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A randomised controlled trial of a consumer focussed e-health strategy for cardiovascular risk management in primary care: the consumer navigation of electronic cardiovascular tools (CONNECT) study protocol

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A randomised controlled trial of a consumer focussed e-health strategy for cardiovascular risk management in primary care: the consumer navigation of electronic cardiovascular tools (CONNECT) study protocol.

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ABSTRACT

Introduction: Fewer than half of all people at highest risk of a cardiovascular event are receiving and adhering to best practice recommendations to lower their risk. In this project we examine the role of an e-health assisted consumer-focused strategy as a means of overcoming these gaps between evidence and practice. Consumer Navigation of Electronic Cardiovascular Tools (CONNECT) aims to test whether a consumer focused e-health strategy provided to Aboriginal and Torres Strait Islander and non-Indigenous adults, recruited through primary care, at moderate to high risk of a cardiovascular disease event will improve risk factor control when compared with usual care.

Methods and Analysis: Randomised controlled trial of 2000 participants with an average of 18 months follow-up to evaluate the effectiveness of an integrated consumer-directed e-health portal on cardiovascular risk compared to usual care in patients with cardiovascular disease or who are at moderate to high cardiovascular disease risk. The trial will be augmented by formal economic and process evaluations to assess acceptability, equity and cost-effectiveness of the intervention. The intervention group will participate in a consumer-directed e-health strategy for cardiovascular risk management. The programme is electronically integrated with the primary care provider's software and will include interactive smart phone and Internet platforms. The primary outcome is a composite endpoint of the proportion of people meeting Australian guideline recommended blood pressure (BP) and cholesterol targets. Secondary outcomes include change in mean blood pressure and fasting cholesterol levels, proportion meeting BP and cholesterol targets separately, self-efficacy, health literacy, self-reported point prevalence abstinence in smoking, body mass index and waist circumference, self-reported physical activity and self-reported medication adherence.

Ethics and dissemination: Primary ethics approval was received from the University of Sydney Human Research Ethics Committee and the Aboriginal Health and Medical Research Council.

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Results will be disseminated via the usual scientific forums including peer-reviewed publications and presentations at international conferences. [Clinical Trials registration number, ACTRN12613000715774].

STRENGTHS AND LIMITATIONS

- This project we will examine the role of an integrated e-health consumer strategy as a means of overcoming such health system inefficiencies.
- The CONNECT study will generate rigorously evaluated findings on an issue of national and international importance.
- The development of a content rich, consumer focused e-health intervention that is fully integrated with the primary health care system will greatly inform the e-health agenda.
- If effective, the CONNECT e-health strategy could be up-scaled and expanded to increase compliance with international e-health strategies. The CONNECT strategy may also have applicability as a stand-alone strategy where electronic integration with primary care is unavailable.
- Potential limitations are that this is an Australian study and relies on integration with the Australian personally controlled e-health record. In addition, the intervention is primarily consumer driven.

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INTRODUCTION

Cardiovascular disease burden

Cardiovascular disease (CVD), including coronary heart disease (CHD) and stroke, is the leading cause of death and disease burden globally.[1] Importantly in Australia, Aboriginal and Torres Strait Islander peoples experience approximately five times greater CVD burden than other Australians.[2] Fewer than 50% of adults who attend Australian general practice or Aboriginal Community Controlled Health Services (ACCHSs) are adequately screened for vascular risk and for those identified at high risk, only about 40% are receiving best practice care.[3-5] Similar findings have been noted in other Australian studies.[6-9] Adherence rates to lifestyle modification are around 30%[10] and adherence to recommended medicines may be as low as 50% after 6 months of therapy.[11] Overall, these studies have demonstrated failure to adequately implement effective interventions (that are also adhered to) to lower CVD risk for those that need it most.

