Future Health Today: Protocol for a pragmatic stratified cluster randomised head-to-head trial of quality improvement activities in general practice compared to active control.

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Abstract

Introduction: The Future Health Today (FHT) program, consisting of a dashboard, active clinical decision support (CDS), quality improvement (QI) activities and cased based learning series, was developed to facilitate QI activities in Australian general practice. The FHT trial aims to evaluate the effectiveness of the program with a focus on two important clinical issues: reduction of cardiovascular (CV) risk in people with chronic kidney disease (CKD) and appropriate follow up for people with pathology test results associated with risk of undiagnosed cancer.

Methods and Analysis: Pragmatic 12-month two-arm cluster randomised controlled trial of QI activities in general practice (pharmacological therapies to reduce CV risk in people with CKD and appropriate investigation of people at increased risk of undiagnosed cancer) compared to active control. The primary outcome for the CKD arm is proportion of eligible patients with a diagnosis or pathology results consistent with CKD at baseline prescribed ACE inhibitors or Angiotensin receptor blockers and/or statins consistent with current guideline recommendations. The primary outcome for the cancer arm is the proportion of eligible patients identified as at risk of undiagnosed prostate, oesophageal, gastric, colorectal, endometrial, lung or ovarian cancer that have been assessed and investigated. Secondary outcomes include clinical measures and number of general practice encounters. Marginal logistic regression model using Generalised Estimating Equations with robust standard errors to adjust for correlation of outcomes within general practice will be used to estimate the intervention effect for primary binary outcomes. A health economics analysis and process evaluation will be conducted.

Ethics and dissemination: This protocol has been approved by the Faculty of Medicine, Dentistry and Health Sciences Human Ethics Sub-Committee at the University of Melbourne (ID: 2056564). Results will be disseminated via website, publications, and conference presentations.

Trial registration: ACTRN, [ACTRN12620000993998](https://trialsearch.who.int/?TrialID=ACTRN12620000993998). Registered 02 October 2020, https://trialsearch.who.int/?TrialID=ACTRN12620000993998

Strengths and limitations of this study

- Trial design is more efficient by facilitating the evaluation of two separate interventions within one broader cluster randomised controlled trial.
- Outcomes were extracted from electronic medical records (EMRs), increasing efficiency and reducing burden of data collection for participating general practices.
- The results may not be broadly generalisable as general practices will be recruited from Victoria and Tasmania and may not be representative of the broader Australian general practice population.

Introduction

More than four in five Australians visit their GP at least once per year, and two million attend every week.[1, 2] As medical knowledge continues to exponentially increase, it is crucial that this knowledge is translated efficiently and effectively into the general practice setting, where the majority of Australians receive their medical care. This is critically important for people at risk of, or with, chronic diseases such as CKD and cancer, where early detection and management have the potential to reduce disease progression and the development of complications, improving quality of life and reducing burden on the health care system.[3] There is increased focus on QI programs in Australian general practices, with payments to practices for participating in QI activities commencing in 2019 [4] and the implementation of CDS featuring prominently in the Commonwealth Government's 10-year Primary Care Plan.[5]

Successful QI programs are multifactorial and can include elements such as audit, feedback and CDS. A Cochrane systematic review of the impact of audit and feedback concluded that potentially important changes in professional practice can be achieved, particularly if feedback is: 1) reported more than once; 2) delivered in multiple formats; and 3) includes explicit targets and action plans.[6] A review of systematic reviews found that changes to professional behaviour are more likely with multi-faceted interventions including reminders, audit and feedback that create a set of 'rules' that can be incorporated into everyday practice rather than single interventions.[7] Education programs such as the Extension for Community Healthcare Outcomes (Project ECHO®) program[8], an evidence-based platform that facilitates case-based learning networks with primary care, facilitated by academic medicine departments, delivered by videoconferencing platforms[8], may also be a useful way of delivering education and feedback to practices.

Computerised CDS has the potential to improve health professional performance [9, 10], and is more likely to be effective if the advice is provided automatically, on the screen, with patient-specific suggestions, and combined with other strategies such as the use of key opinion leaders and educational sessions.[11]

Barriers to implementation of QI activities in general practice include: the time taken to identify patient cohorts, tracking patient outcomes over time, cost and personnel limitations of face-to-face academic detailing, lack of integration within audit platforms and data governance concerns.

