to be invited for recorded Health Checks according to key demographics

		Gender	
		Female	Male
Age (yr)	40-54 yr	4 (3 WBRI/1 BAME)	4 (3 WBRI/1 BAME)
	55-64 yr	3 (2 WBRI/1 BAME)	3 (2 WBRI/1 BAME)
	65-74 yr	3 (2 WBRI/1 BAME)	3 (2 WBRI/1 BAME)

WBRI, White British; BAME, Black, Asian, Minority Ethnic

2) For the 144 used in qualitative analysis:
Once the Health Check has taken place, video recordings will be screened within 48 hours to code quantitatively and identify patients to invite to take part in the VSR interview. Those patients where risk was not discussed by neither patient nor clinician will not be invited for the interview. As far as possible, for the remainder, the below stratification (Table 3) will be used to ensure diversity in the sample within each practice.

3) For the 48 VSR interviews:
To provide data from a range of patients (e.g., socio-demographic, CVD risk), the target is to secure 48 consultations with completed patient VSR interviews (24 per group). Stratified sampling will also be used at this stage to identify the 48 participants to be followed up for VSR interview. Table 3 summarises shows stratified sampling of 24 VSR interviews per group (total 48) from the 144 recorded Health Checks based on gender (m/f), age and CVD risk (note: practices already stratified by IMD).

Table 3. Example of stratified sampling of VSR patient interviews per group based on age, CVD risk and gender.

		CVD Risk*	
		Low (<10%)	Medium-High (≥10%)
Age (yr)	40-54 yr	2 m / 2 f	2 m / 2 f
	55-64 yr	2 m / 2 f	2 m / 2 f
	65-74 yr	2 m / 2 f	2 m / 2 f

*QRISK percentage 10-year risk would be used for stratification purposes for consistency across both groups.

The proposed total of 144 recorded consultations (12 per practice) with 48 patient VSR interviews and 18 clinician VSR interviews, is comparable with a recent study using audio-recording of similar consultations around CVD risk communication in patients with psoriasis (n=130 in 10 practices [(2)]) and the number of interviews in VSR studies (n=9-39 [(3)]).

13. Data collection:

As detailed above, data will be collected in the following ways. The following section on Data Analysis outlines specifically how each data source will be analysed to address the stated objectives.

Prior to taking part in any aspect of the study, telephone informed consent will be gained from patient participants. This procedure will be facilitated by the CRN. Potential participants will be provided with a specific telephone number to use when booking their Health Check if they wish to also take part in the study

(included in the study information sheet). The specific telephone number will be managed by a representative from the CRN who will talk through consent procedures via telephone with the patients. If patients are still happy to take part, verbal consent for the study will be gained and they will return their signed consent form (to be posted out with study information and invitation) when visiting the GP practice for their Health Check. Patients who do not wish to take part in the study but would like a Health Check will be asked to make an appointment using their usual practice methods. In the event of non-response to the postal invitation, the CRN representative will telephone the patient to check that they received the invitation and ask if they are interested in being part of the study before gaining their verbal informed consent.

1. Video-recording of NHS Health Checks

Digital camcorders (with external microphones to ensure high quality audio recording) will be set up to record Health Check clinics. This will provide an audio-visual record of the consultations in which both patient and clinician are visible. Video recordings will be screened after each clinic. If there is no discussion of CVD risk, this will be noted and the file retained for transcription to facilitate quantitative analysis. For all consultations that involve discussion of CVD risk, the audio-record will be separated from the visual (using Adobe Premiere Pro) for transcription, which will allow illustrative quotations to be used for reports, whilst the visual data will provide a record of non-verbal behaviour for additional context in analysis/interpretation.

2. Semi-structured VSR interviews with patients

Semi-structured VSR patient interviews will be arranged within two weeks following a patient's Health Check. The associated consent and contact details to arrange this will be obtained patients in advance of Health Check.

After each clinic, recorded Heath Checks will be watched to identify (and make a note of) sections of the consultation relevant to the study objectives and PMT (e.g., discussion of CVD risk, discussion of the risk score, clinician advice, recommended intervention, patient response to both risk information and advice). Excerpts of videoed Health Checks will be rendered into a single video using Adobe Premiere Pro, and used as a prompt for reflection during interviews.

