Study Protocol

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Actively Choosing How to Cope with an Increased Risk of Cardiovascular Disease: A Randomised Web-Based Experiment

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Title

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Names protocol contributors

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Abstract

- **Background**: This web-based experimental study aims to investigate the effect of promoting an active (i.e. conscious and autonomous) choice process regarding coping with an increased risk of

cardiovascular disease (CVD) on psychological outcomes, compared to usual care; i.e. a general practitioners' (GP) advice. Coping strategies include: changing one's lifestyle; taking medication; doing both; or changing nothing. An active choice process is expected to increase psychological outcomes compared to a passive choice process (i.e. a simple advice).

- **Methods**: We will recruit adults aged 45-65 years who are not on medication to prevent CVD and who do not have are have had CVD. Participants will be randomized to the intervention – active choice – group or the control – usual care – group. Both groups will be presented a hypothetical CVD risk. In the control group, the risk will be presented as a 31% risk of developing CVD within ten years, whereas the intervention group will be presented an equivalent risk in a different format: a 'heart age' of 16 years older than their actual age. The intervention group will additionally receive information about the meaning of the risk, including its causes and potential consequences, and about the four coping strategies. The pros and cons of each strategy will be presented, followed by a value-clarification exercise. The control group will read a hypothetical advice to change their lifestyle, and to take medication to lower their CVD risk. Participants will receive a questionnaire that assesses psychological outcomes, including 'degree of active choice', commitment, and intention to cope with CVD risk. Intergroup differences will be examined by regression analyses. In addition, we will conduct a process evaluation.
- **Discussion**: If an active choice process regarding coping with an increased CVD risk indeed results in better outcomes compared to an advice, the active choice intervention could be implemented by GP's. GP's could either use it as a tool during their consultation, or send it to their patients, so the patients can read the information and clarify their own values before making a choice. Providing patients with a choice – instead of giving advice – respects their autonomy. Ultimately, it is expected that an active choice process will increase patients' adherence to the chosen option; e.g., a healthier lifestyle or medication use.
- **Trial registration**: Prospectively registered at clinicaltrials.gov; 19-11-2021.

Keywords

Cardiovascular disease, Decision making, Active choice, Patient autonomy, Prevention, Lifestyle change, Medication adherence; Randomized Controlled Trial

Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	Actively Choosing How to Cope with an Increased Risk of Cardiovascular Disease: A Randomised Web-Based Experiment
Trial registration {2a and 2b}.	Registry: https://clinicaltrials.gov/. *Number: NCT05142280*
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Funding {4}	No external funding was received.
Author details {5a}	Lorraine L. Landais[a], Judith G.M. Jelsma[a], Olga C. Damman[a], Danielle R.M. Timmermans[a], Evert A.L.M. Verhagen[a,b] [a] Amsterdam UMC, Vrije Universiteit Amsterdam, Department of Public and Occupational Health, Amsterdam Public Health research institute, Amsterdam, The Netherlands [b] Amsterdam Collaboration on Health & Safety in Sports, Department of Public and Occupational Health, Amsterdam Movement Sciences, Amsterdam UMC, Vrije Universiteit Amsterdam, Amsterdam, The Netherlands
Name and contact information for the trial sponsor {5b}	N/A
Role of sponsor {5c}	N/A

Introduction

Background and rationale {6a}

Cardiovascular disease (CVD) continues to be a leading cause of mortality among adults. Adults at increased risk of cardiovascular disease are usually advised by their general practitioner (GP) to change their lifestyle (i.e., quit smoking; eat healthier; become more physically active). In addition, GP's regularly

advice their patients to take antihypertensive and/or lipid lowering medication to decrease the CVD risk. Previous research has shown that many patients at increased risk of CVD have difficulty maintaining lifestyle changes and adhering to their medication regimen – either intentionally or unintentionally. Intentional non-adherence could occur when patients experience side-effects of the medication, whereas unintentional non-adherence usually occurs when patients forget to take their medication.

In the current study, we will investigate whether promoting an active choice regarding coping with an increased CVD risk results in better psychological outcomes (e.g., degree of active choice; commitment toward the chosen option) compared to usual care (i.e. a GP's advice to change one's lifestyle and take medication). By 'active choice' we mean a conscious and autonomous choice in which an individual (a) becomes aware of a discrepancy between the current and desired situation; (b) understands what his/her CVD risk means, and what its causes and consequences are; (c) evaluates the pros and cons of the different options to cope with the risk; and (d) is clear about his/her values regarding the choice. The different options to cope with an increased CVD risk include: changing one's lifestyle; taking medication; doing both; or changing nothing.