The Future Health Today (FHT) program was developed with general practice to overcome these barriers and facilitate QI activities.[12] FHT software program integrates with the EMRs used by over 90% of Australian general practices. It consists of four components: a dashboard, CDS tool, access to resources and QI activities (See Figure 1). FHT can be used to facilitate the optimised management for many conditions; in this trial we have focused on CKD and early detection of cancer, clinical areas with unmet need (detailed in Appendix 1).[13-18]

Objective

To evaluate the effectiveness of the FHT program in general practice, consisting of a technology platform with audit, recall, CDS and monitoring of QI activity capability, and a Project ECHO® educational series on improving guideline-concordant care for patients with two common conditions (CKD and cancer-risk) managed in general practice compared to usual care.

Specific aims:

1. Determine if patients with a recorded diagnosis, or pathology results consistent with a diagnosis of CKD, who attend general practices participating in the FHT QI program (intervention arm) are more likely than similar patients attending practices providing usual care (active control arm) to receive guideline-concordant care to reduce CVD risk at 12 months post-randomisation.
2. Determine if patients with abnormal test results and additional clinical features placing them at risk of an undiagnosed cancer who attend general practice participating in the FHT QI program (intervention arm) are more likely than similar patients attending general practices that provide usual care (active control arm) to be assessed and investigated at 12 months post-randomisation.
3. Identify the barriers and facilitators to successful implementation of FHT in daily practice.
4. Examine general practice service utilisation of patients in the cancer-risk and CKD FHT compared to their respective counterparts in the usual care arm.

Trial design

Stratified cluster randomised head-to-head trial, with an embedded process evaluation to describe the implementation of the QI programs in general practice, and the barriers and facilitators experienced by GPs and staff. Practices will be randomly assigned 1:1 to either the QI CKD program or the QI cancer-risk program, with different target populations and outcomes measured for each QI program.

This protocol describes the trial according to the SPIRIT Statement [19], and findings will be published separately for each sub-study.

Methods

Patient and public involvement

A FHT General Practice Advisory Group was convened in November 2019 and a FHT Consumer Advisory Group followed in May 2020. These groups have agreed to provide their ideas and ongoing guidance on the FHT technology development, study design, input into the interpretation of the findings and translation to enhance dissemination and uptake.

Study settings

Forty general practices in Victoria and Tasmania will be recruited from November 2020 to June 2021. The target population for the CKD model will be patients with a recorded diagnosis, or pathology results consistent with a diagnosis of CKD who attend general practice. For the cancer-risk module the target population will be patients with abnormal test results and additional clinical features placing them at risk of an undiagnosed cancer who attend general practice.

Eligibility criteria

General practices will be included if they:
- See at least 35 adults aged ≥18 years per day, >2,500 active adult patients (defined as patients who attended the general practice at least three times in the last two years) recorded in their EMR and/or have at least 50 patients that fit cohort definitions for people with CKD not on optimal medications and abnormal test results and additional clinical features placing them at risk of an undiagnosed cancer;
- Employ a practice nurse;
- Are contributing or willing to contribute data to the Patron dataset, a repository of data from EMR shared by general practices and curated by the University of Melbourne;[20]
- Use Best Practice or Medical Director EMR software to record clinical consultations, prescription of medications and ordering and receiving pathology results (More than 90% Victorian practices are estimated to meet these criteria [21]);
- Can identify a workstation (i5/i7 and 16GB RAM or *upgradable* to 16GB) with Windows 10 (operating system) that will have GRHANITE[22] the data extraction tool required for Patron and FHT installed.
- Computers have Edge or Chrome installed.

General practices will be excluded if they:
- had previously participated in other FHT projects;
- intend to change to another medical software supplier during the trial period;
- use a cloud-based EMR system that does not have GRHANITE installed.

General practice patients inclusion criteria:

QI CKD program: Individuals aged 18 to 80 years, inclusive, that are not marked as inactive or deceased, with a recorded diagnosis or pathology tests consistent with CKD [23] that may benefit from pharmacological therapy to reduce CVD risk at baseline. Individuals with a recorded history of renal transplant or chronic dialysis will be excluded.

QI cancer-risk program: Individuals aged 40 to 80 years, inclusive, that are not marked as inactive or deceased, identified as increased risk of cancer who may benefit from further investigation from baseline and up to 6 months post-randomisation. Individuals with a previous gastrointestinal, colorectal, lung, endometrial, ovarian, or prostate cancers within 5 years will be excluded.

