Canterbury Health, Ageing and Life Course (CHALICE) study: rationale, design and methodology

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Abstract

Aims New Zealand’s ageing population threatens the financial sustainability of our current model of health service delivery. The Canterbury Health, Ageing and Life Course (CHALICE) study aims to develop a comprehensive and flexible database of important determinants of health to inform new models. This paper describes the design, methodology, and first 300 participants of CHALICE.

Methods Commencing August 2010, CHALICE is a multidisciplinary prospective random cohort study and biobank of 1,000 Canterbury adults aged 49–51 years at inception, stratified by self-identified Māori (n=200) and non-Māori (n=800) ethnicity. Assessment covers sociodemographic, physical, cognition, mental health, clinical history, family and social, cardiovascular, and lifestyle domains. Detailed follow-up assessment occurs every 5 years, with a brief postal follow-up assessment undertaken annually.

Results For the first 300 participants (44 Māori, 256 non-Māori), the participation rate is 63.7%. Overall, 53.3% of participants are female, 75.3% are living in married or de facto relationships, and 19.0% have university degrees. These sociodemographic profiles are comparable with the 2006 Census, Canterbury region, 50–54 years age group percentages (50.7%, 77.2%, and 14.3%, respectively).

Conclusions CHALICE has been designed to provide quality data that will inform policy development and programme implementation across a broad spectrum of health indicators.

Grow old along with me! The best is yet to be…. Never have the words penned by poet Robert Browning in 1864 had such global resonance. We stand on the cusp of a demographic milestone; for the first time in recorded human history the number of people aged 65 years or older will soon outnumber children aged under 5 years.1

Driven by falling fertility rates and rapid increases in life expectancy, population ageing will continue, even accelerate; with the number of people aged 65 years or older worldwide projected to grow from an estimated 524 million in 2010 to nearly 1.5 billion in 2050.1

Population ageing presents both opportunities and challenges.2,3 Older people already make a significant contribution to society, whether it is through the formal workforce, informal work and volunteering, or within the family and community. But towards the end of life, many older people will face health problems and challenges to their independence.
Currently, chronic non-communicable diseases impose the greatest burden on global health and health care delivery,\textsuperscript{1,3} and these diseases more commonly effect older people. There is an urgent need to understand and effectively address the increasing prevalence of age-related illnesses which pose potentially profound economic, social and political implications for the global prosperity in the decades ahead.\textsuperscript{3}

Due to New Zealand’s ageing population, the current approach to health and disability services provision is considered financially unsustainable.\textsuperscript{4,5} Assuming current models of care, real costs have been projected to almost double and health spending outstrip income growth (to be about 50\% higher as a percentage of the gross domestic product by 2030).\textsuperscript{4} Although the veracity of these projections are not without question, due to the healthy ageing effect and the associated compression of morbidity.\textsuperscript{6,7} Regardless, the ageing of our population, and age-related disease, is arguably one of the greatest challenges for health services in New Zealand.

Fundamental challenges include how to preserve the health and independence of older people, and how to prevent age-related disease and disability. New models of care are likely to see patients receiving treatment closer to home, carried out through primary and community-based health services.\textsuperscript{4} However, the evidence-base vindicating such systemic changes is currently wanting. It has been argued that systems must be developed to monitor and understand these patterns and relationships, specifically through longitudinal studies that incorporate measures of health, economic status, family, and wellbeing.\textsuperscript{1}

One response, the Canterbury Health, Ageing and Life Course (CHALICE) project, has been established as a multidisciplinary longitudinal study of ageing. This prospective longitudinal study follows a cohort of Canterbury 50 years old adults in order to track their health and wellbeing with advancing age.

Geographically locating the CHALICE study within the Canterbury region is considered advantageous due to its relatively stable population, a history of high participation in epidemiological studies,\textsuperscript{8} and that Canterbury’s population is experiencing the ageing effects ahead of other regions of New Zealand (31.7\% of Canterbury people aged $\geq$50 years in 2006 Census compared with 29.2\% nationally).\textsuperscript{9} Steeped in a modern population health conceptualisation, the general aims of the CHALICE study are to:

- Explore the interplay of culture, communities, families, environments, nutrition, lifestyle and genes on wellbeing, healthy ageing, heart health and brain health;
- Examine protective factors and risk factors for cardiovascular disease, cerebrovascular disease, dementia, mood disorder, digestive disorders and infections; and
- Report empirically-based findings and recommendations that fill our knowledge gap.