We will investigate this in a web-based RCT among adults aged 45-65 years. The intervention group (i.e. active choice group) and control group (i.e. usual care group) will both receive a hypothetical CVD risk. We expect an active choice regarding coping with an increased CVD risk to result in better psychological outcomes compared to a GP's advice. Ultimately, a more active choice is expected to results in greater behavioural persistence regarding the chosen option; i.e. lifestyle change and/or medication adherence.

Objectives {7}

To test the effect of an online active choice intervention regarding coping with increased risk of cardiovascular disease on psychological outcomes among adults aged 40 to 65 years, and to investigate whether effects differ between men and women.

Trial design {8}

Parallel group design: intervention versus control (1:1)

Methods: Participants, interventions and outcomes

Study setting {9}

Web-based study conducted in the Netherlands among members of an online panel of a research agency.

Eligibility criteria {10}

Inclusion criteria: Adults aged 45-65 years
Exclusion criteria: Suffering/ having suffered from CVD; being on lipid lowering or blood pressure lowering medication; Suffering from diabetes, kidney damage or rheumatism; not being able to walk at least 100

meters; being in a wheelchair; pregnancy.

Who will take informed consent? {26a}

Participants eligible for inclusion will be informed about the study and data storage. Participants will subsequently be asked to provide (online) informed consent; if they provide consent (by clicking a button), they continue to the study.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

N/A

Interventions

Explanation for the choice of comparators {6b}

The control group will receive online information and advice that resembles GP's usual care. This is expected to promote a relatively passive choice process regarding 'how to cope with an increased risk of CVD', since participants receive an advice and are not asked to actively think about their values and preferences.

Intervention description {11a}

The intervention group will be presented a hypothetical 'heart age' of 16 years older than their actual age. They are asked to imagine that this heart age really applies to them. Next, participants will receive information about the meaning of the risk, including its causes and potential consequences, and about four coping strategies: changing one's lifestyle; taking medication; doing both; or changing nothing. The pros and cons of each strategy will be presented, followed by a value-clarification exercise.

Criteria for discontinuing or modifying allocated interventions {11b}

N/A

Strategies to improve adherence to interventions {11c}

N/A

Relevant concomitant care permitted or prohibited during the trial {11d}

N/A

Provisions for post-trial care {30}

N/A

Outcomes {12}

All outcomes will be assessed directly after the intervention. Overview of outcome measures:

Outcome	Number of items	Scale
Intention regarding coping with CVD	1	Nominal; 4 options: Lifestyle change/ Medication use/ Lifestyle change and medication use/ Change nothing
Intention strength	1	Scale of 1 (not strong at all) to 10 (very strong)
Degree of active choice	11	A 5-point scale will be used for the items (1: totally disagree; to 5: totally agree). The average of all 11 items will be used as composite score.
Values congruence	1	A 10-point scale will be used: 1 (not at all) to 10 (totally).
Commitment	3	A 10-point scale will be used: 1 (not at all) to 10 (totally).
Self-efficacy	1	A 10-point scale will be used: 1 (not at all) to 10 (totally).
Response efficacy	2	A 10-point scale will be used: 1 (not at all) to 10 (totally).
Autonomous motivation & controlled motivation	12	The Treatment Motivation Questionnaire will be used. This questionnaire contains 2 subscales: Autonomous motivation and Controlled motivation. Items are on a scale of 1 (not at all true) to 7 (very true).
Knowledge – illness representations	4	4 items on a scale of 1 (totally disagree) to 5 (totally agree).
Risk perception: Cognitive and affective risk appraisal	3	1 item assesses cognitive risk appraisal (on a scale ranging from 'very small risk' to 'very high risk'. 2 items assess affective risk appraisal on a scale of 1 (not at all) to 10 (totally)
Lifestyle intention	1	Nominal; 4 options: Quit smoking; Healthier diet; More physical activity; Other.
Lifestyle intention strength	1	Scale of 1 (not strong at all) to 10 (very strong)
Perceived health	1	Item from RAND-36. Scale: 1 (very bad) to 5 (very good).
Preferred decision-making role	1	Item based the Control Preferences Scale of Degner et al. (1992). Contains 5 options to assess preference for a more passive or more active role in decision-making about treatment.

