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# Process evaluation protocol for a multicentre, single-blind randomized controlled trial: the MODEL study

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# Process evaluation protocol for a multicentre, single-blind randomized controlled trial: the MODEL study

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## ABSTRACT

### Introduction

The Modification of Diet, Exercise and Lifestyle (MODEL) study aims to examine the impact of providing visualisation and pictorial representation of advanced structural vascular disease (abdominal aortic calcification or AAC), on "healthful" improvements to diet and lifestyle. This paper reports the protocol for the process evaluation for the MODEL study.

### Methods and analysis

The overall aim of the process evaluation is to determine how and why the intervention was effective or ineffective, as well as to identify practical difficulties in the delivery of the intervention to inform wider implementation strategies. The process evaluation will employ a mixed-method approach. This will include the use of structured questionnaires and semi-structured in-depth interviews. All 200 participants enrolled in the trial will undertake the quantitative component of the study and maximum variation sampling will be used to select a sub-sample for the qualitative component. The sample size will be determined based on analytical saturation.

### Ethics and dissemination

The MODEL Study, including the process evaluation, has received approval from the relevant Ethics Committee (ECU Human Research Ethics Committee approval, Project Number: 20513 HODGSON and Deakin University HREC, Project number: 2019-220). Written informed consent will be obtained from all participants before they are included in the study. The study results will be shared with the individuals and institutions associated with this study as well as academic audiences through peer-reviewed publication and probable presentation at conferences.

### Trial registration number

Australian New Zealand Clinical Trial Registry ACTRN12618001087246

**Strengths and Limitations of this study**

- This is a pre-planned process evaluation protocol for an innovative study examining how providing visualisation and pictorial representation of advanced structural vascular disease (abdominal aortic calcification or AAC), can result in "healthful" improvements to diet and lifestyle.
- Participants with diverse characteristics will be interviewed to gather interpretations of their experience, perceived barriers to, and facilitators of, short-term behaviour change. The line of questioning will be related to changes (or no changes) stemming from the information given to participants as part of the MODEL study, perceived barriers to change, benefits and experiences of the intervention.
- A strength of the study is the use of mixed methods of data collection and analysis encompassing both depth and breadth of evaluation.
- A limitation of this study is that the findings are context specific and may not reflect perceptions and behaviour change in other societies with diverse cultures.

## INTRODUCTION

Suboptimal lifestyle choices and risky behaviours are the leading causes of atherosclerosis which, in turn, precipitates most cardiovascular disease events (CVD) such as heart attacks and strokes.[1,2,3] Most CVD-related events can be prevented or delayed by improvements to lifestyle factors including diet, physical activity and the cessation of smoking.[2] Despite the known benefits of these factors, few people take up or adhere long-term to existing lifestyle recommendations. Therefore, strategies to encourage individuals to initiate and adhere to long-term "healthful" dietary and lifestyle changes are urgently needed. One strategy that may offer promise in this regard is to provide individuals with visual information about their blood vessel health. New technologies have enabled such information to be provided to

community members in a low-cost, easy-to-disseminate manner, and a randomised controlled trial of the impact of such technology on behaviour change is forthcoming. The purpose of this protocol is to overview the process evaluation that will be embedded within this trial. This trial will be the first study to investigate whether providing individuals with visualisation and pictorial representation of their advanced structural vascular disease in the abdominal aorta can influence short-term fruit and vegetable intake (FV, primary outcome) and other lifestyle behaviours such a adherence to other dietary recommendations (e.g. sodium, fibre, whole grains, seeds and nuts) and physical activity and sedentary behaviour recommendations as well as improve recognised CVD risk factors and other health-related measures (e.g. gut health, physical function, and mental health). All participants will have their abdominal aortic calcification (AAC) assessed from a lateral spine image captured using DXA at baseline.

Calcification within both coronary arteries and abdominal aorta: (i) provides a measurement of the amount of calcium deposited in arteries; (ii) is considered surrogates for atherosclerosis and/or arteriosclerosis; and (iii) predicts future cardiovascular events.[6] AAC is evidence of advanced structural vascular disease, and individuals with AAC have a higher risk of future CVD hospitalisations and deaths as well as poorer long-term prognosis.[7,8] Imaging of the abdominal aorta can be done at a fraction of the cost and the radiation exposure of imaging for coronary arteries.[9] Therefore, this test holds great promise for modifying behaviour in older individuals with no history of clinical cardiovascular disease. However, to date, no study has investigated whether providing visualisation and pictorial representation of the presence of calcification of the abdominal aorta can influence "healthful" behaviour change.

This process evaluation will help the investigators of the Modification of Diet, Exercise and Lifestyle (MODEL) study to determine how and why the intervention was effective or

ineffective, as well as identify practical difficulties in the delivery of the intervention to inform wider implementation strategies.

**The MODEL Study**

The MODEL study will include a total of 200 (n=100 control group; n=100 intervention group) ambulant community-dwelling Australian men and women, aged 60-80 years, recruited from the general population in metropolitan Perth, Melbourne and surrounding areas in Australia. The primary aim of this study is to investigate, for the first time, whether providing visualisation and pictorial representation of the presence and severity of abdominal aortic calcification (AAC) assessed from the lateral spine image using DXA, can increase objective measures of FV intake (plasma carotenoids) after 12 weeks and improve: (i) adherence to other dietary recommendations (e.g. sodium, fibre, whole grains, seeds and nuts); (ii) adherence to physical activity recommendations (including reducing sitting time); (iii) recognised CVD risk factors (such as blood pressure, and lipids and glucose levels); and (iv) other health-related measures (e.g. gut health, physical function, and mental health). A detailed explanation of the methods for the MODEL study is provided in the protocol for the MODEL study in a joint submission to BMJ Open (Radavelli-Bagatini et al in submission).

**Process Evaluation**

The process evaluation will assess the effectiveness of the intervention as well as practical difficulties that were encountered in the course of the delivery and possible ways of improvement using a similar approach in the future. The process evaluation will ascertain the participants' views on the videos, counselling and reaction to their blood vessel disease results (image and illustrative information). It will also be useful in terms of evaluating the factors in the community, social/political context, or other situational issues, that influence their perceptions of CVD severity and susceptibility as well as perceptions of response efficacy (i.e., person's beliefs as to whether the recommended action will avoid the threat)

and self-efficacy (i.e., an individual's belief in his or her capacity to undertake the recommended action). The process evaluation will also be used to assess the potential barriers and facilitators of change in behaviour. This will inform future methods, intervention designs and theories [10,11,12] in addition to ascertaining the direction of the intervention's key components to produce the anticipated results.[13,14] A process evaluation may also determine the conditions under which an intervention can be deemed valid, the groups for which it was useful, and how it can be improved.[13,10]

**Aim**

The overall aim of the process evaluation is to determine how and why the MODEL intervention was effective or ineffective for influencing "healthful" improvements to diet and lifestyle, as well as to identify practical difficulties in the delivery of the intervention and possible ways of improvement to inform wider implementation strategies.