Consumer focused e-health interventions

During the past decade, there has been rapid development in consumer e-health. Several studies have shown the benefits of interactive internet portals for managing chronic conditions (asthma,[12-14] type 2 diabetes,[15] arthritis,[16] hypertension[17] and mental health.[18,19]), for health behaviour change,[20,21] and lifestyle risk factors (physical activity, [22] smoking cessation[23] and weight loss).[24] A Cochrane review of 124 studies concluded that computer-based 'Interactive Health Communication Applications' can also improve cognitive and social outcomes of patients with chronic conditions.[25] The emerging evidence on text message interventions also appears promising. Five randomised controlled trials (RCTs) have demonstrated the effectiveness of mobile phone text messaging to promote smoking cessation[26,27], and a number of small RCTs have shown improved outcomes related to weight loss,[28] physical activity,[29] asthma medication adherence,[30] glycaemic control in diabetes,[31] blood pressure lowering,[32] liver transplantation,[33]

and HIV treatment.[34] Other studies looking at text messaging systems to improve adherence to lifestyle and medication recommendations for people with established coronary artery disease are ongoing.[35,36]

Although the evidence for consumer-focused interventions is promising, there are few randomised evaluations of personally controlled e-health records (PCEHR).[37] The PCEHR is the Australian secure online summary of an individual's health information. This e-health record allows people, their doctors, hospitals and other healthcare providers to view and share health information and ideally improve care. Most studies investigating online personal health records have had small sample sizes and short follow-up periods (< 12 months). This raises concerns about their external validity and sustainability. One Australian system which features a personal health record, tools to assist with making decisions, organising tasks, and a social networking feature has been shown in a community based trial to promote improved uptake of influenza vaccination amongst university students.[38] We are not aware of any RCTs that have incorporated multiple e-health components as part of a multifaceted, complex intervention for chronic disease management and prevention. Critically, there are no trials involving Aboriginal and Torres Strait Islander peoples and attempts to integrate consumer strategies with Australian primary health care electronic health records are at a very early stage.

Digital technologies and access

Equitable digital access is critical to implementation of the national e-health strategy. Digital access is growing exponentially in Australia. In 2010-11, 79% of Australian households had access to the Internet in their home and 77% of these used the Internet daily.[39] Amongst Aboriginal and Torres Strait Islander adults, in 2008, 59% had internet access (up from 41% in 2002).[40] Mobile phone use has been dramatically rising and now outstrips computer access. In

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2006-7, 81% of Australian consumers reported owning a mobile phone. Although growth was originally driven by the younger market, the largest annual increase in mobile phone ownership is among 65+ year olds.[41] Data on mobile phone access for Aboriginal and Torres Strait Islander people are unclear, however in 2008, 67% of non-remote and 61% of remote households had access to a pre-paid mobile phone and 41% and 19% respectively had mobile access via a contract.[41] 'Smart phones', characterised by multimedia and Internet connectivity, are the biggest growth area. In 2010-11, around 25% (3.9 million people) of Australians accessing the internet did so via their phone (up 63% on the previous year).[42]

HealthTracker e-health system

An electronic patient care system called HealthTracker has been previously developed and tested by our research team.[43] This e-health system is essentially a clinical decision support system for CVD risk management in primary care. HealthTracker is fully integrated with the primary health care electronic health record and provides: (1) point of care decision support related to CVD prevention and management; (2) a graphical patient counseling tool; (3) a computerised audit tool that provides rapid snapshots on health service performance combined with a recall and reminder system; and (4) access to a quality improvement web-based portal where health services can view monthly peer-ranked performance and access tools and resources to support quality care. HealthTracker has undergone significant proof of concept testing and validation,[43-45] and is currently being implemented in a large-scale cluster randomised controlled trial (TORPEDO) in Australia.[42] The trial is funded by the Australian National Health and Medical Research Council and involves 20 Aboriginal Community Controlled Health Services (ACCHSs), 40 General Practices and over 50,000 patients (Grant ID #1010547, ACTRN12611000478910). However, HealthTracker is a provider-directed strategy and the added value of a consumer or patient-focused interface remains unknown. Therefore, the