Participant timeline {13}

After clicking the link to the study and providing informed consent, participants will be randomized to the intervention or control group. Directly after the intervention, participants are asked to complete the questionnaire.

Sample size {14}

The study is powered to detect 0.15 points difference in 'Degree of active choice' in men as well as in women, using an alpha level of .05 and a statistical power of 80%. This means that 206 men and 156 women are required per group. Since we have two groups, a sample size of n=724 is required (i.e., 412 men and 312 women).

Recruitment {15}

The research agency will invite panel members by e-mail to participate. If needed, a few reminders will be

sent by e-mail to panel members to achieve adequate enrolment

Assignment of interventions: allocation

Sequence generation {16a}

Participants will randomly be assigned to the intervention or control group by the research agency.

Concealment mechanism {16b}

Random allocation will be done by the computer.

Implementation {16c}

The research agency will randomly assigned panel members to the intervention or control group.

Assignment of interventions: Blinding

Who will be blinded {17a}

Trial participants will be blind to the group they are assigned to; they will not be informed about the other groups.

Procedure for unblinding if needed {17b}

N/A

Data collection and management

Plans for assessment and collection of outcomes {18a}

The questionnaire items are listed in the table of outcomes.

Plans to promote participant retention and complete follow-up {18b}

Participants will receive reminders to participate by e-mail.

Data management {19}

Anonymized SPSS-files with the collected data will be provided by the research agency. These files will be stored at Amsterdam UMC for 15 years (participants will be informed about this).

Confidentiality {27}

The SPSS files will be anonymized by the research agency. Only the research team will be allowed access to participant's data.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

N/A

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Statistical analyses will be performed in SPSS for Windows version 26. Linear and logistic regression analyses will be performed to analyse the data.

Interim analyses {21b}

N/A

Methods for additional analyses (e.g. subgroup analyses) {20b}

We will investigate whether the effects on the outcomes measures are modified by gender (i.e., whether the intervention affects men and women differently). If effect modification is the case, we will perform the analyses for men and women separately. Moreover, we will conduct a sensitivity analysis: we will investigate whether the active choice intervention results in better psychological outcomes in participants who prefer an active decision-making role, or shared decision-making, compared to participants who prefer a passive decision-making role.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Pairwise deletion will be used for missing data.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

Data will be available upon reasonable request.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

Research team CHOiCE of the AmsterdamUMC, Department of Public and Occupational Health, will

coordinate and steer the trial. This team consists of five researchers who meet bimonthly.

Composition of the data monitoring committee, its role and reporting structure {21a}

An independent research agency will collect and monitor the data. After collecting the data, the research agency will send the data to the CHOiCE research team (Amsterdam UMC).

Adverse event reporting and harms {22}

N/A

Frequency and plans for auditing trial conduct {23}

N/A

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Important protocol modifications will be communicated to the ethical committee of Amsterdam UMC.

Dissemination plans {31a}

Publication in a scientific journal.

Discussion

If an active choice process regarding coping with an increased CVD risk indeed results in better outcomes compared to an advice, the active choice intervention could be implemented by GP's. GP's could either use it as a tool during their consultation, or send it to their patients, so the patients can read the information and clarify their own values before making a choice. Providing patients with a choice – instead of giving advice – respects their autonomy. Ultimately, it is expected that an active choice process will increase patients' adherence to the chosen option; e.g., a healthier lifestyle or medication use.

Trial status

Protocol version 1, 19-11-2021. Start recruitment: January 2022. End recruitment: January 2022.

Abbreviations

N/A Not applicable*; CVD* Cardiovascular disease.

Declarations

Acknowledgements

Not applicable

Authors' contributions {31b}

Not applicable

Funding {4}

No external funding was received for this study.

Availability of data and materials {29}

Data will be available upon reasonable request.

Ethics approval and consent to participate {24}

Ethical review is currently being performed at Amsterdam UMC. Reference: 2021.0676. Only participants who provide informed consent will be included in the study.

Consent for publication {32}

Not applicable.

Competing interests {28}

The authors declare that they have no competing interests.

Authors' information (optional)

References