The VSR interviews will be audio-recorded, semi-structured, one-to-one interviews, structured as follows and using a topic guide that will be developed and finalised through PPI:

- Icebreaker questions (to put participant at ease; e.g., where did you hear about the Health Check?)
- Preliminary questions relating to experiences and perceptions of the Health Check
- Specific questions relating to CVD risk (e.g., CVD risk understanding, perceptions and intentions following the Health Check, the role of the computer software in aiding this)
- Participants shown video excerpts from their consultations
- Follow-up questions asking patients to reflect on specific aspects of the consultation (e.g., conversation around CVD risk, the terms used, the clinician's advice, their intentions and subsequent behaviour)

The audio-recorded VSR interviews will be transcribed verbatim for analysis.

3. Semi-structured VSR interviews with clinicians

Semi-structured VSR clinician interviews will be arranged within two weeks of their final recorded Health Check. The associated consent and interview time/location will be arranged in advance.

As above, excerpts relevant to the study objectives and PMT will be extracted and rendered into a single video. The difference to patient VSR material is that clinicians will be shown excerpts from a range of consultations with the patients also selected for VSR interviews. Interviews will be audio-recorded, semi-structured, one-to-one interviews, structured as follows using a topic guide that will be developed and finalised through PPI:

- Icebreaker questions (to put participant at ease; e.g., how long have you worked at your current practice; training received in Health Check delivery)
- Preliminary questions relating to experiences and perceptions of the Health Check
- Specific questions relating to CVD risk communication in Health Checks (e.g., personal understanding of CVD risk score, perception of the risk score they used, confidence in articulating risk, interventions/options they are able to offer patients, and perceived understanding and response of patients, the role of the computer software in aiding this)
- Clinicians shown video excerpts from a range of consultations
- Follow-up questions asking patients to reflect on specific aspects of consultations (e.g., conversation around CVD risk, the terms used, their advice to patients, patient response).

The audio-recorded VSR interviews will be transcribed for analysis.

4. Patient record review

Patient records would reviewed to determine subsequent action. Searches would be designed by the CRN to identify outcomes with searchable read codes that occurred at minimum 12 weeks post-Health Check, such as GP appointment, lifestyle referrals, physiotherapy referral, lifestyle referral, smoking cessation referral, alcohol advice, or statin prescription. This list will be agreed between clinical experts within the team and the CRN.

14. Data analysis:

Qualitative data

Qualitative data collected as described in 1-3 above will be analysed using Thematic Analysis, which has aim of identifying patterns of meaning across a dataset in line with the research question. Patterns are identified through a rigorous process of data familiarisation, coding, and theme development and revision (Table 3 (5)). Given the nature of this research a hybrid approach involving deductive and inductive analysis (65) will be applied:

- Deductive for analysis of Health check consultations (and case studies – see below), where the high volume of data (up to 144 consultations) and use of the PMT as a framework mean that predetermined codes will be applied to explore specific themes
- Inductive for analysis of VSR interview data, where codes and subsequent themes will be generated by the individual reflections of patients and clinicians.

Analysis will be conducted using NVivo 11. Constant comparison will be used throughout. Most analysis will completed 'between groups'; i.e., separately for QRISK2 and JBS3 groups to allow comparison and highlight differences in themes (inductive) or the extent to which predetermined themes are supported (deductive). Case study analysis will also be used in a selected subsample, where a case is a matched consultation, patient interview, and clinician interview, to further explore mechanisms by which intentions for health-protective behaviour are elicited.