Patients who are pregnant will be excluded from both arms.

Risk of contamination
Some patients may fit the criteria for both cohorts. However, there is no overlap between the interventions recommended, and each study arm will only be provided with FHT software to identify one of the cohort types, thus risk of contamination is minimal. Practices will be blinded to the other component of the intervention; however, practices may become aware through word of mouth or if clinicians work across practices allocated to different interventions.

Interventions

Choice of comparators

Patients at risk of an undiagnosed cancer from practices allocated to the QI CKD program will act as an active control (usual care) for similar patients identified in practices receiving QI Cancer-risk program. Similarly, patients with a recorded diagnosis, or pathology results consistent with a diagnosis of CKD, in the practices allocated to the QI cancer-risk arm will act as controls (usual care) and will be compared to similar patients identified in the QI CKD arm.

Intervention description

Practices will receive the FHT program (Figure 1) specific to the condition to which they were randomly allocated (CKD or cancer-risk). This will allow practices to:

- Use FHT in planned (recall) and opportunistic clinical situations
- Use FHT for QI activities (RACGP continuing professional development (CPD) accredited activity)
- Participate in Project ECHO® and education sessions

At trial commencement, practices in the QI CKD arm will generate a list of patients that meet the CKD eligibility criteria using the FHT tool. Similarly, practices allocated to the QI cancer-risk arm will create a list of patients at risk of cancer up to six-month period post-randomisation. Within the patient list available in the FHT tool, practices can prioritise how they recall patients based on additional factors such as age, number of risk factors, and eligibility for Medicare Benefits Schedule item numbers.[25] They may also choose to defer patients from the system based on their knowledge of the patient. CDS at the point of care consisting of a 'pop up' box will opportunistically identify eligible patients who may benefit from optimised management of CKD or further investigation of cancer risk.

Practice staff will be invited to participate in six 1-hour Project ECHO® sessions consisting of a 10-minute didactic education presentation, followed by a de-identified case presentation and discussion with a panel. Three sessions will focus on QI in general practice and three will have a disease specific focus (i.e., CKD or cancer). Project ECHO® sessions for practices in the CKD and cancer-risk arms will be held separately to minimise the risk of contamination. Sessions will be recorded and hosted on the Canvas learning management system for clinicians unable to attend the live sessions.

Appendix 2 has examples of the dashboard and CDS tool.

Practices will receive phone and Zoom support to develop practice-specific QI programs using the FHT QI templates and cohort generation function in the FHT platform. This will be accompanied by a QI toolkit hosted on the FHT platform. Practices will receive quarterly benchmarking reports, describing the management of their trial cohort and comparing progress to other participating practices. Support offered to practices may vary depending on the practice-specific needs identified. A different practice liaison support officer will provide support for each arm.

Outcome

All outcomes will be measured at 12-months post-randomisation. Primary and secondary outcomes specific to the two conditions (CKD and cancer-risk) are presented in Table 1.

Table 1: Primary and secondary outcomes at 12 months post-randomisation for each QI Program