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Consumer Navigation of Electronic Cardiovascular Tools (CONNECT) study aims to enhance the existing HealthTracker system and utilise the growing e-health environment to scientifically test whether a consumer focused e-health strategy provided to Aboriginal and Torres Strait Islander as well as non-Indigenous people at moderate to high risk of a CVD event will improve risk factor control when compared with usual health care. The study also aims to determine the acceptability, equity and cost-effectiveness of such a strategy. We hypothesise that access to an integrated and patient-centred e-health strategy will improve risk factor control when compared with usual health care.

METHODS AND ANALYSIS

Study design

CONNECT is a single blind, randomised, controlled trial involving 2000 regular adult health service attendees at General Practices and Aboriginal Community Controlled Health Services (ACCHSs) with an average follow-up of 18 months (Figure 1). The trial registration number is ACTRN12613000715774. Prior to commencement, formal ethical approval will be obtained from the University of Sydney Human Research Ethics Committee. Written and informed consent will be obtained from all participants.

The study will be conducted across approximately 65 Australian General Practices and ACCHSs. Participants with a diagnosis of CVD or who are at high risk of CVD will be randomly allocated to either the control or intervention group. The control group will continue to participate in usual health care, supported by HealthTracker, the intervention group will participate in the CONNECT programme which is a consumer-directed e-health strategy for cardiovascular risk management. The programme is electronically integrated with the primary care provider's software and will include access to interactive smart phone and Internet platforms. Control arm

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participants will not have access to the portal. However, at the end of study all participants (control and intervention) will be offered portal access for a maximum of 12 months. Participants will be assessed by personnel blinded to treatment allocation at face-to-face appointments at baseline and 12 and at end of study.

Randomisation

Eligible consenting participants will be randomly assigned to the e-health strategy or provision of usual care for an average of 18 months (minimum 12 months, maximum 24 months). In both groups, any advice and/or other interventions provided by the GP/health service will continue at their health provider's discretion. Randomisation will be conducted independently using a central computer-based randomisation service with equal allocation to intervention versus control. A permuted block sequence will be used and will be stratified by level of CVD risk, study centre and Aboriginal and/or Torres Strait Islander status. Study personnel taking follow-up assessments will also be blinded to parallel group assignments.

Participant eligibility

Consenting adult patients (>18 years) with access to the Internet at least once a month via mobile phone, tablet or computer who are at moderate to high risk of a CVD event will be included. Potential participants will be excluded if they have a severe intellectual disability or if they have insufficient English to provide written, informed consent. Moderate-high CVD risk is defined as any of the following:

1. five year CVD risk ≥ 10% using the Framingham risk equation;
2. a clinically high risk condition (Aboriginal/Torres Strait Islander and age >75 years, diabetes and age>60 years, diabetes and albuminuria, eGFR < 45ml/min, systolic BP ≥ 180mmHg, diastolic BP ≥ 110mmHg, total cholesterol > 7.5mmol);[46]

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3. an established CVD diagnosis (ischaemic heart disease, stroke/transient ischaemic attack, peripheral vascular disease).

Recruitment

We will aim to recruit approximately 30 participants from each of a total of 65 General Practices and ACCHSs. Eligible patients will be identified by clinic staff using a customised electronic data extraction facility in the practice software system[47] which was successfully used in the TORPEDO trial.[43] Potential participants will receive an invitation letter from their General Practitioner (GP). Eligibility will then be confirmed during a telephone phone call from a study research assistant. In interested individuals will be invited to a face-to-face registration visit at the practice from which they were identified. At the initial visit, written informed consent will be obtained and the baseline assessment completed by a CONNECT research assistant. Practices will be reimbursed a small fee (in line with a standard consultation fee) for the time required to assist with recruitment if the minimum of 25 patients per practice are recruited. All software license costs and technical support associated with the *HealthTracker* system will be provided free for the duration of the trial.