Table 3. Process of Thematic Analysis (adapted from (5))

Phase		**Summary**
Phase 1	Familiarisation	Analysis will start with a period of familiarisation involving watching and re-watching the video-recorded consultation (or listening to audio-records in the cases of interviews), noting initial thoughts in the transcript
Phase 2	Initial coding	For deductive analysis, codes from the template will be applied to the transcript independently by two researchers; for inductive analysis, codes will be generated based on interesting features, and recurrent patterns, in the data. For both inductive and deductive analysis, the researchers will then go back through and check their own codes, before discussion to verify and agree final codes.
Phase 3	Searching for themes	Agreed codes will be collated into potential themes, gathering all data relevant to each potential theme.
Phase 4	Reviewing themes	Constant comparison will be used to check themes by revisiting data to ensure they are representative, and then generating a thematic 'map' of the analysis.
Phase 5	Defining and naming themes	Ongoing analysis to refine the specifics of each theme, and the overall story, generating clear definitions and names for each theme
Phase 6	Reporting	Illustrative extracts will be selected to include in a narrative that tells the overall story.

Quantitative data

- Quantitative comparison of the content of Health Check consultations (n=240)

The content of each of the 240 recorded consultations (i.e., before sampling of 144 for qualitative analysis) will be characterised in terms of important features, such as: proportion of Health Check spent discussing risk; number of times CVD risk is mentioned; number of references to the risk score(s), ratio of minutes clinician spoke for vs. minutes patient spoke for; number of questions patients ask about CVD risk; proportion of Health Check spent discussing intervention/changes; number of times the clinician manipulated the risk score to illustrate amenability of risk to change.

The process of coding will involve: development of a coding process and guide; two researchers will code a minimum of four consultations by consensus to reach consistency in approach; two researchers will code the remainder independently (118 each); for every 20 coded consultations, two would be subject to independent verification (whereby researchers code both independently and determine agreement) on an ongoing basis periodically throughout the data analysis phase (i.e., >10% independently verified). This approach would ensure ongoing quality assurance and prevent deviation in researchers' coding approaches.

In the absence of research which would provide an indication of what effect size to expect, we have calculated statistical power based on the proposed sample size to indicate what the minimum effect size would need to be to provide adequate power. With 120 consultations per group, using a between subjects t-test with a two tailed probability and alpha of .05, we will have statistical power of at least .8 to detect an effect size (Cohen's d) = 0.37 (between what Cohen considered to be a small and a medium effect size). The sample of 120 in each group will mean that the effect sizes derived from the study will have good levels of precision for estimating the effect sizes in future studies and so provide more accurate power analysis for such studies.

To explore possible cohort effects within the data, Intra class correlations (ICCs) will be calculated (i.e., to examine possible clustering within practices). Multi-level modelling is not appropriate; the study has been designed to allow the novel qualitative enquiry, but is not powered for multi-level statistical analysis.

- Quantitative description of patient records (n=240)

Patient records would be interrogated to identify possible outcomes with searchable read codes that occurred at minimum 12 weeks post-Health Check, such as GP appointment, lifestyle referrals, physiotherapy referral, lifestyle referral, smoking cessation referral, alcohol advice, or statin prescription. This list will be agreed between clinical experts within the team and the CRN, and the CRN would design the searches.

These data would be tabulated for an exploratory descriptive comparison of the two groups. The primary purpose will be to provide additional context to qualitative data, particularly the VSR interview and case study analysis. As we know that clinical information is often limited by poor and inconsistent recording, we anticipate that missing data will prevent formal statistical analysis.

Please note that this is not a trial and the primary aim is not to be powered for inferential statistical analysis on these data for both of these quantitative data types.

Analysis plan against objectives

The following outlines how the different sources of data will be analysed to address the stated objectives.

1. Recorded Health Check consultations (Objective 1,2,5)

Health Check consultation data will be analysed deductively. A coding template will be developed based around the PMT (and broader risk communication literature). Each consultation video and associated transcript will be uploaded to NVivo and the transcript analysed using the above TA process, annotating the transcript and using the visual information from videos for additional context (e.g., to identify where patient's verbal data suggest that they understand, but body language indicates otherwise, using objective criteria such as lean and eye-gaze). This will be completed separately for consultations in the QRISK2 and JBS3 groups for comparison. This will allow interpretation of how QRISK2 and JBS3 are used to communicate risk in the context of PMT factors (e.g., verbal persuasion, influencing patient prior beliefs and priorities; Obj.1) and how patients respond (Obj.2), which will reflect that nature of their appraisal (threat/coping) within the consultation. Both will allow inferences about the mechanisms at work in consultations that appear more and less successful (Obj.5).

