SHARE-D: a Decision Tool to Help Patients Make Informed Lifestyle Choices

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Purpose and relevance
This project will inform development of a definitive shared decision tool and methods for its use in practice (eg. mobile application, with/without health professional). Further, it will be sustainable beyond the grant's lifetime as it will inform the design of a RCT and increase awareness of peoples' needs and resources in supporting lifestyle change.

To our knowledge the tool which we propose to test, is novel. It is paper-based in its current format, designed to be carried out in consultation with a health professional, focuses on PA and diet, and considers individuals' personal circumstances. Our tool ('*SHARE-D'*) aims to help people consider why and how they may change their lifestyles by guiding their decisions and taking account of their personal circumstances. Good decision-making, identifying the means of developing habits and routines, is the first step in the process of sustaining long-term change and healthy lifestyles. A novel instrument, targeting individuals with, and at risk of, chronic disease, to improve their decision-making through shared decision-making interventions thus has the potential to improve public health measurably.

Study aims and objectives
This feasibility study aims to examine the use of a questionnaire tool *('SHARE-D'*) for shared decision-making in primary care practice for patients with, and at high risk of, coronary heart disease (CHD), using both quantitative and qualitative methods. The project has six key objectives:

1. To test the feasibility of using a novel shared decision tool for diet and PA behaviour change, for patients in primary care.
2. To assess participants' diet and physical activity behaviour by administering the Dietary Instrument for Nutrition Education (DINE) questionnaire and Recent Physical Activity Questionnaire (RPAQ).
3. To make an objective assessment of participants' level of PA by using an accelerometer.
4. To explore patients' views regarding the usefulness and acceptability of the decision tool.
5. To explore practitioners' views of the decision tool.
6. To refine the design of a decision tool, for shared decision-making and for use in clinical practice, to facilitate initiation of sustained behaviour change.

Methods
Selection of practices
We propose to invite five general practices in Northern Ireland (NI) to participate, one from each of the five regional Health and Social Care Trusts. Practices will be selected purposively to include a range of geographical locations (rural/urban, with varying levels of socio-economic deprivation and social contexts) and practice size. With the assistance of the NI Clinical Research Network (Primary Care), we will telephone a key staff member in each of the selected practices to explain what the proposed study is about and explore their interest in participating. For those who express interest, we will post study information to the practice, allowing them time to discuss the study and decide whether to take part or if more information is needed. With their agreement, the researcher will arrange a suitable time to visit the practice and explain further the planned protocol. If an invited practice declines to participate we will identify a further practice with a similar profile for invitation to ensure that 5 practices participate.

Selection of patients
We propose to ask GPs to identify eligible patients (*see criteria below*) from their medical records or opportunistically and invite participation from people with a range of ages (18 years and above), different genders and, for those with established CHD, a range of time since diagnosis. We will ask GPs to identify 12 patients in each practice for invitation to take part in the study and to exclude from invitation patients whom they deem are physically or mentally unable to answer the proposed questionnaires, those who would be unable to make lifestyle changes because of physical or mental limitations and those who do not live freely within the community. It is anticipated that five or six invitees will agree to take part and include a range of possible co-morbidities and characteristics of interest. We recognise that GPs may choose to invite those whom they consider most likely to participate and to be compliant with the study protocol, thus introducing a possible risk of selection bias. However, we consider that the inclusion criteria will identify patients for whom the tool has relevance and they will have valuable contributions to make to the study findings. Moreover, possible factors influencing GPs' selection of patients will be sought through their participation in focus groups which will explore their perceptions of the applicability of the tool to a wider population than that included in the study sample.

Inclusion/exclusion criteria
Participants will have a Body Mass Index (BMI) greater than 30, indicating obesity, or low levels of physical activity (assessed by their general practitioner (GP), using the General Practice Physical Activity Questionnaire (GPPAQ), a tool recommended for use in primary care). We will include patients who have been diagnosed as having CHD and patients without a diagnosis of CHD but who are at high risk of CVD (10-year estimated risk of at least 20%, as assessed by the GP). Thus, our sample will include patients who would most benefit from behaviour change. Exclusion criteria, as listed above, are based on limitations in using the *'SHARE-D'* tool in its current format or in making diet or PA change.

Sample size
As a feasibility study is planned, a formal sample size calculation has not been conducted. We plan to interview five patients from five practices (expecting less than 50% response from invitees in each practice) giving a total study sample size of 25. This size of sample will allow inclusion of patients with a range of conditions, socio-economic characteristics and community support. Selecting a practice from each of five different health and social care trusts allows inclusion of patients who have access to different models of health and social care provision of services to support healthy lifestyles.

Recruitment of patients
The researcher will provide a study invitation letter for the lead GP from each practice to, if he/she approves the content, send to selected patients with a study information sheet, reply slip and stamped addressed envelope so that patients will be encouraged to return the reply slip, indicating their decision about taking part in the study, to the practice. Those who agree to participate will, with their consent, be telephoned by the researcher to arrange a mutually convenient time and location for a meeting at which the researcher will explain the study fully and ask the patient to sign a consent form if they still agree to participate. They will have the opportunity to ask any questions about the study and will be assured of confidentiality.