**Specific Objectives**

1. To explore participants' experiences in terms of clarity of information, counselling, reaction to their level and extent of their blood vessel disease results (image and illustrative information), and cardiovascular risk factors.

2. To better understand the contribution of the context (community, social/political, or other situational issues) on perceptions of CVD severity and susceptibility and perceptions of response efficacy and self-efficacy.

3. To explore the perceived barriers to, and facilitators of, behaviour change and the participants' experiences of the intervention (e.g., perceived benefits and shortcomings, possible improvements).

**Conceptual Framework for the Process Evaluation**

This process evaluation design was informed by the guidance for process evaluations as

specified by the Medical Research Council (MRC) [13,14]. Specifically, the process evaluation will examine three key features—context, implementation, and mechanisms of impact—to understand the processes through which one can achieve outcomes (Figure 1).

- **Implementation of the MODEL study program**: An assessment will be undertaken of what is delivered and how the MODEL study delivery is achieved. The structures, resources and the procedures used to deliver the intervention as well as the extent to which the intervention was delivered as intended will be described. In this instance, participants will be asked about the clarity of information in the video, and whether they are satisfied with the counselling process. Any adaptations made to the program and participants' sociodemographic characteristics will be described. How delivery is achieved under this domain will be assessed based on decision-making and diet and lifestyle/behaviour change concerning participating in the MODEL study. What is delivered will be assessed by the clarity of information in videos, counselling as well as image and illustrative information given to participants.

- **Mechanisms of impact:** The process evaluation will highlight processes through which the program affects outcomes. This includes how participants react to their level and extent of advanced blood vessel disease results, the perceived benefits of the intervention and how the intervention and potential mediators [family, perceptions of CVD severity and susceptibility/perceptions of response efficacy and self-efficacy, friends, GP, finances as well as access to information (internet, social media)] support change (or not). Mechanisms of impact will be assessed based on participants' views and experiences of the MODEL study program and materials, which elements of the program were viewed as helpful and unhelpful in supporting them to make changes and how the factors in the community, social/political context, or other situational issues influenced their

perceptions of CVD severity and susceptibility as well as response efficacy and self-efficacy.

- **Context**: The contextual aspects of the process evaluation will include an investigation of how the contextual factors within the two study sites (Melbourne and Perth) influences the functioning of the components of the MODEL study. The third domain of the framework which is context will be assessed by exploring the perceived barriers and facilitators of behaviour change. The different sociodemographic characteristics of participants at the two study sites (Melbourne and Perth) that influence activities and intention to adapt to the MODEL study intervention will be explored.

The Research Objectives for the process evaluation component of the MODEL study were structured around the three domains of implementation, mechanisms of impact and context. This is required to assess the intervention using a standardised process evaluation framework.[14] It will also aid us to address the three objectives of the process evaluation.

## PROCESS EVALUATION METHODS

### Design considerations

The intervention is expected to influence behaviour change based on certain mediators/moderators such as perceptions of severity and susceptibility as well as perceptions of response efficacy and self-efficacy. Factors in the community, social/political context, or other situational issues have been associated with tobacco use, physical inactivity, and poor diet.[15-20] Therefore, in the course of the intervention, situations which may influence the outcome of the intervention such as family, friends, GP, cultural differences, finances as well as access to information (internet, social media) will be part of the context to be explored. Whilst we anticipate that these influences will be relevant mediators/moderators, we remain

open to other potential moderators obtained from the qualitative interviews where participants describe their experiences in their own words.

**Overall design**

The process evaluation will employ a mixed-method approach using both qualitative and quantitative methods of data collection and analysis. This will include the use of a structured questionnaire and semi-structured in-depth interviews to be administered to participants. There are several reasons for focusing on the perspectives of participants. The intervention is intended to relate to the perspective of participants; their perception of the effectiveness of the components is critical to identify key components and effective techniques. In other words, the intervention is likely to depend upon participants' interpretations of, and reactions to, the intervention; hence, it is important to consider those perspectives. Also, the participants will not be passive receivers of the intervention and it will likely influence their circumstances, attitudes, beliefs, social norms and resources.[21]

All participants recruited for the MODEL study will respond to a closed-ended questionnaire that has been designed for the process evaluation. Maximum variation sampling (also known as maximum diversity sampling or maximum heterogeneity sampling),[22] a form of purposeful sampling, will be used to select participants with characteristics that maximize the diversity relevant to the research objectives. This sampling will be used to assess what influences behaviour change among participants at Perth and Melbourne study sites. Participant characteristics such as ethnicity/culture, age, profession, household income as well as sources of income will be considered in the selection. A key attribute that will be considered in selecting participants is the time they participated in the study. To gather accurate feedback on videos, counselling and behaviour change, participants who were enrolled at different stages of the study will be recruited to maximise the chances of achieving all the objectives of

the study. The sample size will be determined based on analytical saturation.[23] This is commonly taken to indicate that, on the basis of the data that have been collected or analysed, further data collection and/or analysis are unnecessary.[23] We anticipate achieving saturation with 15 to 20 trial participant interviews.

The research team will be composed of investigators with diverse backgrounds, such as psychology, nutrition, exercise physiology, social work, with some being part of the core team of the RCT (MODEL study).

**Data Collection**

Quantitative data will be collected using a questionnaire. Qualitative data will be collected using a semi-structured in-depth interview. A semi-structured interview guide will be used to enquire about experiences of participants in terms of clarity of information, counselling, reaction to their blood vessel disease results (image and illustrative information) and cardiovascular risk factors. It will also be used to explore the perceived barriers and facilitators of behaviour change and the perceived benefits of the intervention. The use of semi-structured interviews will ensure confidentiality and allow the investigators to be flexible in exploring any relevant and interesting matters as raised by participants. This will enable pre-specified areas to be explored and remain open to exploring other ideas and thoughts that will arise in the interview.[24]

**Table 1 Methods for Objectives**

| Objective | Sample | Data Collection |
|---|---|---|
| 1. To explore the experiences of participants in terms of clarity of information, counselling, reaction to their blood vessel disease results (image and illustrative information) and cardiovascular risk factors. | 15 to 20 trial participant interviews. The actual sample size will be dependent upon the point of saturation | A semi-structured interview will be used to explore participants 'understanding of the message in the videos and the effectiveness of the counselling sessions they had as well as their reaction to their blood vessel disease results (image and illustrative information) and cardiovascular risk factors. |
| 2. To better understand the contribution of the context (community, social/political, or other situational issues) on perceptions of CVD severity and susceptibility and perceptions of response efficacy and self-efficacy | All 200 participants | A semi-structured interview and a closed-ended questionnaire to explore/identify the variables in the community, social/political context, or other situational issues that influenced the perceived CVD severity and susceptibility/response efficacy and self-efficacy. |
| 3. To explore the perceived barriers and facilitators of behaviour change and the perceived benefits of the intervention among participants | 15 to 20 trial participant interviews | A semi-structured interview to explore perceived barriers and facilitators of behaviour change and the benefits of the intervention. |

All consenting trial participants will be invited to respond to a questionnaire with a sub-sample invited to participate in an interview.