2. Semi-structured VSR interviews with patients (Objective 3,4,5)

Patient VSR interview transcripts will be analysed using inductive TA, where codes and themes are generated from data based on individual reflections, perceptions and experiences. This will be completed separately for QRISK2 and JBS3 groups for comparison. The resulting thematic map for each group will provide insight into patient perceptions and understanding of CVD risk (Obj. 3), with video-stimulated reflections on that experience, and further reflections on their thoughts, feelings and intentions to undertake health-protective behaviour following the Health Check (Obj. 4). Data will also allow inferences about the underlying mechanisms (Obj.5).

3. Semi-structured VSR interviews with clinicians (Objective 3,4,5)

Similar to the patient VSR interviews, clinician VSR interview transcripts will be analysed using inductive TA, where codes and themes are generated from data based on individual reflections, perceptions and experiences. This will be completed separately for QRISK2 and JBS3 groups for comparison. The resulting thematic map for each group will provide insight into clinician perceptions and understanding of CVD risk (Obj. 3), with video-stimulated reflections on aspects such as how they communicate risk in consultations, their use of the calculator, the types of intention and advice they offer, patient responses, and so on (Obj. 4). Data will also allow inferences about the underlying mechanisms (Obj.5).

4. Within-case analysis (Objective 5)

Case study analysis will involve deductive analysis of 'cases', where a case is a matched consultation, patient interview, and clinician interview, with additional context provided by quantitative data on the content of the specific consultation and the subsequent actions according their patient record. The aim would be to further explore and check apparent mechanisms by which the risk calculators may lead to changes in patient or clinician behaviour (inferred from 1-3 above). A subsample of 10 patients who demonstrated the most positive intentions and/or behaviours to reduce CVD risk following the Health Check will be selected. A coding framework related to the mechanisms of eliciting health-protective intentions/behaviours would be generated from 1-3 above and applied to qualitative data to each case study (from consultation, and patient and clinician VSR interviews). The quantitative data on Health Check content and subsequent actions would be used to provide a basic profile for each patient to aid interpretation.

15. Dissemination and projected outputs:

The main outputs from this research are listed below, as part of a multi-faceted dissemination strategy. An overarching aim will be to engage practitioners, commissioners and policy makers (as well as patient groups) involved in the NHS Health Check programme. A key target organisation will be Public Health England (PHE), who lead the national programme, and associated NHS Health Check networks. We are confident in engaging with these audiences as: the team have a good working relationship with PHE (see letter of support); the team includes two high profile clinical researchers who are linked in to important regional and national networks (Professor Ruth Chambers - Co-Applicant; Dr Matt Kearney - Advisor); members of the team have working relationships with members of the NHS Health Check Expert Scientific and Clinical Advisory Panel (ESCAP).

• PUBLICATIONS at least 3 publications in scientific peer-reviewed medical and public health journals are planned, including findings from analysis of the Health Check consultations using the two risk calculators (target journal BMJ), from analysis of patient VSR interviews (target journal BMC Public Health), and from clinician VSR interviews (target journal British Journal of General Practice).

• DISSEMINATION EVENT: An event would be organised at the North Staffordshire Medical Institute at the end of the study to promote findings to clinicians, health practitioners and patients to present findings.

• CONFERENCE PRESENTATIONS: We would submit abstracts to present at relevant conferences, such as the PHE Annual Conference, the Annual NHS Health Check Conference, UK Society for Behavioural Medicine Annual Scientific Meeting, Royal College of General Practitioners Annual Conference and FPH Annual Conference.

• LAY SUMMARIES & EVIDENCE BRIEFS: Evidence Briefs summarising findings will be disseminated through social media and to our network of practitioners, policymakers, and academics, including relevant organisations (e.g., PHE, Department of Health, British Heart Foundation, British Hypertension Society, British Cardiac Society, Diabetes UK, Heart UK, Primary Care Cardiovascular Society, The Stroke Association). Lay summaries will be produced for end-users (e.g., general practices; PPGs; PPI panel members; study participants). Lay summaries will be reviewed by patient groups, such as county Healthwatch Reader Panels to ensure their appropriateness and reach for the intended audience.