Within these general aims, various specific aims will be investigated, such as: cardiovascular risk factors associated with mid-life cognitive decline; the relationship between diet quality and wellbeing; cognitive impairment and its association with...
stroke risk factors; genetic influences on healthy aging; and how differences in health knowledge, health beliefs, perceived discrimination and perceived barriers in health care interact with older Māori and non-Māori people.

Adopting apposite and current best-practice strategies, such as the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guidelines, the study will provide age-specific information to a variety of stakeholders on which to base interventions and inform policy development to enhance the health and wellbeing of people throughout life.

Methods

Design—Prospective random cohort study, stratified by Māori and non-Māori ethnicity. Māori are oversampled so that they represent approximately 20% of the sample. Commencing August 2010, baseline assessment is undertaken on the inception cohort and detailed follow-up will occur every 5 years thereafter. On an annual basis a brief postal follow-up assessment will also be undertaken.

Target population—50-year-old adults residing within the Canterbury District Health Board (CDHB) region at entry. Census 2006 figures show that 25,224 adults aged 45–49 years were within the CDHB region, of whom 1,782 identified as Māori.

Sample frame—New Zealand Māori and non-Māori electoral roll mapped to the CDHB region. Of the target population, 94.9% are estimated to appear on the electoral roll.

Participant eligibility—Adults aged 49–51 years residing within CDHB region upon enrolment, living in the community (i.e. not in prison or rest home) and able to competently complete assessment (e.g. proficiently speak English).

Recruitment—New Zealand has a compulsory electoral roll for those aged ≥18 years which is actively maintained. Extracts from the Canterbury rolls are made annually for electors turning 50 years within the next 12 months, stratified by self-declared Māori ethnicity status. Potential participants are randomly sampled from these stratified extracts, using different ethnic-specific sampling fractions. Those selected are sent a letter that briefly outlines the study, and invites them to contact the research team (by free-post). Where no return contact is made, the ensuing follow-up protocol is initiated. A maximum of four telephone calls are made at various days/times (including evenings and weekends) over 10–20 days. If contact is unsuccessful, then a second invitation letter is sent approximately 4–6 weeks after the first and a further four telephone calls over 10–20 days is undertaken. If no contact can be made, then two home visits are scheduled (where practical). There is no set time limit for these home visits.

Once contact is made, the study is re-outlined, potential participants who express interest in the study are screened for eligibility, and an appointment is scheduled to attend the CHALICE study office. Additional community networks have been developed to assist with the recruitment of selected Māori potential participants.

All potential participants are reminded by telephone the day before the assessment of their appointment time, that they should be fasting, and the time for their last meal. Extensive ongoing local media coverage of the CHALICE study commenced in 2009, so that potentially eligible subjects are likely to have heard about the study prior to receiving an invitation letter to participate.

Consent—Informed written consent is obtained from all participants for each study component. Consent is also specifically sought for whether participants want to receive a summary of their study results, having their general practitioner (GP) notified of study participation, and having their GP sent a summary of study results. Additionally, consent is sought for access to medical records through the National Health Index (NHI) database; storage and analysis of blood and plasma, urine, and DNA samples for ethics-approved research; and being contacted in future to ask about participation in related studies. Participants are also explicitly informed that they can withdraw from the study at any time and request that their biological samples be destroyed. Participants can elect to have their samples disposed of with an appropriate karakia (Māori prayer).

Assessment—After eligibility is formally determined and written informed consent obtained, the 4–6 hour baseline assessment interview commences. This interview consists of seven modules, each
structured to take approximately 30–60 minutes, using internationally recognised standardised instruments with good psychometric properties where possible.

Fasting urine and blood samples are collected and biobanked. A detailed description of the seven modules is included in Table 1. The brief annual postal questionnaire will assess some core health measures (highlighted in Table 1) and some novel pertinent questions of interest (such as personal impact of the Canterbury earthquakes). This questionnaire also serves to maintain regular contact with participants, and allows the tracking database to be updated where needed.