Data collection will begin after 12 weeks (end of RCT) where all measurements performed at baseline will be repeated.

Investigators involved in data collection will discuss the aims of the questionnaire/interviews and provide information on any potential benefits and harm of participation. Participants will be assured of the confidentiality of the information they will provide. Interviews will be conducted at a mutually convenient site. The first author will administer the questionnaires

and conduct the interviews. Each interview will be audio-recorded and transcribed verbatim later.

The research team will develop the questionnaire, and the interview guide based on the objectives of the process evaluation, secondary data on the topic and further discussions and brainstorming among the research team. The questionnaire and interview guides will be piloted in the initial stages of the study to assess suitability for the study. As suggested by Given[25], interview guides will be amended as necessary by the research team.

**Management of data and analysis**

Questionnaire data will be entered into SPSS data management and analysis software. Interviews will be digitally recorded and transcribed verbatim. All identifying aspects will be removed to maintain anonymity and confidentiality and pseudonyms will be assigned.

**Analysis**

The quantitative data will be analyzed using SPSS version 21.0. The analysed data will be organized into frequency tables and represented on pie charts and tables. The analysis of the primary data will be entirely descriptive (summaries, frequencies, and cross-tabulation tables).

The qualitative data will be analysed thematically. The analysis and interpretation of the interviews will be guided by Miles and Huberman's framework for thematic content analysis.[26] The stages will involve the identification of meaning units, an initial grouping of meaning units into categories, and the creation of emergent category names. Following this stage, initial themes will be developed using a constant comparison method to ensure those meaning units are reflective of emergent themes. This will also focus on examining intra-theme coherence/consistency and inter-theme distinctiveness. The first author will lead the analysis and other authors will review that analysis and NVivo12 software will be used to

assist the data analysis. Using this software will enable the investigators to examine themes and structure in the content as well as visualize the findings and support findings with detailed evidence. An experienced qualitative researcher (M. St.) will be engaged for peer debriefing and member checking will be conducted to enhance rigour.

Investigators undertaking the MODEL RCT's assessment and counselling (SRB, CPB; MaSi.; LCB; EC; JTS; MPS; JG; BDR) will not be involved in the process evaluation data analysis or interpretation. Qualitative data will be collected and reported according to COREQ guidelines.[27]

## ETHICS AND DISSEMINATION

The study results will be shared with the individuals and institutions associated with this study as well as academic audiences through peer-reviewed publication and presentation at conferences.

This process evaluation will complement and add value to the MODEL Study by providing a better insight into study results. It will help the investigators to evaluate the moderators/mediators of behaviour change in this study.

**Patient and Public Involvement:** Patients or the public will not be involved in the design, or conduct, or reporting, or dissemination plans of our research

**Study status:** Data collection for the process evaluation will commence in January 2020.

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**Author's contributions:**

RA, SRB, LB, MS, JH and JL developed the study concept. RA, MS, JL, JH drafted the manuscript. RA, MS, JL, LB, JD, BJ contributed to the design of the study and are responsible for study coordination. RA will implement the protocol as well as oversee the collection of the data and will code all transcripts. All authors contributed and approved the final manuscript.

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**Competing interests statement**

The authors declare that there is no competing interest

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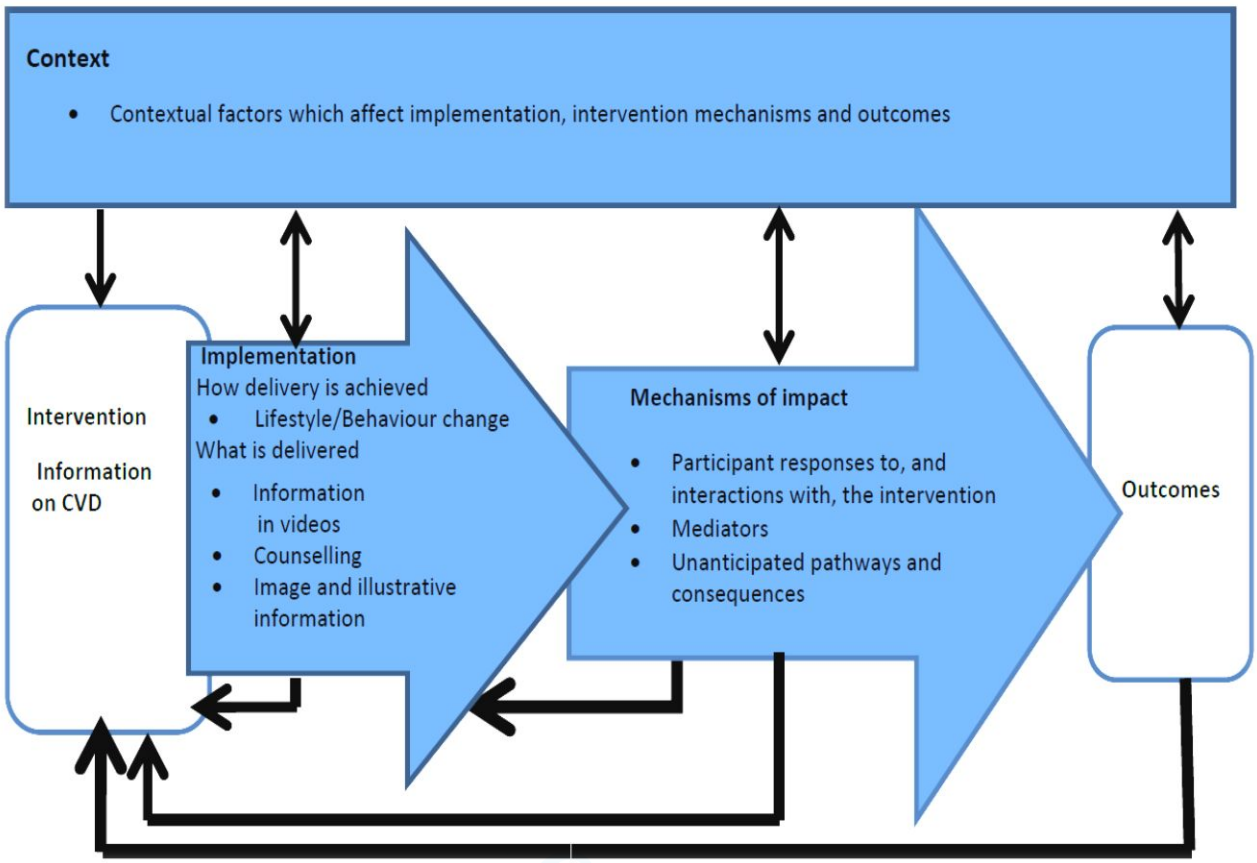


**Figure 1** Design of the process evaluation for the MODEL study. Adapted from Moore et al[16] and modified for the MODEL study.