• PRACTITIONER PUBLICATIONS/NEWS LETTERS: Brief reports would be written for practitioner publications (e.g., Pulse, The Practitioner, Nursing Times) and would be sent for distribution via the PHE NHS Health Check bulletin and the posting on programme website (www.healthcheck.nhs.uk).

16. Plan of investigation and timetable:

The project is scheduled to last 30 months as detailed in the Project Gantt chart (Appendix 1). Specific milestones and projected timelines are summarised (Appendix 1). In advance of the project, the two researchers would be appointed and lead institution processes established (e.g., finance; set up of Co-Applicants; establish project management processes).

17. Approval by ethics committees

There will be two phases to the ethical review process:

1. Independent Peer Review (IPR) will be sought from the Staffordshire University IPR panel, with a submission in April 2017 for approval by June 2017. This will allow time for PPI activities for development work around aspects such as VSR protocols and participant information sheets in advance.
2. All NHS ethical approval will be sought through submission to the new Health Research Authority (HRA) process, which brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Departments' Research Ethics Service. This replaces the need for local checks of legal compliance and related matters by each participating organisation in England. We would aim to submit in May 2017 for approval by August 2017.

We do not foresee major ethical issues as:

- The patient sample will receive an invitation for the NHS Health Check regardless of this study (as they are being identified and invited through usual practice processes).
- Patients will be sent participant information sheets and a consent form with their Health Check invitation letter via post. If the patient wishes to take part in the study they will ring a dedicated member of the CRN who will guide them through informed consent procedures via telephone. In the event of non-response to the invitation letter, the dedicated CRN representative will follow up the postal invite approximately one week later to ask if the patient received the postal invitation and if they would like to take part in the study. In this way, patients are provided with a reasonable amount of time to consider their participation and will have opportunities to discuss any questions or queries before taking part.
- When patients arrive at the practice for the Health Check, a researcher and/or CRN staff member will be present to answer questions, gather the written consent form that had been posted to the participant with the study information and invitation, and provide further verbal and written information about the VSR interview participation.
- The consent form would seek permission to record the Health Check for analysis, contact them regarding a VSR interview (with provision of contact details to arrange), and for review of their patient record (by CRN).

There are three considerations to note.

1. Video-recording of Health Check consultations. This is not anticipated to pose an ethical issue as: recording of clinician-patient consultations is a common feature of clinical training in general practice so should not be new to research active or training general practices; feedback from PPI indicated broad acceptability of this approach among patients; patients will give written informed consent to this procedure and will be given the

opportunity to attend other Health Check clinics that will not be recorded or request that recording does not take place on the day (should they change their mind following initial consent).

2. Oversampling of video-recorded consultations. This is necessary to acquire sufficient (12 per practice) that contain discussion of CVD risk. For example, Paskins et al. (4) recorded 205 GP consultations to obtain 19 useable video-recordings; 176 did not contain discussion of the topic of interest (osteoarthritis) and 10 were excluded for other reasons (withdrawal of consent, technical failures, etc). There will be far fewer exclusions in the proposed study as Health Checks *should* centre around CVD risk (whereas Paskins was relying on patients presenting with OA in routine general practice – not specific clinics). However, from an ethical perspective, oversampling is justified to obtain sufficient quality data to give the study scientific merit. Moreover, consultations that contain little/no discussion of CVD risk will be subject to quantitative analysis.

3. Review of patient records. This is not anticipated to pose an ethical issues as the review will be limited to outcomes following the NHS Health Check. The search will be created by the CRN and run by them or the practice. It will only be run for patients who provide written consent. The resulting data provided by the practice will be anonymised using a numeric patient study identifier.