Intervention

The intervention group will participate in the CONNECT programme which is a consumer focused e-health strategy aimed at assisting with the management and prevention of CVD (Figure 2). The programme components focus on cardiovascular risk assessment, medication adherence, lifestyle change and seamless patient-provider communication. CONNECT content has been informed by a detailed analysis of factors that drive uptake of Internet-based programmes for CVD secondary prevention.[48] HealthTracker assessment data (e.g. CVD risk factors and scores, medications and other treatment advice) are uploaded securely to a consumer-

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focused CVD specific module built using a e-health record architecture. Patients will then be able to securely register for access to the integrated portal. Throughout the trial, a minimum of one upload from their software to the CONNECT portal will be performed by the GP or an authorised staff member for participants randomised to the intervention. Subsequent uploads to the CONNECT system will be at the discretion of the treating practitioner and will depend on visit frequency and availability of new data (based on changes in patient care and frequency of visits). An alert will be flagged in the application if a new upload has occurred. CONNECT was systematically developed through an iterative process and using user-centred design approach.[49] The intervention development process involved collaborative design workshops (including journey mapping and persona building),[49] sketching and iterative validation by consumers.

The portal will be accessible via the Internet and also via a downloadable application for use on a mobile device. As described in Figure 2, participants in the intervention arm will be able to securely access the consumer portal via a secure login process. Patient data will be electronically uploaded from the clinic record to the portal. As part of the intervention, an implementation team of 'CONNECT coordinators' will provide face-to-face training to participants on how to use the various features in the portal. Key training features include: (i) viewing personal health record summary including information such as medicines, test results, blood pressure, weight; (ii) use of interactive tools and resources (eg. the *HealthTracker* risk calculator that visually plots CVD risk projections and allows people to perform 'what if scenarios' to explore the relative risk reductions from various CVD risk factors), (iii) access to simple medication and healthy lifestyle reminders and motivational message prompts depending on their choice and health profile (e.g. smokers wanting to quit will be able to receive a series of random messages to assist with cessation) and; (iv) an interactive goal setting and social media feature where people will be able to set their own goals and receive virtual rewards and also communicate with other users using

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CONNECT. As part of the intervention, participants will be contacted at months one and two by telephone and additional support will be provided as needed. At any time assistance will also be available via a helpdesk number or via an on-line or mobile text help request. A CONNECT coordinator will receive these requests and provide appropriate medical support or arrange technical advice if needed. The CONNECT coordinators will be separate from the recruitment and assessment team so as to maintain blinding of outcome assessments.

Control group

Participants in both the intervention and control groups will continue with usual health care. Control arm participants will not have access to the portal however, at the end of study all participants (control and intervention) will be offered portal access for a maximum of 12 months.

Data collection and study outcomes

Centrally employed CONNECT research assistants (blinded to group allocation) will conduct study visits at baseline, 12 months and 24 months and ensure all clinical measures are entered into a purpose-built and secure online database. Clinical and survey data will be collected via face-to-face or phone interviews (if necessary) and entered into a secure central web-based database. During 12 and 24 month assessments we will assess access to CVD management services for both groups such as the frequency of GP and specialist visits (self-report), access to allied health services (eg, dietitian and psychologists) and community groups or activities (eg, local walking group, online smoking cessation program). In addition, analytic information from the CONNECT portal and smartphone application will be extracted on a monthly basis to determine usage patterns (website and smartphone/tablet application). This study will be monitored and managed centrally with periodic site monitoring visits.

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The primary endpoint is the proportion of participants at end of study whose blood pressure AND fasting low density lipoprotein (LDL) cholesterol are meeting Australian guideline targets (defined as: ≤ 130/80 for participants with CVD, diabetes or albuminuria OR ≤140/90mmHg for all others participants) AND LDL-cholesterol < 2.0mmol/L).[50] Secondary outcomes include the mean difference from baseline in systolic and diastolic BP and fasting LDL cholesterol levels, proportion meeting BP and LDL targets separately, self-efficacy, health literacy, self-reported point prevalence abstinence in smoking, mean difference from baseline in body mass index and waist circumference, self-reported physical activity and self-reported medication adherence (Table 1).