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# Implementation, mechanisms of impact and key contextual factors involved in outcomes of the Modification of Diet, Exercise and Lifestyle (MODEL) randomized controlled trial in Australian adults: protocol for a mixed-method process evaluation

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# Implementation, mechanisms of impact and key contextual factors involved in outcomes of the Modification of Diet, Exercise and Lifestyle (MODEL) randomized controlled trial in Australian adults: protocol for a mixed-method process evaluation

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## ABSTRACT

### Introduction

The Modification of Diet, Exercise and Lifestyle (MODEL) study aims to examine the impact of providing visualisation and pictorial representation of advanced structural vascular disease (abdominal aortic calcification or AAC), on "healthful" improvements to diet and lifestyle. This paper reports the protocol for the process evaluation for the MODEL study.

### Methods and analysis

The overall aim of the process evaluation is to understand the processes that took place during participation in the MODEL study trial and which elements were effective or ineffective for influencing "healthful" behaviour change, and possible ways of improvement to inform wider implementation strategies. A mixed-method approach will be employed with the use of structured questionnaires and semi-structured in-depth interviews. All 200 participants enrolled in the trial will undertake the quantitative component of the study and maximum variation sampling will be used to select a sub-sample for the qualitative component. The sample size for the qualitative component will be determined based on analytical saturation. Interviews will be digitally recorded and transcribed verbatim. Qualitative data will be analysed thematically and reported according to the consolidated criteria for reporting qualitative research (COREQ) guidelines.

### Ethics and dissemination

The MODEL Study process evaluation has received approval from Edith Cowan University Human Research Ethics Committee (Project Number: 20513 HODGSON). Written informed consent will be obtained from all participants before they are included in the study. The study

results will be shared with the individuals and institutions associated with this study as well as academic audiences through peer-reviewed publication and probable presentation at conferences.

**Trial registration number**

Australian New Zealand Clinical Trial Registry ACTRN12618001087246

**Strengths and Limitations of this study**

- A comprehensive evaluation of all components/elements of a complex intervention will be achieved using a mixed-methods approach.
- Maximum variation sampling will be used to select participants for interview to maximize the diversity relevant to the research objectives.
- A reliable method of inquiry will be employed using standardised set of questions for the survey (quantitative component).
- Qualitative findings will give rich insights into perspectives of participants engaged in the MODEL study intervention.
- A limitation of this study is the risk of recall bias (unintentional and intentional responder bias) due to poor memory or the life-threating/life-changing nature of cardiovascular disease.

## INTRODUCTION

Suboptimal lifestyle choices and risky behaviours are the leading causes of atherosclerosis which, in turn, precipitates most cardiovascular disease (CVD) events, such as heart attacks and strokes. [1-3] Most CVD-related events can be prevented or delayed by improvements to lifestyle factors including diet, physical activity and the cessation of smoking.[2] Despite the known

benefits of these factors, few people take up or adhere to existing lifestyle recommendations. Therefore, strategies to encourage individuals to initiate and adhere to long-term dietary and lifestyle changes are urgently needed. One strategy that offers promise in this regard is to provide individuals with visual information about their blood vessel health using vascular imaging modalities. New technologies have enabled information about blood vessel health to be provided to study participants,[4-7] and a randomised controlled trial (RCT) of the impact of such information on behaviour change is forthcoming. This RCT holds great promise for modifying behaviour in older individuals with no history of clinical cardiovascular disease. The purpose of this protocol is to overview the process evaluation that will be embedded within the Modification of Diet, Exercise and Lifestyle (MODEL) randomised control trial.

Critics of RCTs contend that there's a set of 'positivist' assumptions that drive RCTs which are discordant with understanding the context of complex interventions.[8] Berwick,[9]; Clark et al.,[10]; Pawson and Tilley [11] opined that there is an oversimplification of cause and effect in RCTs of complex interventions and investigators often ignore the agency of participants and implementers as well as the context in which the intervention is experienced and implemented. There is emerging evidence to support the line of reasoning that a more critical realist framework should guide the conduct of RCTs of complex interventions. This will enable methods to be applied and interpreted critically while social realities are viewed as valid objects of scientific study.[12] The Medical Research Council (MRC) framework[13, 14] does not support the arguments against RCTs but acknowledges that 'effect sizes' alone are not sufficient, and that process evaluations should be conducted alongside of RCTs to limit biases when estimating effects. Process evaluations provide insight into implementation processes and mechanisms of impact in complex interventions, assisting with interpretation of overall study outcomes.[13, 15] [16] They can

also provide detailed information that could support the interpretation of causality by a systematic reviewer, practitioner or policymaker. [13, 14] Process evaluations have been demonstrated to be useful at the time of explaining trial results for complex interventions. [17] [18] [19] [20]

For example, Van Dongen et al.,[17] used a comprehensive process evaluation plan to examine the delivery and receipt of a diabetes prevention intervention by evaluating the intervention components that contributed to effective prevention of type 2 diabetes.[17] They concluded that it is feasible to implement a diabetes prevention intervention in Dutch primary health care after completion and reporting results of the process evaluation.[17]Another process evaluation assessed the quality of the execution of a programme for a self-management intervention for people with polyarthritis from the participants' perspective.[12] The process evaluation results identified the extent to which specific exercises and programme were highly valued and therefore the need to use various components such as writing exercises, use of role models and combined individual trajectory and group training to create an attractive intervention for a broad audience.[18] Also, the ProActive study (a physical activity intervention) process evaluation[19] [20] identified various reasons for trial outcomes using an explicit a priori hypothesised causal model while the Welsh National Exercise Referral Scheme intervention [21] process evaluation reported that there were limitations in communication, training and support which impacted the fidelity of some components.[21] Moreover, a process evaluation for an adolescent sexual health programme intervention in Tanzania reported the extent to which young people were engaged with the programme and quality of programme implementation.[22] All of these process evaluation examples have reported on the impact of contextual factors on the effectiveness of an

intervention[22] as well as contextual factors and implementers' actions that shaped delivery[21] and the fidelity of implementation [19] using mixed-methods [21, 22] or quantitative approaches.[19]

This study will evaluate the implementation, mechanisms of impact and key contextual factors involved in outcomes of the MODEL study using a mixed-method approach. This will enable the investigators to better understand how and why the intervention was effective or ineffective, as well as identify contextual factors involved in outcomes to inform wider implementation strategies. It will also be useful in the interpretation of trial results.