18. Patient and Public Involvement

Contributions of patients through PPI have been and will continue to be extremely valuable to this project as they provide alternative views from those of the research team or NHS staff, leading to alternative judgements about the aspects of study design or interpretation. Patients might also have different aspirations and thoughts about CVD risk and Health Checks that health care professionals and researchers not have considered.

Patient and public involvement (PPI) has already informed our approach, methods and procedures through discussions and feedback with Patient Participation Groups (PPG) in Staffordshire, which have involved a total of 48 patients and 3 practice staff. PPI will continue throughout the project as summarised below.

Aims of ongoing PPI

It is important that service users are actively engaged in the study throughout to inform:

- Development of study resources, such as participant information sheets
- Procedures for obtaining of consents within practices to minimise burden on patients
- VSR interview protocols
- Interpretation of findings
- Dissemination of findings to participants and patient groups
- Recommendations for practice based on findings (from the patient perspective).

PPI will, therefore, improve the feasibility and acceptability of the study, and the impact of findings through contributing to how data are translated in to practice recommendations.

Patients / public to be involved

Patients who are broadly representative of the NHS Health Check target population will be engaged (adults aged 40-74 years within the West Midlands).

Methods of involvement

Continued PPI will use the following methods, the costs of which are summarised in Table 5

- Two lay members recruited from PPGs will sit on the project steering group, thereby contributing to management of the research.
- PPG meetings in a number of practices (already engaged) will be attended periodically to update the group and ask for feedback/input on specific aspects (e.g., protocols, participant information sheets),
- Establishing a virtual PPG using social media, primarily in the form of a closed Facebook group specific to this study. The latter was discussed at two PPG meetings and welcomed as a means of reaching patients that span the NHS Health Check age range (40-74 years) and accommodating different preferences for communication. Additional value of the virtual PPG will be the broader reach

and immediate feedback on specific issues as they arise, whilst limiting the cost of travel for patients and the research team.

19. Expertise

Expertise and contributions
Dr Christopher Gidlow (CG), Associate Professor has published over 40 research publications, including studies of NHS Health Checks, lifestyle/CVD risk, and primary care health promotion (66,27,22,26,67–69,23,70,71). CG will line manage appointed researchers and have overall management responsibility.

We would appoint one full-time post-doctoral researcher for the duration to lead day-to-day research activities (Grade 7) and one junior researcher (Grade 5) full-time for data collection/analysis (months 6-24). Both would be based at Staffordshire University, line-managed by the PI.

For Co-Applicants:
- Dr Naomi Ellis, Senior Lecturer – expertise in health check research and general practice engagement; will lead PPI and contribute to data analysis
- Dr Elizabeth Cottrell, GP and NIHR Academic Clinical Lecturer in Primary Care - expertise in behavioural insights in primary care; will contribute of her time to help with coding template for deductive analysis and behaviour change expertise
- Sarah Grogan (SG), Professor of Psychology Health and Wellbeing - qualitative research methodologist; will contribute to qualitative data collection/analysis, with contribute
- Diane Crone (DC), Professor of Exercise Science – expert in qualitative research in health interventions (e.g., NHS Health Checks); will oversee qualitative data collection/analysis
- Professor Ruth Chambers (RC) OBE, GP and Director of Stoke-on-Trent CCG - clinical and primary care research expertise; will contribute to patient record review, interpretation and dissemination to clinical, commissioning and policy audiences
- Dr Zoe Paskins (ZP), Clinical Lecturer - a leading expert in VSR techniques (3,20); will advise on VSR protocols
- Dr Matt Kearney will help to disseminate findings for national policy and commissioning audiences
- David Clark-Carter, Professor of Psychological Research Methods; to provide statistical expertise
- Part-time project manager support (e.g., coordinate HTA progress, finance updates, risk logs).

All Co-Applicants will contribute to papers and dissemination.