Statistical Considerations

For the primary outcome measure, assumptions used in the sample size and power estimates have been determined from TORPEDO data of 10,181 routinely attending patients at moderate to high CVD risk. Calculations assume that 25% of people are meeting guideline recommended BP and LDL targets (as defined above) at baseline with mean systolic BP 136mmHg (SD 17.2) and mean LDL cholesterol 2.5mmol (SD 0.70). A total sample size of 2000 participants, allowing for a 20% loss to follow-up would have 90% power to detect an absolute improvement of at least 7.5% in the proportion of people meeting recommended targets using two-sided tests, with p values of less than 0.05 judged as significant. For secondary outcomes this translates to a 2.8mmHg absolute difference in systolic BP and a 0.11mmol/L absolute difference in LDL cholesterol.

Although there is little literature on effect sizes of e-health interventions for CVD risk factors, we have powered the study on effect estimates that could be considered clinically meaningful for a moderate-high risk population. Based on previous work on modelling cardiovascular risk factor

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reductions, the BP and LDL cholesterol effect sizes above could each translate to around a 5-10% relative risk reduction (RRR) or a combined RRR of 10-19% in cardiovascular events.[56]

Primary analyses will be unadjusted, following an intention-to-treat principle and conducted blind to treatment allocation. If necessary, multivariate analyses will be performed to adjust for any significant differences between each study arm. Pre-specified analyses will be conducted on the following sub-groups: established CVD versus high risk non-CVD; Aboriginal versus non-Aboriginal; proportion meeting/not meeting the primary endpoint at baseline; proportion adherent/not adherent to guideline-recommended BP and lipid medicines at baseline. Characteristics will be compared between groups using independent t tests for continuous or X^2 tests for categorical variables. Mean risk factor levels will be compared between groups in terms of relative risks, 95% confidence intervals and two-sided p values. Mann-Whitney U tests will be used where data are not normally distributed.

Process evaluation

Process evaluations explore the implementation, receipt, and setting of an intervention and help in the interpretation of outcome results.[57] Our team has extensive experience in such evaluations.[44,48,58] Analyses will be informed by the Pawson and Tilley realistic evaluation model,[59] which seeks to understand human actors' choices and actions, within the context of the systems in which these players operate. We will use mixed methods to investigate why the e-health strategy may or may not have been effective and which intervention components were most influential. Four data sources will be used: (1) quantitative data on patient measures described above; (2) usage data extracted directly from the consumer portal; (3) patient and provider surveys of satisfaction, tool utility and health actions taken; (4) semi-structured interviews with participants and care providers (including GPs) toward the end of study.

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Multivariate sub-group analyses will assess for any differential impact of the intervention on outcome measures by Aboriginal status, postcode, income, education level, language spoken at home, age, gender and internet and mobile phone access. Qualitative data will explore participant views on benefits, disadvantages and acceptability of the portal. Taking an equity perspective, interviews will seek to understand barriers and enablers to uptake by particular sub-populations, including factors such as Internet/smartphone connectivity and geographical remoteness. To obtain a broad range of views we will use a maximum variation sampling method based on patient demographics and health service characteristics.[60] Sampling will continue until no new themes or categories emerge ('thematic saturation'). We anticipate around 80 interviews will be required based on previous experience. In ACCHSs, Aboriginal participants will be interviewed by Aboriginal researchers. As with previous research collaborations, support and training will be provided for Aboriginal health researchers in the process evaluation, focusing not only on data collection but also analysis and reporting. Analyses will be thematic and coding will be carried out inductively based on emergent themes. NVivo 9 will be used to assist with interview data management. Given the focus of CONNECT on consumer engagement with an e-health strategy, assessment of health literacy (including communication with providers and understanding of information provided) will allow greater understanding and explanation of potential clinical outcomes as well as barriers and enablers to engagement with the intervention. The process evaluation will provide important narratives on the role of e-health tools in the patient and care provider experience. These standalone research findings will make a novel contribution to translating findings into policy and practice.

