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Understanding how patients perceive their cardiovascular risk and respond to personalized risk information

Submission date 02/11/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/11/2026	**Overall study status** Ongoing	
Last Edited 09/11/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Cardiovascular disease, including heart attacks, strokes and heart failure, is a major cause of illness and death. Many people do not accurately understand their own risk of developing cardiovascular disease. This can affect their decisions about healthy lifestyle changes and preventive care.
This study aims to find out how people perceive their cardiovascular risk and whether learning their personalised risk affects their motivation to improve their health. The study will also compare different ways of explaining cardiovascular risk to determine which methods help people understand and remember the information most effectively.

Who can participate?
Adults aged 30 to 79 years who receive care at the Heart Care outpatient cardiology clinic in Frisco, Texas, may be able to take part. Participants must not have an existing diagnosis of cardiovascular disease and must meet the study eligibility criteria. They must also be able to complete study questionnaires in English or Spanish and provide informed consent.

What does the study involve?
The study has two phases.
In the first phase, participants complete a questionnaire about how they view their cardiovascular risk and how motivated they are to take preventive actions. Clinic staff then calculate and explain the participant's cardiovascular risk using the American Heart Association PREVENT risk calculator. Participants complete a second questionnaire immediately afterwards. People aged 30 to 59 years may receive both 10-year and 30-year risk estimates, while older participants receive age-appropriate risk information.
In the second phase, eligible participants aged 30 to 59 years are randomly allocated to one of four different methods of receiving personalised cardiovascular risk information. Some participants receive standard risk information, while others receive the same information with additional explanations or comparisons designed to improve understanding.
Participants complete questionnaires before and after receiving their risk information. They are also asked to complete a follow-up questionnaire 14 days later to assess how well they

remember and understand the information. Additional follow-up assessments may take place at around 3, 6 and 12 months to examine health behaviours and selected cardiovascular risk factors.

What are the possible benefits and risks of participating?
Participants may gain a better understanding of their cardiovascular risk and learn more about ways to reduce that risk. However, there may be no direct personal benefit from taking part. The risks are expected to be low. Some participants may feel worried or anxious after learning about their cardiovascular risk. There is also the inconvenience of completing questionnaires and a small risk to confidentiality whenever personal information is collected. Measures will be used to protect participants' privacy and research analyses will use appropriately de-identified data.

Where is the study run from?
The study is being run by Heart Care, an outpatient cardiology clinic in Frisco, Texas, United States of America.

When is the study starting and how long is it expected to run for?
November 2026 to January 2030.

Who is funding the study?
Heart Care.

Who is the main contact?
Dr Shahnaz Begum
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Cardiovascular risk perception, personalized risk communication, and preventive motivation and behavior: a prospective study using the American heart association PREVENT equations

Acronym
PREVENT-CARE

Study objectives
The objectives of this study are to evaluate how adult patients in a cardiology clinic perceive their cardiovascular disease risk in comparison with PREVENT-estimated risk, to determine whether individualized disclosure of PREVENT-estimated risk changes preventive motivation, and to compare different clinician-delivered risk communication strategies with respect to immediate motivation, understanding, and short-term recall. A secondary objective is to explore whether these changes are associated with subsequent self-reported preventive behaviors and selected longitudinal clinical outcomes over follow-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/10/2026, Sterling IRB (6300 Powers Ferry Road Suite 600 – 351, Atlanta, GA 30339, United States of America; +1 770-690-9491; accountrelations@sterlingirb.com), ref: 17941-SBegum

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Prevention, Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Cardiovascular disease (CVD) risk perception and awareness

Interventions
This is a phased prospective study conducted in an outpatient cardiology clinic.