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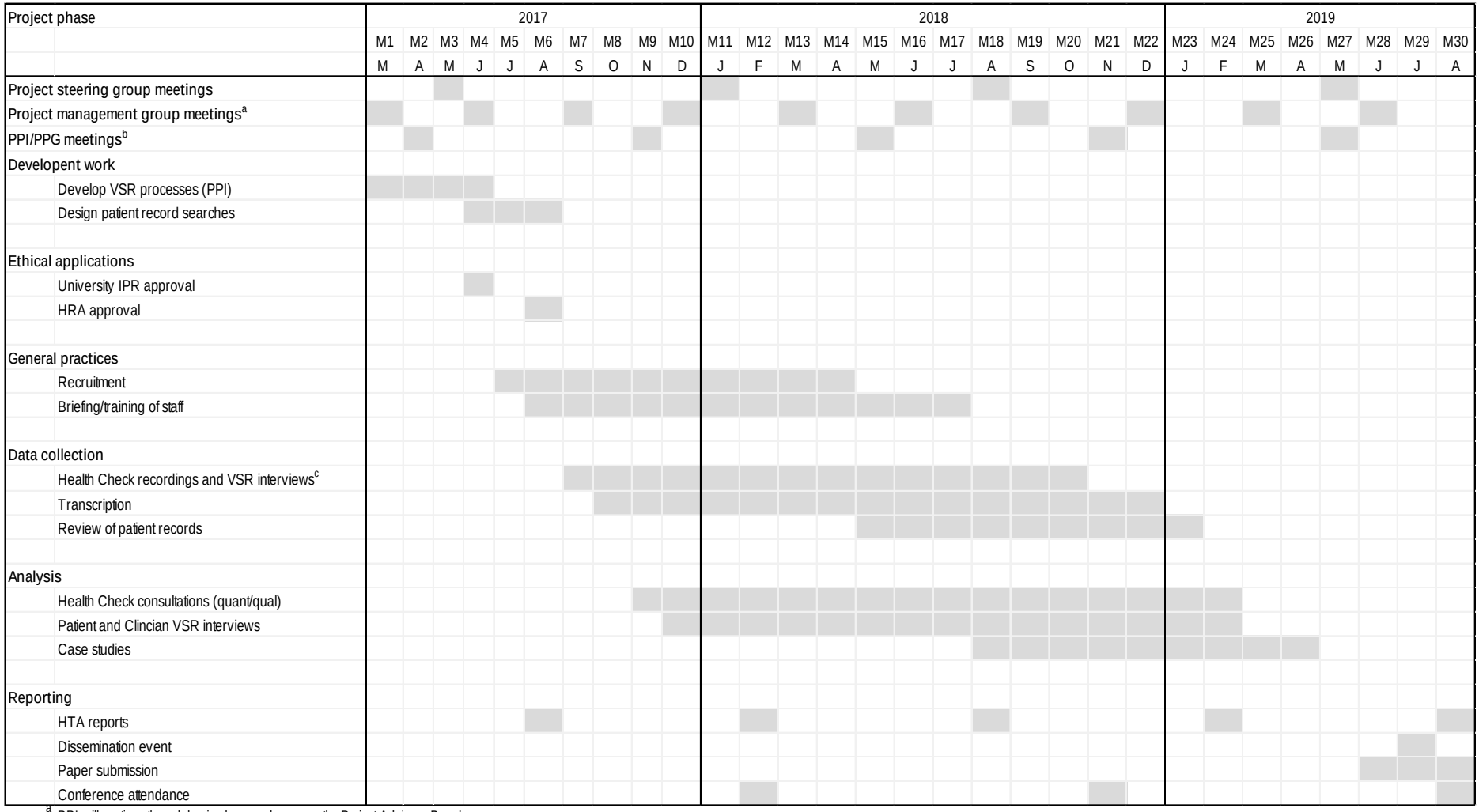
Appendix 1: Project Gantt Chart & Summary of Study Milestones

Figure 1. Project Gantt Chart



[a] PPI will continue through having lay members ason the Project Advisory Board

[b] PPG - attendance at specifici Patient Particpation Groups (PPGs)