Table 1. Modules and instruments employed at the CHALICE baseline measurement phase

Post-consent, pre-assessment

Birmingham Irritable Bowel Syndrome symptom questionnaire (IBS),22 Short Form 36 (SF-36) version 2,23 self-completed Warwick Edinburgh Mental Well-Being Scale (WEMWBS),24,25 and a questionnaire on food behaviour.

The food behaviour questionnaire comprised of questions relating to nutrition knowledge and decisions related to food choice (including beliefs and attitudes towards food and potential facilitators and barriers to healthy eating). All questions were adapted from previously validated questionnaires where possible,26-32 and were pretested in a sample of 50 year olds before use in CHALICE.

Module 1: Physical

Height, weight, (derived body mass index (BMI)), body composition (measured by bioimpedance), heart rate, blood pressure, blood (100 ml) and urine (50 ml) including DNA extraction and biobanking, retinal photography, eye health questions to determine sun exposure sensitivity.33

Module 2: Health history

Interview questions were taken or adapted from the 2006/07 New Zealand Health Survey,26 including demographics: date of birth, ethnicity, relationship status, education, income, employment, home ownership, medical insurance; chronic conditions: current medication, long-term conditions, infection and immunisation history, digestive disease, sleep patterns; health service utilisation: general practitioner use, medical specialist, complementary or alternative health care workers, secondary health care services use; risk and protective factors: screening programmes, environment conditions, tobacco consumption.

The Economic Living Standards Index Short Form (ELSI-SF)34 and the Alcohol Use Disorders Identification Test (AUDIT)35 were also employed. Māori participants were asked about their ethnic identity, family, cultural involvement, fluency and knowledge using questions derived from the Hauora Manawa study.36

Module 3: Family and social

Interview questions covered family medical history, attitudes to health,37 job satisfaction,38,39 Attitudes to Ageing Questionnaire (AAQ),40 felt and ideal age,41 experience of aging,42 questions adapted from the Brief Illness Perception (BIP)43 for participants with children ill with disorders, the Carers of Older People in Europe index44 for participants who are primary carers for someone with illness or disability, abbreviated positive and negative social exchanges (PANSE),45 questions adapted from lay beliefs about major health condition preventability,46 medical scepticism,47 adapted List of Threatening Experiences Questionnaire (LTE-Q),48 abbreviated coping under stress scale (Brief COPE),49 abbreviated purpose in life (LIF) questionnaire,50 attitudes to religion/spirituality,51,52 selected social capital and social standing questions,53,54 and discrimination.26,55

Module 4: Heart

ECG, echocardiogram (supine, 15–20 minutes cardiac data acquisition), 5-minute carotid intima-media thickness (with 15MHz high frequency probe) and blood pressure (manual and automatic).
Module 5: Mental health

Most questions were derived from the Mini International Neuropsychiatric Interview (M.I.N.I.). Interview questions on major depressive episodes (current and lifetime), dysthymia, suicidality, (Hypo) manic episodes, panic disorder, agoraphobia, social phobia, obsessive-compulsive disorder, post-traumatic stress disorder, alcohol abuse and dependence, non-alcohol psychoactive substance use disorders, generalised anxiety disorders. Compulsive hoarding was also assessed, as was personality using the short form of the Temperament and Character Inventory (TCI-R).

Module 6: Cognitive

Cognitive assessment included the Montreal Cognitive assessment (MoCA) on visuospatial/executive, naming, memory, attention, language, abstraction, delayed recall and orientation functions. A non-word consonant-vowel-consonant (CVC) test as a verbal test of learning and memory adapted from the Rey Auditory Verbal Learning Test (RAVLT). Assessment hand dominance in everyday activities was undertaken using the Edinburgh Handedness Inventory.

Module 7: Lifestyle

Interview questions elicited on lifestyle, exercise, and diet. Recent physical activity (last 7 days and 12 months) was assessed using the New Zealand Physical Activity Questionnaire – Short Form (NZPAQ-SF), and physical functional assessed using balance tests, a gait speed test (4 m walk) and chair stand tests (5 chair stands). Participants were asked to keep a prospective food and exercise diary in the days following the main assessment.

