

# The Effect of a Digital Heart Health App and Lifestyle Intervention for Heart Disease in Primary Care.

NCT06919302

---

Status	RECRUITING
Phase	Not Applicable
Sponsor	University of Toronto
Enrollment	1,100 participants

## Key Eligibility Criteria

---

### Inclusion (8)

- Be taking statin medication with or without other antihyperlipidemic therapy (stable dose for at least 3-months).
  - Fall under either of the 2 categories:
    - \) Secondary prevention participants: males and females e45 years of age with established atherosclerotic cardiovascular disease (ASCVD) defined as at least one of the following: i. Prior myocardial infarction (MI); ii. Acute coronary syndrome (ACS); iii. Stroke/TIA; iv. Coronary revascularization; v. Documented carotid disease (endarterectomy, carotid stenosis e50%); vi. Stable angina; vii. Coronary artery disease (CAD) by angiography; viii. Peripheral artery disease (PAD); ix. Abdominal aortic aneurysm (AAA)
    - \) High-risk primary prevention participants: males and females e50 years of age plus type 2 diabetes requiring treatment with medication and at least one additional risk factor: i. Males e55 years of age and females e65 years of age; ii. Cigarette smoker or stopped smoking within 3 months before Visit 1; iii. Hypertension and on antihypertensive medication for at least 6-months; iv. Chronic kidney disease (CKD); v. Retinopathy, defined as any of the following: non-proliferative retinopathy, pre-proliferative retinopathy, proliferative retinopathy, maculopathy, advanced diabetic eye disease or a history of photocoagulation
  - Be on a stable dose for at least 3-months of all antihyperlipidemic, antihyperglycemic, antihypertensive, and antiobesity therapies.
- ... and 3 more (see full listing online)

### Exclusion (14)

- Major disease expected to result in death within 2 years (except cardiovascular disease)
  - Active sever liver disease
  - Malabsorption disorders
  - Drug or alcohol abuse disorders (within past 6 months)
  - Intolerance or allergies to soy protein and tree nuts, peanuts, or seeds
- ... and 9 more (see full listing online)

## Locations (1 total)

---

C. David Naylor Building, Toronto, Ontario, Canada