[c] 2 months per practice; 2 practices concurrently

Table 1. Summary of study milestones

Year	Month	Milestone
2017	June	PPI development work to finalise protocols and study materials
	June	Ethics: Independent Peer Review (IPR) approval
		General practices recruited
	Aug	Ethics: Health Research Authority (HRA) ethical approval
	Sep	Data collection: Health Check consultations and VSR interview data collection begins
		HTA progress report
	Nov	Data analysis: Health Check consultations (quantitative/qualitative) and VSR interview data analysis begins (ongoing analysis of data as collected)
	Sep	HTA progress report
2018	May	Data collection: patient record begin
	Aug	Data analysis: Case study analysis begins
		HTA progress report
	Oct	Data collection: qualitative data collection complete
2019	Jan	Data collection: patient record reviews complete
	Feb	HTA progress report
	Apr	Data analysis: Case study analysis complete
	Jun	Dissemination event
	Aug	HTA final report

Appendix 2: Project Management Plan

Management of the Project will occur through the following mechanisms**:**

- Project Management Board *(Principal Investigator*, Project Manager and Co-Applicants)*
- Everyday Management: *(Project Manager)*
- Project Advisory Board: *(Includes Independent Chair – Provisional Chair is Dr Rosie McEachan, health psychologist specialising in behaviour change and the development of interventions to improve health. Dr McEachan is current programme manager for Born in Bradford, a visiting senior research fellow at the University of Leeds (Institute for Psychological Sciences) and an executive committee member of the UK Society for Behavioural Medicine.*

*Note: as a single site study, the Chief Investigator (CI) and Principal Investigator (PI) are the same person, and will be referred to as Principal Investigator only.

Project Management Board

The Project Management Board (PMB) will be the highest level of authority within the project. The PMB will meet quarterly throughout the project. The PMB will be chaired by Dr Christopher Gidlow *(PI)*, with support from the Project Manager and will include all Co-Applicants within the project. Meetings will be formally recorded and circulated to all project partners.

The main responsibilities of the PMB;

- Monitor progress of work against milestones
- Confirm quality and acceptability of project outputs
- Project level risk and issue management and contingency planning
- Agree on any requested project changes
- Authorise project management plan (and subsequent variations)
- To ensure a work environment with close cooperation, guarantee equal opportunities for all participants, and encourage active communication
- Agree and monitor communication and dissemination plan

Project Management (PM)

The PM will deal with the application of processes, methods, knowledge, skills and experience to ensure that the project is completed on time and within budget and that the project's objectives are met. The PM will coordinate written reports on aspects including (1) progress against milestones (2) current project summary and financial situation and (3) a log of all risks and steps to mitigate. The PM will hold full responsibility to ensure adequate records and other supporting documentation are on file to prove that the corresponding tasks and actions have been implemented appropriately and will ensure all the records are kept on file for the appropriate period after the final balance is paid.

Project Advisory Board (PAB) or Steering Group

The project advisory board will consist of external stakeholders and be chaired by an independent senior academic with subject-specific expertise. The PAB will advise on quality standards and agree for scientific and technical deliverables and impact activities from an end user and informed stakeholder perspective. The specific PAB composition will be determined should funding be secured. The provisional composition would be: Independent Chair; 2 Independent Members – providing clinical and qualitative expertise; 2 Lay Members – recruited from PPG groups engaged through PPI; Principal Investigator; representatives of the project team (Dr Naomi Ellis; Professor Diane Crone; Professor Ruth Chambers; Professor Sarah Grogan). They will meet at approximately 6-month intervals (four meeting during the project life) and report into the PMB. Meetings will be recorded by the PM.

- To monitor and supervise the progress of the project towards its interim and overall objectives
- To review at regular intervals relevant information from other sources (e.g. other related research)
- To consider the recommendations of the Research Ethics Committee (REC) (where appropriate)

- To review and endorse the annual report prepared by the Principal Investigator (PI) on the progress of the trial, prior to this being submitted to the funders (NIHR)
- To advise the PI and funder on publicity and the presentation of all aspects of the project.

Risk and Issue Management

Project risk and issue logs will be established to capture all risks and issues which will (or have the potential) to impact on project delivery. Risk and issues will be assigned an individual owner and categorised in terms of chances of occurrence and impact occurrence. Potential contingency plans will be prepared at the request of the PMB by the risk or issue owner.