Data collection
With consent, at their initial meeting, participants will complete the DINE (Roe et al, 1994) and RPAQ (Besson et al, 2010) questionnaires, administered by the researcher, a post-doctoral fellow with experience in working with patients with coronary heart disease, to provide a baseline measure of diet fat and fibre intake and a measurement of physical activity. Then, in consultation with a health professional in the practice (nurse or general practitioner), they will complete a decision tool, a paper-based questionnaire which will highlight the need for personal decisions regarding lifestyle behaviour. Based on current evidence, relating to factors known to be important in behaviour change, this tool will provide information about benefits and risks associated with diet and physical activity and will include a series of questions to encourage individuals to consider their personal lifestyle behaviours and how to make changes. Based on a review of theories of behaviour change, with a focus on health beliefs, social support and self-determination, this will facilitate their consideration of their own beliefs, attitudes and values, as well as conditions existing within their social and physical environments, which would support or hinder possible changes in their behaviour. The duration of the meeting and data relating to their age, gender, medical conditions, medication and social circumstances will also be recorded. Participants will be offered some Northern Ireland Chest, Heart & Stroke literature/leaflets outlining the importance of healthy lifestyles and they may keep these and refer to them at their convenience.

The decision tool to be tested is designed to encourage conversation between a patient and health professional and support shared decision-making. It allows opportunities for the patient to ask questions at any time. After a shared decision has been made regarding possible changes in diet and physical activity, the researcher will arrange contact again for one month later.
At the end of the initial meeting participants will be invited to wear an Actigraph GT3X accelerometer for a 7 day period, to provide an objective measure of their physical activity. If they agree to do so, arrangements will be made to collect the device at the end of this period. We have considered the risk of potential confounding effects on behaviour change of using an accelerometer (reactivity effects) but concluded that these would be outweighed by the additional information gained through testing the feasibility of its use. In a definitive study it would be valuable to include an objective measure to assess the impact of the intervention on physical activity behaviour change.

Follow-up contact
At a one month follow-up meeting the researcher will ask about progress in lifestyle change, repeat the DINE and RPAQ questionnaires, consider and record possible unmet needs for support in change, help participants to identify appropriate sources of support, provide 'signposting' to these and answer any queries. A written record will be made of whether they have been in contact with their GP or practice nurse or have received any support from health professionals, community based organisations/facilities or friends and family, relating to lifestyle change. At the completion of this meeting the researcher and participant will agree arrangements for contact to be made again, two months later.

At 3 months after the initial meeting, the researcher will again meet participants to repeat the DINE and RPAQ questionnaires and record unmet and met needs for support, with particular note of the availability and use of health service and community resources in supporting lifestyle behaviour change. Following a semi-structured interview approach, participants' views of the decision-making tool will be sought and noted in writing by the researcher. Questions will be asked about each section, and each question, in relation to usefulness, clarity and relevance regarding helping them to adopt and sustain healthy lifestyles. Opinions will be sought regarding possible different or preferred methods of its administration (eg. mobile application, with/without health professional). Responses will not be audiotaped in order to minimize possible inhibition of expression of frank opinion, since there is recognition that people who attempt to make lifestyle changes and do not succeed may be embarrassed by their lack of success and sensitive about an ongoing need to make changes. Also at this 3-month meeting patients will be again invited to wear an accelerometer for a 7-day period to record physical activity.

Semi-structured interviews with health professionals
After patients' interviews and questionnaires have been completed in all five practices and their views on the decision tool have been explored, interviews will be conducted in each practice with GPs who invited patients' participation and health professionals with whom the patients have consulted during the time of the study. We hope to recruit at least one GP or one practice nurse per practice. If more than two health professionals in a practice wish to participate then we would attempt to conduct a focus group in that practice. The aim of the focus groups is to ascertain if the patients have shared any information relating to their use of the decision tool in consultations and the views of GPs and nurses regarding its potential utility in everyday practice. This will include their opinions on how the tool could be used during a consultation, the types of patients for whom the use of the tool would be considered appropriate, the questions included in it and what could be included in a potential electronic application of the decision tool. Primary questions for these groups will also be informed by analysis of the patients' interviews. The interviews or focus groups with health professionals will be audio-taped, with consent, and the recorded data will be transcribed verbatim, anonymously, for analysis.

Data analysis
The lifestyle questionnaires DINE, to ascertain diet habits, and RPAQ, to measure physical activity, will be used in order to record a measure of these aspects of participants' lifestyles during the time of the study, in order to provide objective contextual detail for the qualitative findings. Comparisons will be made of DINE fibre, fat and unsaturated fat scores and of RPAQ scores between the baseline measurements and at one month and at 3 months, so that change may be tracked for individuals. Descriptive statistics will be reported only. These data will guide in sample size estimations for a later study. Data derived from the accelerometers (minutes of moderate and vigorous physical activity), at baseline and at the 3-month follow-up point, will provide an objective measure of physical activity. Qualitative analysis of patients' opinions of the decision tool and reasons for any behaviour change undertaken during the study, which will have been noted in writing by the researcher at the second and third meetings, will be carried out. Experiences of incentives and barriers to lifestyle behaviour change will be sought. Data collection and analysis will be iterative. Thematic analysis will be employed, using the constant comparative method and the support of the computer software programme NVivo (QSR, 2010). Focus groups and interviews with health professionals at the five practices will be analysed qualitatively using a theoretical framework analysis. All data will be recorded anonymously and no individual will be identified in any report of the study.