The dietary diary contained three parts: (i) an adapted home food inventory; (ii) questions on how and what is eaten (to assist with coding of records); (iii) a 4-day (3 weekdays, 1 weekend) food and drink record. The exercise diary is a prospective 7-day log developed to capture different domains of physical activity including recreational physical activity, active transport, occupational physical activity and sedentary activities as well as sleeping habits.

*The first-year follow-up questionnaire included: general and physical health questions of the SF-12 version 2; new diagnoses since baseline assessment of 11 specified medical conditions; Warwick Edinburgh Mental Well-Being Scale (WEMWBS); whether baseline test results were discussed with GPs, further tests undertaken, and whether any medical, dietary or lifestyle changes were commenced due to any identified abnormal finding(s); the disruption section, difficulties and events since the quake, and impact of the quake over the last 7 days questions from the Newcastle Earthquake Impact Study (EIS); and any changes in contact details (name, postal address, telephone, mobile phone, and email address).

Laboratory measures—A number of laboratory analyses and measurements are undertaken, including [1] extraction of DNA; [2] routine biochemistry and haematology, including glucose and lipids; and [3] Vitamin D, parathormone, insulin. A wide range of other biochemical and genetic measures will be made as funding permits.

Data management—For multi-modal longitudinal studies, effective data management is critical. In recognition and response, a Data Management Committee was established at the inception of the CHALICE study. This committee ensures that apposite technologies and best practice methods are employed for handling the diverse data. Most data are directly entered into a Progeny database (Progeny Software, Needham, South Norfolk, UK), which incorporates a sophisticated laboratory integrated management system using bar-codes to track samples biobanked for subsequent analyses. Data from food diaries and echocardiograms are stored independently but summary variables, matched by study ID, are merged into the Progeny database. Data integrity and reliability is assessed using a formal protocol: a 10% randomly selected participant group is derived, re-entered into the Progeny database using a new ID number, exported and compared with the original entries, disparities recorded and error rates determined. For discrepant records, the original data sources are consulted to determine which data are correct, and amendments within the Progeny database are undertaken, if required.

The Progeny database includes no personal identifiers and is held in secure, password-protected storage under the responsibility of the CHALICE Study Director in accordance with the requirements of the New Zealand Privacy Act (1993) and the Health Information Privacy Code (1994).
Participant labelling in this database is made by study ID only. Personal identifying information is stored on a separate database in a password-protected file. All data are considered both sensitive and confidential, and only CHALICE study staff, authorised by the Director, have access to computerised data.

Sample size—Balancing the competing demands for increased statistical power in longitudinal studies\textsuperscript{12} against conducting a feasible, efficient and cost-effective study, a final cohort of approximately 1,000 adults will be targeted; 200 Māori and 800 non-Māori. This sized cohort would generally have adequate statistical power for bi-ethnic comparisons although it is recognised that power will not always be adequate for analyses involving the detection of small differences between groups or for more complex analyses involving a greater number of categories. However, as the number of follow-up waves increase, so too will the corresponding statistical power.\textsuperscript{12}

For cross-sectional analyses of baseline measurements, the sample size of 1,000 adults has 80\% power at the 5\% level of significance to detect a prevalence of 1.4\% in the non-Māori given a prevalence of 5\% in Māori. For greater differences and for higher prevalences, the associated power is higher.

Statistical analyses—Data will be exported after checking and cleaning into specialist statistical packages including: SAS (SAS Institute Inc., Cary, NC, USA), Stata (StataCorp, College Station, TX, USA) and R (R Foundation for Statistical Computing, Vienna, Austria). The precise analytical approach and corresponding power will depend on the specific research question under investigation. In general, cross-sectional analyses at each assessment time will be undertaken using generalised linear models, allowing the prevalence of key outcomes to be estimated and associated with risk factors. As further waves of data are added, these approaches will be augmented by more sophisticated longitudinal analyses and variable selection techniques using methods that include survival analysis, structural equation modelling, multilevel mixed-effects models and generalised estimating equations (GEE). Binomial GEE models will be employed to determine whether differential attrition occurs over time. Should systematic differential attrition be identified then sensitivity analyses will be employed, including multiple imputed or probabilistic weighting methods. All analyses will be overseen by the CHALICE study biostatistician(s).