**The MODEL Study**

The MODEL study will investigate whether providing individuals with visualisation and pictorial representation of structural vascular disease in the abdominal aorta can influence short-term fruit and vegetable (FV) intake (primary outcome), adherence to other dietary recommendations (e.g. sodium, fibre, whole grains, seeds and nuts intake), physical activity, gut health, physical function and psycho-emotional and mental health outcomes (motivation to initiate behaviour change, perceived risk of CVD, depression, quality of life). All participants will have their abdominal aortic calcification (AAC) assessed from a lateral spine image captured using dual-energy X-ray absorptiometry (DXA) at baseline.

The MODEL study will include a total of 200 (n=100 control group; n=100 intervention group) ambulant community-dwelling Australian men and women, aged 60-80 years, recruited from the general population in metropolitan Perth, Melbourne and surrounding areas in Australia. A detailed explanation of the methods for the MODEL study is provided in the protocol for the MODEL study (Radavelli-Bagatini et al in press).

**Process Evaluation**

The process evaluation will ascertain the participants' views on the counselling session (including information about atherosclerosis and diet and lifestyle advice provided in videos and summarised in a booklet) and reaction to their blood vessel disease results (image and illustrative information). It will also be useful in terms of evaluating the factors in the community, socio-economic context, participant characteristics or other situational issues, that may influence the process of changing behaviour. This will inform future methods, intervention designs and theories [23-25] in addition to ascertaining the direction of the intervention's key components to produce the anticipated results.[13, 14]

**Aim**

The overall aim of the process evaluation is to understand the processes that took place during participation in the MODEL study trial and which elements were effective or ineffective for influencing "healthful" behaviour change, and possible ways of improvement to inform wider implementation strategies.

**Specific Objectives**

1. To evaluate the resources, structures, and the procedures used to deliver the MODEL study intervention from the perspective of participants.

2. To assess participants' responses to the MODEL study intervention and mediating processes which may influence the process of changing behaviour and subsequent changes in outcomes.

3. To better understand the contribution of external factors which may influence intervention outcomes (i.e. behaviour change).

The Research Objectives for the process evaluation were structured around the three domains of implementation, mechanisms of impact and context. This is required to assess the intervention using a standardised process evaluation framework.[14] The conceptual framework will aid us to address the three objectives of the process evaluation.

**Conceptual Framework for the Process Evaluation**

This process evaluation design was informed by the guidance for process evaluations as specified by the MRC.[13, 14] Specifically, the process evaluation will examine three key features—implementation, mechanisms of impact and context—to understand the processes through which one can achieve outcomes (Figure 1). Table 1 further illustrates the domain/constructs, objectives and how the objectives will be addressed.

**Table 1 Domain/constructs, objectives and how the objectives will be addressed**

| DOMAIN / CONSTRUCTS | DESCRIPTION OF DOMAINS/ CONSTRUCTS | OBJECTIVES | HOW THE OBJECTIVES WILL BE ADDRESSED |
|---|---|---|---|
| IMPLEMENTATION | The structures, resources and the procedures used to deliver the intervention. | To evaluate the resources, structures, and the procedures used to deliver the MODEL study intervention from the perspective of participants. | Explore participants' views on the clarity of information in the videos, counselling process and any other materials or resources provided during participation. |
| MECHANISMS OF IMPACT | Participant responses to the intervention and mediating processes that may influence subsequent changes in outcomes. | To assess participants' responses to the MODEL study intervention and mediating processes which may influence the process of changing behaviour and subsequent changes in outcomes. | a) Response to intervention – Gathering information on participants' reaction to their level and extent of their blood vessel disease results (image and illustrative information), videos and cardiovascular risk factors.<br><br>b) Mediators – Gathering information related to perceived risk of CVD, perceptions of CVD severity and susceptibility and perceived self-efficacy. |
| CONTEXT | External factors that may influence intervention implementation | To better understand the contribution of external factors which may influence intervention outcomes (i.e. behaviour change). | Identify participant characteristics (age, gender, employment status), community socio-economic status, or other situational issues outside of the intervention such as influence from family and friends, information from their General Practitioner (GP), as well as access to information (internet, social media) that support change (or not). |

## PROCESS EVALUATION METHODS

### Design considerations

The intervention is expected to influence behaviour change based on certain mediators/moderators such as perceptions of severity and susceptibility. Factors in the community, social/political context, or other situational issues have been associated with tobacco use, physical inactivity, and poor diet.[26-31] Therefore, in the course of the intervention, situations which may influence the outcome of the intervention such as family, friends, GP, cultural differences, finances as well as access to information (internet, social media) will be part of the context to be explored. Participants perceived risk of CVD, perceptions of CVD severity and susceptibility and perceived self-efficacy is also expected to be key mediators of behaviour change. Whilst we anticipate that these influences will be relevant contextual factors and mediators/moderators, we remain open to other potential contextual factors and mediators/moderators obtained from the qualitative interviews where participants describe their experiences in their own words. Health-related behaviour change will be explained and predicted in this study using the social-psychological health behaviour change model known as the Health Belief Model.[32]

### Overall design

The process evaluation will employ a mixed-method approach using both qualitative and quantitative methods of data collection and analysis. This will include the use of a structured questionnaire and semi-structured in-depth interviews (to be administered to participants. There are several reasons for focusing on the perspectives of participants. The intervention is intended to act upon the perspective of participants; their perception of the effectiveness of the components is critical to identify key components and effective techniques. In other words, the

intervention is likely to depend upon participants' interpretations of, and reactions to, the intervention; hence, it is important to consider those perspectives. Also, the participants will not be passive receivers of the intervention and it will likely influence their circumstances, attitudes, beliefs, social norms and resources.[14]

All participants recruited for the MODEL study will respond to a questionnaire that has been designed for the process evaluation. Maximum variation sampling (also known as maximum diversity sampling or maximum heterogeneity sampling),[33] a form of purposeful sampling, will be used to select participants with characteristics that maximize the diversity relevant to the research objectives. This sampling will be used to assess what influences behaviour change among participants at Perth and Melbourne study sites. Participant characteristics such as ethnicity/culture, age, profession, household income as well as sources of income will be considered in the selection. The sample size will be determined based on analytical saturation.[34] This is commonly taken to indicate that, based on the data that have been collected or analysed, further data collection and/or analysis are unnecessary.[34] We anticipate achieving saturation with 15 to 20 trial participant interviews.

The research team will be composed of investigators with diverse backgrounds, such as psychology, nutrition, exercise physiology, social work, with some being part of the core team of the RCT (MODEL study).