Difference between the QI CKD arm and the active control arm in the:	Difference between the QI Cancer-risk arm and the active control arm in the:
Primary Outcome	
Proportion of eligible patients with a diagnosis or pathology results consistent with CKD at baseline prescribed angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor (AR) blockers and/or statins consistent with the RACGP Red Book [41], Kidney Health Australia (KHA) [42] and National Vascular Disease Prevention Alliance (NVDPA) [43] guidelines at 12 months.	Proportion of eligible patients identified as at risk of undiagnosed prostate, oesophageal, gastric, colorectal, endometrial, lung or ovarian cancer that have been assessed and investigated according to NICE [45], Victorian Government Department of Health and Human Services [49], Cancer Council Australia [50], Prostate Cancer Foundation of Australia guidelines.[51]
Secondary outcomes	
Proportion of patients with a diagnosis or pathology results consistent with CKD that are prescribed an ACE inhibitor or AR blocker consistent with the RACGP Red Book [41], KHA [42] and NVDPA guidelines.[43]	Proportion of patients with markers of anaemia1 that have been assessed for upper and lower gastrointestinal symptoms and/or haematuria who have had at least one of the following investigations ordered: a repeat full blood count, iron studies, coeliac disease serology2 [44], faecal occult blood test [44], transvaginal ultrasound [45] and referrals for further investigations.
Proportion of patients with a diagnosis or pathology results consistent with CKD that are prescribed statin medication consistent with NVDPA guidelines [43] and ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease. [46]	Proportion of patients with markers of anaemia1 that have been prescribed oral supplements and/or had an iron infusion [47] in the general practice clinic.
Mean systolic blood pressure (mmHg) based on most recently recorded results.	Proportion of patients with raised platelet count [48] assessed for symptoms defined in Victorian Department of Health [49], NICE [45], and Cancer Council [50] guidelines as indicative of oesophageal, gastric, colorectal, endometrial, lung or ovarian cancer that have been followed up with one or more of the following: a repeat platelet count, chest x-ray [50], faecal occult blood test, transvaginal ultrasound [45] and CA125, and referrals for further investigations.
Mean lipid results (mmol/L) based on most recently recorded results. Total cholesterol LDL cholesterol HDL cholesterol Triglycerides	Proportion of patients with one raised PSA that have been followed up with a second PSA and/or free-to-total PSA percentage as per Cancer Council Australia guidelines [50] and referrals for further investigations.[51, 52]
Mean urine albumin:creatinine ratio (ACR)	Proportion of patients with a diagnosis of prostate, oesophageal, gastric, colorectal, endometrial, lung or ovarian cancer.
Cardiovascular risk: Proportion of people at low/moderate/high CVD risk as per NVDPA guidelines.[43]	Rate of encounters per patient identified as at risk of undiagnosed prostate, oesophageal, gastric, colorectal, endometrial, lung or ovarian cancer.
Mean estimated glomerular filtration rate (ml/min/1.73m2) based on most recently recorded results.	Time to referral/re-testing for patients with abnormal pathology result for patients identified as at risk of undiagnosed prostate, oesophageal, gastric, colorectal, endometrial, lung or ovarian cancer.
Rate of encounters per patient with a diagnosis or pathology results consistent with CKD at baseline.	

1 Defined as: Haemoglobin <130g/L in men and <115g/L in women) or MCV <80fl or MHC <27pg or ferritin<30μg/L

2 Any of the following tests: Tissue transglutaminase antibodies; tTG IgA; tTG IgG; Anti-tTG; Gliadin antibodies; Endomyseal antibodies; Endomysium Ab; Gluten-sensitive enteropathy tests

Symptoms will be identified in the diagnosis, reason for encounter and reason for prescription components of the electronic medical record.

Participant timeline and recruitment

Participant flow is illustrated in Figure 2.

General practices will be recruited via our practice-based research and education network, VicREN,[24] and through advertisements in Primary Health Network newsletters, and via the University of Tasmania's Northern Tasmania practice-based research and education network. We will initially target practices contributing data to the Patron dataset. We will follow up with site visits and information evenings until our target number of practices are recruited.

To ensure staff understand the trial, the research team will meet with the clinical and administrative staff before randomisation. After this session, FHT software will be installed at the site and staff will be able to access when the trial commences. Training on using the FHT platform (up to 90 minutes) will be offered to practices; these will typically be held via zoom. They will be provided with study staff telephone and Zoom support and resources such as free training modules (https://courses.trainitmedical.com.au/)

Sample size

We require 5,560 eligible patients (average 139 per practice) with a recorded diagnosis or pathology results consistent with CKD at baseline and 1200 eligible patients (average 30 per practice) who have clinical features that place them at risk of an undiagnosed cancer within the first 6 months post-randomisation from 40 practices (20 per arm).

Sample[20] size was determined separately for each sub-study to detect the following minimally important differences:

CKD: An absolute 10% increase in the percentage of patients with CKD who are on optimal pharmacological management in the CKD intervention arm at 12 months post-intervention [26, 27] compared to the control arm, assuming 55% of active control patients with CKD will be on optimal pharmacological management.

Cancer-risk: An absolute 20% increase in the percentage of patients at risk of cancer who have been assessed and investigated appropriately over the 6- to 12-month follow-up period in the cancer intervention arm compared to the active control arm, assuming that 30% of patients at risk of an undiagnosed cancer are managed appropriately in the active control arm [28] [29-31].