Ethics—Careful consideration is continually given to the ethical aspects of this longitudinal study. Ethical approval for the CHALICE study was obtained from the Upper South A Regional Ethics Committee on the 14 June 2010 (reference: URA/10/03/021). The study complied with the ethical standards for human experimentation as established by the Helsinki Declaration 1964 (sixth revision 2008).

Results

Recruitment—Recruitment commenced in August 2010, and despite the significant series of Canterbury earthquakes, over 340 participants have been recruited and have completed the baseline assessments. This methodological paper reports on the first 300.

Figure 1 depicts the participant flow chart for these 300 participants; of whom 44 (14.7\%) self-identified themselves as being Māori. Of those who responded to the invitation and were eligible, 63.7\% agreed to participate (58.3\% for Māori).

Figure 2 displays the monthly participant assessment numbers since recruitment began, and graphically illustrates the impact of the Canterbury earthquakes on these numbers.
Figure 1. CHALICE participant flow chart as of 20 June 2012

Invitation letters sent
N=690 (138 Māori)

No response to date
Uncontactable: n=96 (37 Māori)
Following-up: n=48 (9 Māori)

Responded
n=546 (92 Māori)

Did not participate
Ineligible: n=44 (8 Māori)
Declined: n=184 (37 Māori)

Agreed to participate
n=320 (49 Maori)

Assessment incomplete
Interview scheduled: n=19 (4 Māori)
Interview to be scheduled: n=1 (1 Māori)

Assessment completed
n=300 (44 Māori)
Figure 2. Participant assessment numbers per month since study inception. (The 22 February 2011 earthquake resulted in significant loss of life and damage to the city, including cordoning and long-term closure of the central business district and temporary closure of the CHALICE office.)

Sociodemographics—By design, all participants were aged 49–51 years. Table 2 includes the frequencies of these basic sociodemographics overall, and partitioned between the Māori and non-Māori groups. No significant ethnic differences were noted except for higher levels of tertiary qualifications found among non-Māori compared with Māori (p=0.003).

In the 50–54 years age group for the Canterbury region, Census 2006 figures reveal that 50.7% were female, 77.2% were living in married or de facto relationships, and 14.3% had university degrees.
Table 2. Sociodemographic profile of the first 300 participants overall, and partitioned by self-identified Māori/non-Māori ethnic status

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Māori</th>
<th>Non-Māori</th>
<th>P-value</th>
</tr>
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<tr>
<td></td>
<td>n</td>
<td>(%)</td>
<td>n</td>
<td>(%)</td>
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<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Females</td>
<td>160</td>
<td>(53.3)</td>
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<td>(52.3)</td>
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<td>Males</td>
<td>140</td>
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<td>(47.7)</td>
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<td>(75.3)</td>
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<td>(65.9)</td>
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<td>(2.3)</td>
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<tr>
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<td>(15.7)</td>
<td>14</td>
<td>(31.8)</td>
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<td>(34.1)</td>
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<td>(19.0)</td>
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<td>(9.1)</td>
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<td>(22.7)</td>
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<td>12</td>
<td>(27.3)</td>
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<td>(20.5)</td>
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<td>(19.0)</td>
<td>3</td>
<td>(6.8)</td>
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<td>17</td>
<td>(38.6)</td>
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<td>(50.0)</td>
<td>24</td>
<td>(54.5)</td>
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P-values calculated using Fisher’s exact test. *‘Unknown’ category omitted from calculation.
Discussion

CHALICE is a large, multidisciplinary, comprehensive, longitudinal study that aims to generate a better understanding of the change in health with age. This research will provide evidence for cost-effective ways to maintain healthful lifestyles and everyday functioning within Canterbury, New Zealand, in the face of our rapidly changing demographic profile.¹

There are many determinants of health and wellbeing¹³ but nutrition, physical activity, and lifestyle factors are influential and potentially modifiable, and will receive particular interest within CHALICE. Maintaining or improving health and wellbeing may be one of the most important health strategies to delay the onset of age-related diseases. As such, this research project will have a key focus on the determinants of health and wellbeing, and in the longer term on the determinants of healthy ageing.