Economic evaluation

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A cost-effectiveness analysis will be undertaken to compare the e-health strategy with usual care. The economic evaluation will entail two components: a trial-based economic evaluation and a modeled economic evaluation of long term costs and outcomes. The trial based economic evaluation will estimate the incremental cost-effectiveness of the e-health strategy in in terms of quality adjusted life years (QALY) as measured over the follow-up period. This will enable an incremental cost per QALY gained to be estimated. The direct costs of the intervention over and above usual care, including training support and software maintenance, will be assessed. Alongside these will be cost offsets, in which the difference between the costs incurred in the utilization of health services, medications and tests between treatment groups will be assessed. Data for these costs will be drawn from automated extracts of health service records (e.g. service utilisation) and from self-reported questionnaires (eg, events, hospitalisations and quality of life). Details on medications, laboratory tests, and service utilisation will be costed at prevailing rates. Hospitalisations will be costed using standard Australian National Diagnosis Related Groups (AN-DRG) cost weights.

A modeled economic evaluation will be built onto the trial to enable quality of life and survival to be examined over a longer time frame than the trial follow-up period. Patients in usual care and the e-health strategy would be tracked over this extended period to capture various health states (including death and various cardiovascular events). Transition across these health states will be based on probabilities in relation to long term treatment effects, safety and disease progression derived from the trial findings and/or literature review. Data on costs and quality of life attached to various health states will also be drawn from literature review and trial data. With appropriate discounting, estimates of long-term costs and outcomes will fold out of the model. Sensitivity analyses will be conducted on variables such as discount rate, uncertainty in outcome estimates and assumptions made in costings. Different pricing scenarios will also be tested to

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determine threshold values for achieving cost-effectiveness, including cost-effectiveness of different components of the strategy.

ETHICS AND DISSEMINATION

The findings of this study will be disseminated via the usual scientific forums including peer-reviewed publications and presentations at international conferences. The study will be administered by The George Institute for Global Health, with the design and conduct overseen by a Steering Committee. This committee has expertise in large-scale clinical trials and qualitative research, economic analysis, clinical cardiovascular disease management and healthy policy implementation. This study will adhere to the National Health and Medical Research Council ethical guidelines for human research. Formal ethical approval for this study has been obtained from the University of Sydney Human Research Ethics Committee and the Aboriginal Health and Medical Research Council. Written and informed consent will be obtained from all participants.

CONCLUSION

Less than half of all people at highest risk of a CVD event are receiving and adhering to best practice recommendations to lower their risk. In this project we will examine the role of e-health assisted consumer strategies as a means of overcoming such health system inefficiencies. With the availability of the Personally Controlled E-Health Record (PCEHR) for all Australians in 2012, consumer focused e-health is set to become a key component of the health system. Despite the scale of this initiative, uptake has been slow and there is little research on the factors that will support its uptake. Innovative strategies that are practical to implement and support negotiation of care between consumers and care providers are therefore urgently needed.

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The CONNECT study will generate rigorously evaluated findings on an issue of national and international importance. The development of a content rich, consumer focused e-health intervention that is fully integrated with the primary health care system will greatly inform the e-health agenda. Equitable access to these emerging technologies is essential and this study, both quantitatively and qualitatively, tests the acceptability and effectiveness of the intervention for Aboriginal and Torres Strait Islander peoples and other socio-economically disadvantaged groups. The intervention will be compliant with Australian PCEHR specifications, thus allowing for seamless inter-operability. This maximises its viability for large scale implementation across Australia. If found to be successful, the CONNECT e-health strategy could be up-scaled and expanded to increase compliance with international e-health strategies. The CONNECT strategy may also have applicability as a stand-alone strategy where electronic integration with primary care is unavailable.