Sample sizes were based on achieving 80% power for the CKD study and 99% power for the cancer-risk study, for a two-sided 5% significance level, an intra-cluster correlation (ICC) of 0.03 to account for the effect of clustering by practice and coefficient of variation (CV) of 0.41 to allow for variable cluster sizes. No adjustment was made for multiplicity as the sample size was determined separately for each primary outcome. The ICC and CV were estimated using the condition-specific patient cohorts in 77 general practices available in the Patron dataset.[21] We allowed for the loss of four practices by 12 months (e.g., practice closure, withdrawals, merges) and the addition of one extra practice per arm for the t-distribution.

Assignment of interventions

General practices will be allocated in a 1:1 ratio to either QI CKD program or the QI cancer-risk program, using a computer-generated schedule, stratified by relative social economic disadvantage (IRSD) terciles [32] and the number of full-time equivalent (FTE) GPs (four or fewer versus greater

than four), using random permuted block sizes within stratum. To ensure concealment the block sizes will not be disclosed until all practices have been randomised, and practices will be randomly allocated after they have all been recruited and practices' baseline measures collected.

The random allocation schedule will be generated by the statistician, not involved in the practice recruitment or data collection. After practices are recruited, the statistician will randomly allocate the de-identified practices to one of the two intervention arms and will then inform the clinical liaison staff who will contact the practices via email to notify them of their allocated arm.

Blinding of general practice participants and the team providing QI support will not be possible. However, the statistician conducting the analysis and study investigators not involved in practice support and engagement will remain blinded and allocation of practices will be revealed after the data are analysed and results interpreted.

Data collection and management

Practice characteristics, including number of GPs and other general practice staff, billing method and regionality will be collected via survey before randomisation.

Outcomes presented in Table 1 will be measured using data extracted from general practice EMRs and stored in the Patron database. Patron data are stored in a secure virtual machine at the University of Melbourne and is only accessible by the study statisticians. Confidentiality is maintained because practice and patient records are de-identified when extracted using the data extraction tool GRHANITE and are assigned a unique code [29].

Details of the data extraction and coding of the outcomes and condition phenotypes using the EMR will be detailed in the statistical analysis plan (SAP) that will be made available on the trial registry.

Short surveys (approximately 5-10 minutes to complete) will be sent to participants attending each Project ECHO® session via email to ensure the sessions meet the participants' needs; this is also required for CPD accreditation. Surveys will be hosted on the Redcap platform [33]. For the process evaluation, a usability survey to explore experience of using the software will also be administered in Redcap.

General practice health services use will be determined using the Patron dataset.

All other data collected via surveys will be de-identified and analysed in aggregated form. No identifying information will be included about the general practices, staff or patients when reporting the trial findings.

Statistical analysis

Descriptive statistics will be used to summarise general practice, clinician, and patient characteristics for the CKD and cancer-risk cohorts, by study arm. Primary analysis will use an intention to treat (ITT) approach, where all practices will be analysed by their allocated study arm, irrespective of whether they received all, part or none of the QI program components. The intervention effects for the respective primary outcomes for CKD and cancer-risk will each be estimated with a marginal logistic regression model using Generalised Estimating Equations with robust standard errors to adjust for correlation of outcomes within general practice, and include the stratification factors, GP FTE (>4 vs 4 or less) and IRSD terciles, as covariates. Sensitivity analyses will adjust for pre-specified potential confounders measured at baseline, such as practice participation in a formalised QI program (yes,

no), patient's age and sex [34]. The absolute (difference in proportions between the intervention and control arms), and relative (odds ratio) estimated intervention effects for each primary outcome (CKD and cancer-risk) will be reported with 95% confidence intervals and p-values with no multiplicity adjustment.

A detailed SAP made available prior to data analysis will elaborate on the statistical methods for the secondary outcomes (e.g., logistic for binary outcomes, linear for continuous outcomes and survival analysis for time to an event) and supplementary analyses, including other sensitivity and pre-planned explanatory analyses, non-adherence adjusted analyses, and the handling of missing outcome data where appropriate. Analysis will be conducted using Stata statistical software 17.

Process evaluation

Practice Champions or delegates from each practice will be offered the opportunity to participate in short (approx. 20min) interviews at one, seven and 11 months for feedback about the implementation strategies and to describe the use of FHT in their practice. Targeted interviews in months 6 to 11 will focus on FHT reporting functionality and/or medico-legal risk. The interviews will be conducted via zoom or phone, according to the interviewee's preference. They will also be sent a survey about the software's usability at one and six months.