A central component of the CHALICE study is the development of an extensive repository of biological samples (biobank) for each participant. The purpose of this biobank will be to facilitate a wide range of genetic, biochemical and immunologic analyses (beyond those included in the initial assessment).

The biobank will be an enduring archive of carefully consented and stored samples that will be available to address future research questions, and allow analysis with novel technologies not yet available. The CHALICE biobank initially consists of genomic DNA extracted from peripheral blood, as well as multiple aliquots of serum, plasma, and urine.

Over the past few years genome wide association studies (GWAS) have yielded over 2,000 common genetic variants and copy number variants that influence risk of complex diseases and phenotypes.¹⁴,¹⁵ CHALICE is designed to investigate the influence of such common genetic variants on many aspects of health, ageing and disease. In particular, relevant genotypes will be integrated with a phenotype rich data set inclusive of clinical, cardiovascular, neuropsychiatric and gastrointestinal phenotypes. In conjunction with specific environmental factors, CHALICE is also designed to evaluate the relative importance of genetic variation on measures of wellbeing, disease and phenotypes such as vitamin levels, hormone levels and metabolic characteristics.

Among diseases of ageing, those affecting the heart and the brain are leading causes of death and disability for Māori. Many of the major recent advances in these conditions are the development of biomarkers that assist in early identification and monitoring of treatment.¹⁶,¹⁷

Māori are at risk of being excluded from health gains created through non-Māori research because of inadequate representation in most of these study types. The requirement for Māori consultation when involving genetic research may be perceived as a barrier for non-Māori researchers, as well as the perception among researchers that Māori are reluctant to participate in biomedical and genetic research. Arguably these factors may have been exacerbated through poorly reported research that leads to further negative Māori stereotypes.¹⁸
Additionally, the single disease focus of many research projects with exclusion of people with significant comorbidities may contribute to systemic barriers to Māori inclusion.

The development of this longitudinal cohort of Māori participants willing to contribute to a resource of carefully consented biomedical samples and comprehensive health information that recognises the importance of whakawhanaungatanga (the process of establishing and maintaining relationships), manaakitanga (reciprocity of kindness, respect and humanity), tinorangatiratanga (self determination) has the potential to be an important resource for Māori and researchers.

While biomedical markers have the potential to yield future improvement in Māori health status, through identification of risk factors and early detection, this must be balanced by an ability to understand the cultural, community, whānau (family), sociodemographic and health care context of Māori.

Sociodemographic factors\textsuperscript{19} and health care\textsuperscript{20} are dominant factors in mortality inequalities. This study aims to unite the individual and community context of illness affecting Māori as they age with gains by adopting international biomedical research and validating its utility for Māori.

While having several salient strengths, such as the scientifically robust longitudinal design, oversampling of Māori, breath of domains investigated, and comparability with available Census figures, the CHALICE study also has potential weaknesses. It might be opined that the geographical localisation of the cohort might limit generalisability. However, generalizability of findings depend on a number of considerations, divorced from time and place, and stems from the particular research question being addressed.\textsuperscript{21}

Stability, amenability to research participation,\textsuperscript{8} and the age-profile of Canterbury’s population\textsuperscript{9} will also offset this potential limitation for many investigations. Undoubtedly, the Canterbury earthquakes have had a profound effect on its residents and communities. Despite this, and throughout this enormously difficult period, recruitment and participation has continued with only a small interruption.

Finally, Pacific and Asian ethnic group representation within the CHALICE study is likely to be small and will generally provide insufficient numbers to inform ethic-specific comparisons beyond the Māori and non-Māori stratification groupings; although, again, this will depend on the particular research question that is being addressed.

The CHALICE study has been designed to advance scientific knowledge in a number of disciplines and provide public benefits through the provision of good quality information. Findings from this study will inform policy development and assist programme implementation for a variety of stakeholders working towards maximising the potential of older people within broader New Zealand society.

Competing interests: Nil.

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