**Data Collection**

Qualitative data will be collected using a semi-structured in-depth interview. A semi-structured interview guide (Supplementary Appendix 1) will be used to enquire about experiences of participants in terms of clarity of information, counselling, reaction to their blood vessel disease

results (image and illustrative information) and cardiovascular risk factors. Interviews will be conducted approximately one month after participants complete the baseline component of the intervention. Participants must complete a 30-minute counselling session at baseline (including watching three educational videos, receiving a booklet with diet and lifestyle information), and receive their AAC results and baseline biochemistry results. Quantitative data will be collected using a questionnaire (Post counselling health status questionnaire -- Supplementary Appendix 2). This questionnaire will be used to obtain information on the perceived risk of CVD, perceptions of CVD severity and susceptibility and perceived self-efficacy. It will be administered immediately after participants complete their baseline counselling session.

The use of semi-structured interviews will provide flexibility in exploring relevant and interesting matters as raised by participants. This will enable pre-specified areas to be explored and remain open to exploring other ideas and thoughts that will arise in the interview. [35] Table 2 presents information on study objectives, sample, data collection tools and what data will be gathered at each stage of the trial.

**Table 2 Methods for Objectives**

| Objective | Sample | Data Collection tool | Stage of trial |
|---|---|---|---|
| 1. To evaluate the resources, structures, and the procedures used to deliver the MODEL study intervention from the perspective of participants. | 15 to 20 trial participant interviews. The actual sample size will be dependent upon the point of saturation | A semi-structured interview guide (Supplementary Appendix 1) | Post baseline intervention - one month after participants complete the baseline component of the intervention |
| 2. To assess participants responses to the MODEL study intervention and mediating processes which may influence subsequent changes in outcomes. | a) All 200 participants (survey – quantitative component)<br>b) 15 to 20 trial participants interviews | a) Questionnaire (Mediators- perceived risk of CVD, perceptions of CVD severity and susceptibility and perceived self-efficacy -- Supplementary Appendix 2)<br>b) A semi-structured interview (Responses to intervention) | a) Post baseline intervention - immediately after participants complete their baseline counselling session<br>b) Post baseline intervention - one month after participants complete the baseline component of the intervention |
| 3. To better understand the contribution of the external factors which may influence intervention implementation (i.e. behaviour change). | a) All 200 participants (survey – quantitative component)<br>b) 15 to 20 trial participant interviews | a) Questionnaire (Demographic characteristics).<br>b) A semi-structured interview (Community, social/political, family or other situational issues outside of the intervention). | a) Pre baseline intervention<br>b) Post baseline intervention - one month after participants complete the baseline component of the intervention |

All consenting trial participants will be invited to respond to a questionnaire with a sub-sample invited to participate in an interview.

Investigators involved in data collection will discuss the aims of the questionnaire/interviews and provide information on any potential benefits and harm of participation. Participants will be assured of the confidentiality of the information they will provide. Interviews will be conducted at a mutually convenient site. The first author will administer the questionnaires and conduct the interviews. Each interview will be audio-recorded and transcribed verbatim later.

The research team will develop the questionnaire, and the interview guide based on the objectives of the process evaluation, secondary data on the topic and further discussions and brainstorming among the research team. The questionnaire and interview guides will be piloted in the initial stages of the study to assess suitability for the study. As suggested by Given [36], interview guides will be amended as necessary by the research team.

**Management of data**

Questionnaire data will be entered into SPSS data management and analysis software. Interviews will be digitally recorded and transcribed verbatim. All identifying aspects will be removed to maintain anonymity and confidentiality and pseudonyms will be assigned.

**Analysis**

The quantitative data will be analyzed using SPSS version 21.0. The analysed data will be organized into frequency tables and represented on pie charts and tables. The analysis of the primary data will be entirely descriptive (summaries, frequencies, and cross-tabulation tables).

The qualitative data will be analysed thematically. The analysis and interpretation of the interviews will be guided by Miles and Huberman's framework for thematic content analysis.[37] The stages will involve the identification of meaning units, an initial grouping of meaning units into categories, and the creation of emergent category names. Following this stage, initial themes will be developed using a constant comparison method to ensure those meaning units are reflective of emergent themes. This will also focus on examining intra-theme coherence/consistency and inter-theme distinctiveness. The first author will lead the analysis and other authors will review that analysis and NVivo12 software will be used to assist the data analysis. Using this software will enable the investigators to examine themes and structure in the content as well as visualize the findings and support findings with detailed evidence. An experienced qualitative researcher (M. St.) will be engaged for peer debriefing and member checking will be conducted to enhance rigour. Investigators undertaking the MODEL RCT's assessment and counselling (SRB, CPB; MaSi.; LCB; EC; JTS; MPS; JG; BDR) will not be involved in the process evaluation data analysis or interpretation. Qualitative data will be collected and reported according to COREQ guidelines.[38]

**Integration of process and outcomes data**

Survey data on contextual factors (participant characteristics) and mediators (perceived risk of CVD, perceptions of CVD severity and susceptibility and perceived self-efficacy) will be analysed prior to analysis of outcome data. After the interviews (on the impact of contextual factors such as family, GP etc.) are conducted and analysed, the process evaluation investigators will be able to conclude that the MODEL study intervention has been successful by communicating clear information on CVD risk and prompting lifestyle/behaviour change. The process data will also highlight the role of contextual factors and mediators enabling participants

to change lifestyle/behaviour or not. This data will be used for post-hoc explanation after trial outcomes are known.

## DISCUSSION

This is a detailed protocol for a process evaluation embedded within a randomised control trial, the MODEL study. The process evaluation will provide useful information on the MODEL study intervention and how and why the key components/elements (provision of information on CVD risk) impacted on lifestyle/behaviour change or not. This process evaluation will complement and add value to the MODEL Study by providing a better insight into study results. The investigators of the MODEL study will, therefore, be confident after the report of the process evaluation data that it is feasible or otherwise to use similar approaches to conduct this type of study or influence lifestyle/behaviour change. The researchers will also derive insight into possible methods for improvement to inform wider implementation strategies as demonstrated in previous process evaluations. [17, 18, 39]

This process evaluation will employ a comprehensive approach to evaluate the resources, structures, and the procedures used to deliver the MODEL study intervention. Interviews will be conducted to gather information on participants experiences throughout the intervention. This would be useful in identifying reasons for lack of intervention effect (if any) or any significant changes in lifestyle/behaviour. This is in contrast with some other process evaluations such as the ProActive study (a physical activity intervention)[19] [20] which did not include any qualitative component to identify reasons for lack of intervention effect and a significant increase in physical activity among participants.[19] [20]

Although a mixed-method approach was employed for the process evaluation for the Welsh National Exercise Referral Scheme intervention,[21] the logic model focused more on links between intervention activities and mechanisms of impact and only limited focus on delivery mechanisms. The MODEL study process evaluation aims to focus equally on delivery mechanisms (i.e. application of resources such as videos and counselling to ensure implementation), intervention components, mechanisms of impact and intended outcomes (behaviour change).

The MODEL study process evaluation also aims to gather extensive data on theoretical determinants of behaviour change such as risk perception and self-efficacy. However, a process evaluation for an adolescent sexual health programme intervention in Tanzania [22] gathered inadequate data on the impact of the intervention on the theoretical determinants of behaviour change.