Interview transcripts, FHT field and diary notes, and QI work sheet data will be entered in NVivo 12 (QSR International). Data will be coded by at least two researchers and analysed using Framework Analysis[35], drawing on Clinical Performance Feedback Intervention Theory [36] and RE-AIM.[37]

Quality of implementation will be assessed, using indicators such as reach (proportion of general practices that are approached that elect to participate; engagement of GPs within participating practices), dose (use of FHT, number of in-practice QI activities) and perceived quality of delivery.[37, 38]

Health economic analysis

Health economic analysis will assess the extent to which FHT changes the health service expenditure associated with general practice attendance of patients at risk of undiagnosed cancer and patients with a confirmed diagnosis or pathology results consistent with a diagnosis of CKD. We hypothesise that the short-term increase in the health service cost will be offset by the long-term cost savings resulting from improved health outcomes associated with the implementation of FHT. Quantification of the long-term impact of FHT requires development of a model to simulate disease progression and predict incidence of events that require the use of health care resources in patients receiving FHT as well as usual care. Only patients with CKD will be simulated because considerable time is required to develop such a complex simulation model. Briefly, the long-term evaluation of FHT will involve the prediction of the incidence of major CV events, dialysis, and kidney transplant in patients with CKD and the extent to which FHT reduces the health care costs associated with these events compared to usual care. Major CVD events are defined as the occurrence of myocardial infarction, ischaemic stroke, haemorrhagic stroke, heart failure, percutaneous coronary intervention, coronary artery bypass grafting, peripheral vascular disease, and hospitalisation due to angina. See Appendix 3 for modelling approach and data sources.[39, 40]

Monitoring

The principal data utilised in this study is electronic medical record data extracted from general practice. The intervention is a CDS with recommendations and QI activities. As such, a formal data monitoring committee was deemed not required.

General practice staff will be able lodge queries regarding the CDS via the FHT portal and through direct engagement with practice liaison teams.

No interim analyses are planned.

Discussion

The FHT program is a multi-faceted approach to implementing QI in general practice to be delivered at scale. It will include evidence-based components of successful QI programs, including audit and feedback and CDS support combined with other strategies such as practice champions, key opinion leaders and educational sessions. Expected benefits include the scalable delivery of QI programs into daily general practice that improves management of a chronic condition or follow up of abnormal test results.

The trial will provide insights into service utilisation costs of a QI program and the enablers and barriers to implementing QI programs, including those perceived by health professionals. While the focus is on CVD risk reduction in people with CKD and cancer risk, the FHT program could be replicated for other conditions.

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Declarations

Ethics approval and consent to participate

This protocol has been approved by the Faculty of Medicine, Dentistry and Health Sciences Human Ethics Sub-Committee at the University of Melbourne (ID:2056564). Any adverse events will be reported to this sub-committee.

Clinical liaison staff will obtain written consent from participating GPs, practice nurses and practice managers interested in taking part in the FHT trial. New general practice staff members that express an interest in participating after randomisation will be able to join data collection activities, however their patients will not be added to the baseline patient cohort if not already included. Not all staff members need to consent to participate in the study. We will ask practices to nominate key informants and a Practice Champion at recruitment.

General practices will be asked to alert general practice patients to the study using waiting room posters, information pamphlets, and (where possible) a generic message about the study on the practice's telephone "on hold" message, online booking system, or website. A waiver of individual consent will be sought according to the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research [25] as we are not collecting patient-reported outcomes and it will be infeasible to obtain consent explicitly from individual patients. Patients will be able to advise their practice if they wish to withdraw from the study, and this will be recorded using the FHT dashboard and the GRHANITE desktop tool. Once marked as withdrawn, no further data for that patient will be utilised in FHT nor extracted from the EMR for the trial analysis.

Date material and availability

A summary of results will be provided to project participants if requested when they signed their consent form or on request if requested after recruitment. This will be provided in written format, by email or post depending on preference. We will support practices to develop information to share results of the study to the wider patient population in media such as posters or newsletters if they wish to do so. Project results will be made public through presentations at conferences, publication in peer reviewed journal and newsletters and study communications.

A summary of results will also be made available via the University of Melbourne Data for Decisions website (www.gp.unimelb.edu.au/datafordecisions) and Future Health Today website.

All investigators will have access to the final trial dataset which will be managed by the Primary Care Trials Unit at the University of Melbourne.

Figure 1 Legend
Components of the Future Health Today program.

Figure 2 Legend
Expected participant flow through the trial.