In the initial non-randomized lead-in phase, eligible adult patients will complete a baseline survey assessing perceived cardiovascular risk and preventive motivation before receiving individualized PREVENT-based cardiovascular risk disclosure from clinic staff. PREVENT-estimated risk will be calculated using routinely collected clinical data. Participants aged 30-59 years will undergo both 10-year and 30-year risk assessment when applicable, whereas older

participants will undergo age-appropriate PREVENT-based risk assessment. Participants will then complete an immediate post-disclosure assessment. Participants enrolled in the longitudinal follow-up component will undergo additional assessments at approximately 3, 6, and 12 months, with a maximum follow-up duration of 12 months. This phase also includes an observational cohort of adults aged 60–79 years undergoing 10-year cardiovascular risk assessment.

In the second phase, participants will be assigned in an open-label, parallel-group randomized design to an active comparator arm consisting of standard clinician-delivered personalized risk disclosure, or to one of several enhanced cardiovascular risk communication strategies that communicate the same personalized risk information using different formats. Outcomes will include immediate preventive motivation, risk understanding, short-term recall, and longer-term self-reported preventive behaviours and selected clinical outcomes.

During the second (randomized) phase, eligible participants aged 30-59 years will be allocated in a 1:1:1:1 ratio to four parallel communication groups:
1. Arm A: Clinician-delivered 10-year PREVENT-CVD risk alone
2. Arm B: Clinician-delivered 10-year and 30-year PREVENT-CVD risks (active comparator)
3. Arm C: Both risk estimates supplemented by an age- and sex-specific 30-year risk percentile comparison
4. Arm D: Both risk estimates supplemented by an explanation of PREVENT-Age (cardiovascular risk-equivalent age)

All groups will undergo the same baseline and immediate post-disclosure assessments, followed by a 14-day recall assessment, and longitudinal assessments at approximately 3, 6, and 12 months. The maximum follow-up duration will be 12 months for all randomized arms. The primary randomized comparisons will be Arms A, C, and D against concurrent randomized Arm B participants. Participants in the initial non-randomized lead-in cohort will not be included in the primary randomized comparisons.

Randomization process: Randomization will begin only during the second (randomized) phase, anticipated in 2027. Our current plan is to use a computer-generated randomization sequence prepared using R statistical software, with randomly permuted blocks of varying sizes and equal allocation among the four groups. The sequence will be prepared by a designated research team member who is not involved in patient recruitment. Allocation will initially be planned through sequentially numbered, opaque, sealed envelopes, opened only after eligibility confirmation, informed consent, and completion of baseline assessments. The study will be open-label following assignment.
Since randomization is not required until the second phase, we may adopt a secure web-based randomization platform if a more practical solution becomes available before that phase begins. Any such modification will preserve the four-arm, 1:1:1:1 allocation design and allocation concealment. We will document the final method, obtain any required IRB review, and notify ISRCTN of changes before randomization begins.

Intervention Type
Behavioural

Primary outcome(s)
1. Accuracy of patient-perceived cardiovascular risk compared with AHA PREVENT-estimated risk measured using absolute difference in percentage points between patient-perceived and PREVENT-estimated 10-year cardiovascular risk (ages 30–79) and 30-year cardiovascular risk

(ages 30–59). Perceived risk is obtained using a baseline 0–100% numerical survey before disclosure. Signed differences and proportions of underestimation, approximately accurate estimation (within ±5 percentage points), and overestimation will also be reported. Measured at baseline, before clinician disclosure of personalized PREVENT risk estimates (initial lead-in phase).

2. Change in preventive motivation following personalized cardiovascular risk communication measured using change in self-reported motivation to adopt cardiovascular preventive behaviors, measured using the same 0–10 numerical rating scale before and immediately after risk disclosure (0 = not at all motivated; 10 = extremely motivated). Change is calculated as post-disclosure minus baseline score. The randomized phase will compare Arms A, C, and D with concurrent randomized Arm B, using three prespecified pairwise comparisons with adjustment for multiple testing. Measured at baseline (before risk communication) and immediately after clinician-delivered risk communication during the enrollment visit (2nd randomized phase).