COMPETING INTERESTS

None to declare.

AUTHORS CONTRIBUTIONS

JR and DP conceived the study and intervention, and drafted the protocol. TU, MH, AR, NH, KP, CC, EH, AP, NZ and EC contributed the scientific design and protocol development. SJ led the economic analysis aspect of the design. AL, LN, GC, FH, contributed to the practical components of the intervention design and delivery. All authors read and approved the final manuscript.

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TABLE 1: Primary and secondary outcomes (measured at baseline, 12 months and end of study)

Primary

Proportion of participants meeting Australian guideline blood pressure (BP) AND lipid targets[50]

Targets are defined as:

≤130/80 for people with CVD, diabetes or albuminuria OR

≤140/90mmHg for all others; AND a LDL cholesterol <2.0mmol/L.

BP is based on an average of 3 resting, sitting digital recordings with the mean of last two readings and LDL-cholesterol is measured on a fasting blood sample.

Secondary

- Proportion meeting guideline recommended BP and LDL-cholesterol targets separately
- Difference in mean systolic and diastolic BP at end of study
- Difference in mean cholesterol levels at end of study (TC, LDL, HDL)
- Difference in mean body mass index and waist circumference at end of study
- Difference in health literacy scores - Health Literacy Questionnaire (HLQ)[51] and the e-health Literacy Scale (eHEALS)[52] at end of study
- Cardiovascular and renal events, new onset diabetes – self report and confirmed with medical records
- Physical activity – World Health Organisation Global Physical Activity Questionnaire[53]
- Point abstinence in smoking (≤ five cigarettes in the previous seven days[54] or recent smoking according to assessment using carbon monoxide meter)
- Fruit and vegetable intake, fish, salt and saturated fat intake – self report portions

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consumed in 7 days prior and compared with published guidelines recommendations • Cardioprotective medication adherence – self report and verified by medical record and pharmaceutical benefits scheme data • All cause mortality – medical record • Hospital readmissions – self report and verified by medical record • Health-related Quality of life – EQ5D (version 5L with Australian standardised weights[55])
CVD = cardiovascular disease, LDL = low density lipoprotein cholesterol, BP = blood pressure, TC = total cholesterol, HDL = high density lipoprotein cholesterol

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FIGURE 1 :CONNECT Study Schema