Evaluating and reporting what works for which group and what constitutes an effective intervention is an essential consideration for practitioners, researchers and policymakers.[40, 41] The MODEL study process evaluation will contribute to existing knowledge and understanding of the processes that took place during participation in the MODEL study trial. It will also serve as a guide for future studies that will be conducted for such complex trials.

## STRENGTHS AND LIMITATIONS

This study will employ a comprehensive mixed-method approach to evaluate the resources, structures, and the procedures used to deliver the MODEL study intervention. The process evaluation will assess participants responses to the MODEL study intervention and mediating processes which may influence subsequent changes in outcomes and identify key contextual

(external) factors which may influence the process of changing behaviour. Core intervention components that were effective in influencing lifestyle/behaviour change will be identified, forming the basis for guidance for replication in future studies and implementation in other programmes.

This process evaluation will not evaluate the fidelity of the MODEL study and the associated challenges in delivery from the perspective of the study investigators. Another limitation is the risk of recall bias specifically referring to responder bias (unintentional or intentional) or possible difficulties on the part of participants recalling all information gathered from the intervention. Unintentional responder bias may be attributed to incomplete or poor memory recall and intentional responder bias may be attributed to embarrassment with admitting truth about previous event or nature of disease under investigation. The MODEL study intervention will utilise several resources and procedures in its delivery and it is anticipated that recalling all information gathered from the intervention may be a challenge. Also, some participants may intentionally give inaccurate details about their lifestyle/behaviour change due to the life-threating/life-changing nature of cardiovascular disease or embarrassment associated with not changing behaviour.

## ETHICS AND DISSEMINATION

The MODEL Study process evaluation has received approval from the relevant Ethics Committee (Edith Cowan University Human Research Ethics Committee approval, Project Number: 20513 HODGSON).

The study results will be shared with the individuals and institutions associated with this study as well as academic audiences through peer-reviewed publication and presentation at conferences.

**Patient and Public Involvement:** There will be no involvement of patients or the community in the design, conduct, reporting, or dissemination plans of the process evaluation.

**Study status:** Data collection for the process evaluation will commence in August 2020.

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**Author's contributions:**

RA, SRB, LCB, M.St., JMH and JRL developed the study concept. RA, M.St., JRL, JMH drafted the manuscript. RA, M.St., JRL, LCB, JD, BJ contributed to the design of the study and are responsible for study coordination. RA, SRB, JRL, JD, BJ, DPK, JTS and JMH contributed to the design and development of the data collection instruments. RA will implement the protocol as well as oversee the collection of the qualitative data and will code all transcripts. RA and CPB will oversee the collection of the quantitative data. RA and NPB will be involved in the analysis of quantitative data. RA, SRB, MaSi., CPB, EC, RJW, KZ, MPS, WHL, PS, RMD, KLC, AD, PLT, JG and BR contributed to the writing of the study content. All authors contributed and approved the final manuscript.

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**Competing interests' statement**

The authors declare that there is no competing interest.

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**Figure 1: Key functions of MODEL study process evaluation and relations among them. Adapted from Moore et al[14] and modified for the MODEL study process evaluation.**

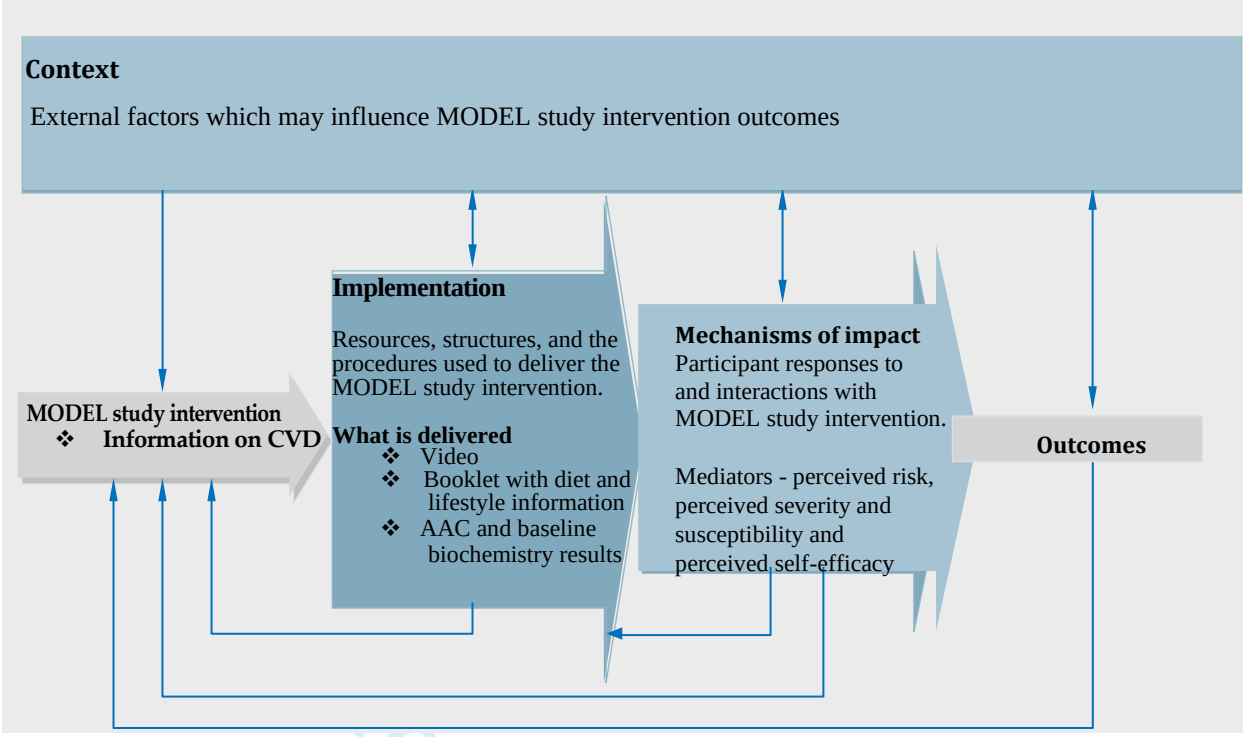


Figure 1: Key functions of MODEL study process evaluation and relations among them. Adapted from Moore et al[14] and modified for the MODEL study process evaluation.

## INTERVIEW QUESTIONS

1. Tell me about how you came to be involved in this study.

   Prompt

   - Tell me more about that, what was it that interested you?
   - Why was that?

2. What do you remember about the videos?

3. What did you think of the 3 videos (Heart Foundation, Cardiovascular and D&L) and information booklet provided to you in the counselling session (E.g. duration, clarity of the language used and expressions, etc.)?