Key secondary outcome(s)

1. Change in preventive motivation following personalized PREVENT risk disclosure in the initial lead-in phase measured using change in self-reported preventive motivation using a 0–10 numerical rating scale, calculated as the immediate post-disclosure score minus the baseline score. Mean change and the proportions of participants reporting increased, decreased, or unchanged motivation will be evaluated. Associations between baseline risk-perception error and motivation change will also be explored. Measured at baseline (before personalized risk disclosure) and immediately after clinician-delivered risk disclosure during the initial lead-in phase.

2. Accuracy of recall of communicated cardiovascular risk at 14 days measured using absolute difference in percentage points between the participant's recalled 10-year cardiovascular risk estimate and the individualized 10-year PREVENT-estimated risk communicated at the baseline visit. The proportion of participants recalling the estimate within ±5 percentage points will also be reported. Comparisons will be performed across the four concurrent randomized arms. Recall of 30-year risk will be explored separately in arms receiving 30-year risk information. Measured at 14 days after clinician-delivered risk communication in the second (randomized) phase only.

3. Patient comprehension of personalized cardiovascular risk information measured using proportion of correct responses on a standardized, study-specific questionnaire assessing understanding of the communicated 10-year cardiovascular risk estimate, interpretation of the estimated probability, and implications for cardiovascular prevention. The same core comprehension questions will be administered across all four randomized arms. Measured at immediately after clinician-delivered risk communication in the second (randomized) phase

4. Change in self-reported weekly physical activity during longitudinal follow-up measured using change from baseline in self-reported minutes per week of moderate-to-vigorous physical activity, measured using a standardized physical activity questionnaire. The principal longitudinal assessment will occur at 6 months, with additional assessments at 3 and 12 months. Longitudinal changes will be evaluated descriptively in the initial lead-in cohort and comparatively across randomized arms in the second phase. Measured at baseline and 3, 6, and 12 months following risk disclosure, with the principal longitudinal assessment at 6 months

5. Change in systolic blood pressure during longitudinal follow-up measured using change from baseline in systolic blood pressure (mmHg), using measurements obtained during routine clinical care and documented in the electronic medical record. Analyses will include participants with available baseline and follow-up measurements. No additional research-specific blood pressure

testing will be required. Measured at baseline and approximately 12 months following risk disclosure, using available measurements from routine clinical care

Completion date
30/01/2030

Eligibility

Key inclusion criteria
1. Adults aged 30–79 years at enrolment
2. Patients receiving outpatient care at Heart Care, Frisco, Texas
3. No known established cardiovascular disease
4. Sufficient clinical information to calculate a valid 10-year cardiovascular risk estimate using the AHA PREVENT-CVD equations. Participants aged 30–59 years must also have sufficient information to calculate a 30-year PREVENT-CVD risk estimate to be eligible for the paired 10-year/30-year analysis and the randomized study
5. Able to understand and complete the study questionnaires in an approved language (English or Spanish)
6. Willing and able to provide informed consent and participate in baseline risk-perception and immediate post-disclosure assessments
7. For participants enrolled in the randomized phase, willingness to undergo randomized allocation to a risk-communication format and participate in the planned follow-up assessments

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 Years

Upper age limit
79 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Age younger than 30 years or older than 79 years at enrolment
2. Known established cardiovascular disease, including previous myocardial infarction, stroke, coronary revascularization, or clinical heart failure
3. Conditions for which the AHA PREVENT equations are not recommended, including severe subclinical cardiovascular disease (e.g., left ventricular ejection fraction <40% or coronary artery calcium score ≥300), known pathogenic variants associated with inherited cardiovascular disease, end-stage kidney disease, or life expectancy less than 1 year
4. Insufficient clinical information to calculate a valid 10-year PREVENT-CVD risk estimate

5. Inability to provide informed consent or complete study questionnaires in an approved study language (English or Spanish)
6. Unwillingness to participate in the required study procedures or previously enrolled in the same study

Date of first enrolment
16/11/2026

Date of final enrolment
31/01/2029

Locations

Countries of recruitment
United States of America

Study participating centre
Heart Care
14688 State Highway 121
Suite 120
Frisco
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75035

Sponsor information

Organisation
Heart Care

Funder(s)

Funder type

Funder Name
Heart Care

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available