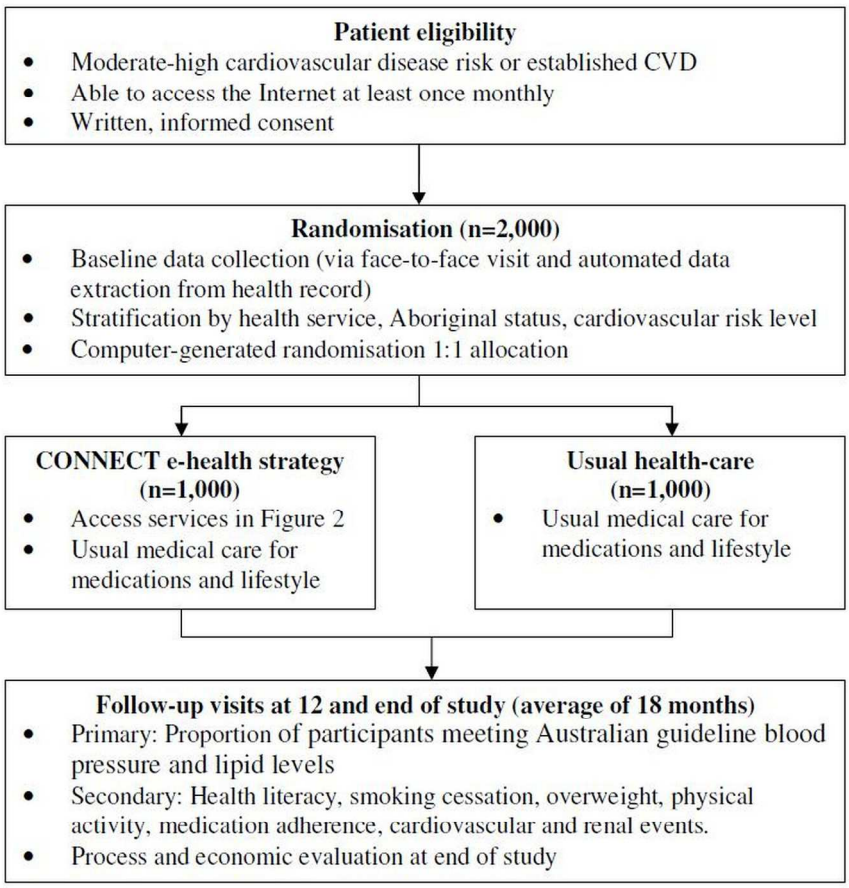

FIGURE 1 :CONNECT Study Schema
223x230mm (300 x 300 DPI)

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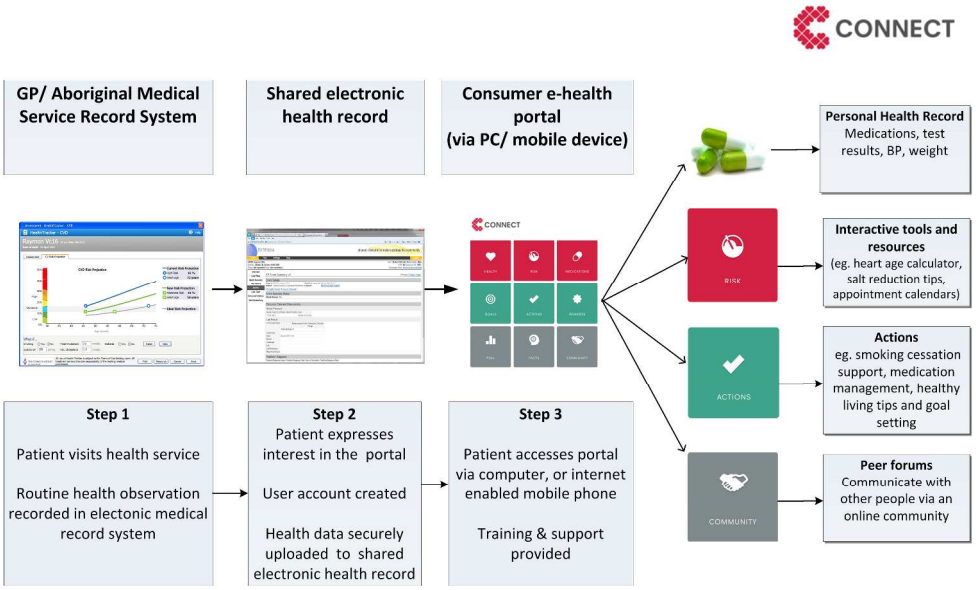

FIGURE 2: The consumer focused e-health strategy linked to primary health care
297x210mm (300 x 300 DPI)

view only

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-7
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	8-9
Participants	4a	Eligibility criteria for participants	8-9
	4b	Settings and locations where the data were collected	9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-11, Fig 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11-12, Table 1
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	13
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8-9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

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		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	n/a - protocol
Recruitment	14a	Dates defining the periods of recruitment and follow-up	n/a - protocol
	14b	Why the trial ended or was stopped	n/a - protocol
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	n/a - protocol
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	n/a - protocol
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	n/a - protocol
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a - protocol
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a - protocol
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a - protocol
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	n/a - protocol
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	n/a - protocol
Other information			
Registration	23	Registration number and name of trial registry	3,7
Protocol	24	Where the full trial protocol can be accessed, if available	n/a - protocol
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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