4. Please describe your initial reaction to seeing your own level of advanced blood vessel disease (AAC) for the first time (i.e., the image, illustrative representation and information about your cardiovascular disease status)?

5. What was the immediate effect, if any, that this image/information had on you?

   Prompt

   - How did it make you feel?
   - Can you please explain why and how?

6. What was the immediate effect, if any, that the dietary and lifestyle counselling had on you?

   Prompt

   - How did it make you feel?
   - Can you please explain why and how?

7. How has the image/information on your own level of advanced blood vessel disease changed your behaviour?

Prompt

- If so, why and how?
- What was the easiest/hardest part of making the changes, and why?
- In what ways?
- Can you share with me some examples?

8. Did you share your results with healthcare providers?

Prompt

- If so, what did they say and how did it make you feel?
- Can you please explain why and how?
- If you haven't discussed it yet, are you planning on discussing the results with your GP?

9. Did you share your results with family and friends?

Prompt

- If so, what did they say and how did it make you feel?
- Can you please explain why and how?

10. So what or which specific parts of the diet and lifestyle video were helpful to you?

Prompt

- What recommendations do you have for improving its delivery?

11. What other elements of the consultation (i.e., non-AAC materials, such as BP, lipids, and interaction with the counsellor, booklet) influenced your feelings or behaviour?

Prompt

- If so, how and why, and if not, why not?
- What element of the consultation has influenced you most (if any)?

12. What other information provided was helpful for you?

    How?

Prompt

- What recommendations do you have about how best to present the advanced blood vessel disease image/information?
- What questions did you have after being presented with the image/information (if any)?

13. Is there anything else you wanted to say about the duration, clarity of the language used and expressions in the 3 videos, the counselling sessions and any other information in this study?

# The MODEL Study

| Sticker with Participant's ID, full name and DOB | |
|---|---|
| Visit: 1 2 3 4 5 | Date of visit: _____/_____/_____ |

*To be answered at end of conversation – counselling visit 3, once all elements have been completed*

A) For each of the following statements, please indicate to what extent you agree with that statement, using the following scale:

| | Totally disagree | Agree a little bit | Moderately agree | Strongly agree | Very strongly agree |
|---|---|---|---|---|---|
| 1. The information provided made me think that I am susceptible to cardiovascular disease | 1 | 2 | 3 | 4 | 5 |
| 2. The information provided made me think that I am at risk of cardiovascular disease | 1 | 2 | 3 | 4 | 5 |
| 3. The information provided made me feel that my health is at risk | 1 | 2 | 3 | 4 | 5 |
| 4. Having cardiovascular problems is a severe health problem | 1 | 2 | 3 | 4 | 5 |
| 5. Having cardiovascular problems is a significant health risk | 1 | 2 | 3 | 4 | 5 |
| 6. Having cardiovascular problems is serious for my health | 1 | 2 | 3 | 4 | 5 |

B) For each of the following statements, please indicate how each sentence best applies to you, using the scales:

| | Poor | Fair | Good | Very good | Excellent |
|---|---|---|---|---|---|
| 7. How would you rate your cardiovascular health? | 1 | 2 | 3 | 4 | 5 |

| | Very low level | Low level | Moderate level | High level | Very high level |
|---|---|---|---|---|---|
| 8. Please estimate your level of atherosclerosis | 1 | 2 | 3 | 4 | 5 |

The MODEL Study

| | Not at all certain | Confident | Somewhat certain | Certain | Very certain |
|---|---|---|---|---|---|
| 9. How certain are you of your level of atherosclerosis? | 1 | 2 | 3 | 4 | 5 |

C) **The following questions refer to the 3 goals on diet and physical activity.** For each of the following statements, please indicate to what extent you agree with that statement, using the following scale:

| | Totally disagree | Agree a little bit | Moderately agree | Strongly agree | Very strongly agree |
|---|---|---|---|---|---|
| 10. Meeting the goal for fruit and vegetable intake will reduce my risk of cardiovascular problems | 1 | 2 | 3 | 4 | 5 |
| 11. Meeting the goal for fruit and vegetable intake is one of the most important things I can do to protect my cardiovascular health | 1 | 2 | 3 | 4 | 5 |
| 12. Meeting the other dietary goal (e.g., reducing salt, alcohol, processed meats, and increasing grains and nuts) will reduce my risk of cardiovascular problems | 1 | 2 | 3 | 4 | 5 |
| 13. Meeting the other dietary goal (e.g., reducing salt, alcohol, processed meats, and increasing grains and nuts) is one of the most important things I can do to protect my cardiovascular health | 1 | 2 | 3 | 4 | 5 |
| 14. Meeting the goal to increase physical activity and reduce sitting time will reduce my risk of cardiovascular problems | 1 | 2 | 3 | 4 | 5 |
| 15. Meeting the goal to increase physical activity and reduce sitting time is one of the most important things I can do to protect my cardiovascular health | 1 | 2 | 3 | 4 | 5 |

The MODEL Study

D) **The following questions refer to the 3 goals on diet and physical activity.** For each of the following statements, please indicate to what extent you agree with that statement, using the following scale:

| | Totally disagree | Agree a little bit | Moderately agree | Strongly agree | Very strongly agree |
|---|---|---|---|---|---|
| 16. Right now, I think I can meet the goal for fruit and vegetable intake | 1 | 2 | 3 | 4 | 5 |
| 17. Right now, I am confident in my ability to meet the goal for fruit and vegetable intake | 1 | 2 | 3 | 4 | 5 |
| 18. Right now, I think I can meet the other dietary goal (e.g., reducing salt, alcohol, processed meats, and increasing grains and nuts) | 1 | 2 | 3 | 4 | 5 |
| 19. Right now, I am confident in my ability to meet the other dietary goal (e.g., reducing salt, alcohol, processed meats, and increasing grains and nuts) | 1 | 2 | 3 | 4 | 5 |
| 20. Right now, I think I can meet the goal to increase physical activity and reduce sitting time | 1 | 2 | 3 | 4 | 5 |
| 21. Right now, I am confident in my ability to meet the goal to increase physical activity and reduce sitting time | 1 | 2 | 3 | 4 | 5 |

E) **The following questions refer to your intentions towards dietary and lifestyle advice. For** each of the following statements, please indicate to what extent you agree with that statement, using the following scale:

| | Totally disagree | Agree a little bit | Moderately agree | Strongly agree | Very strongly agree |
|---|---|---|---|---|---|
| 22. I intend to meet the goal for fruit and vegetable intake | 1 | 2 | 3 | 4 | 5 |
| 23. I intend to meet the other dietary goal (e.g., reducing salt, alcohol, processed meats, and increasing grains and nuts) | 1 | 2 | 3 | 4 | 5 |
| 24. I intend to meet the goal to increase physical activity and reduce sitting time | 1 | 2 | 3 | 4 | 5 |

Entered on: ____/____/____ by _____