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The Natural Helper approach to culturally responsive disease management: protocol for a type 1 effectiveness-implementation cluster randomised controlled trial of a cultural mentor programme

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ABSTRACT

Introduction Chronic disease is a leading cause of death and disability that disproportionately burdens culturally and linguistically diverse (CALD) communities. Self-management is a cornerstone of effective chronic disease management. However, research suggests that patients from CALD communities may be less likely to engage with self-management approaches. The Natural Helper Programme aims to facilitate patient engagement with self-management approaches (ie, 'activation') by embedding cultural mentors with lived experience of chronic disease into chronic disease clinics/programmes. The Natural Helper Trial will explore the effect of cultural mentors on patient activation, health self-efficacy, coping efforts and health-related quality of life (HRQoL) while also evaluating the implementation strategy.

Methods and analysis A hybrid type-1 effectiveness-implementation cluster-randomised controlled trial (phase one) and a mixed-method controlled before-and-after cohort extension of the trial (phase 2). Hospital clinics in highly multicultural regions in Australia that provide healthcare for patients with chronic and/or complex conditions, will participate. A minimum of 16 chronic disease clinics (clusters) will be randomised to immediate (active arm) or delayed implementation (control arm). In phase 1, the active arm will receive a multifaceted strategy supporting them to embed cultural mentors in their services while the control arm continues with usual care. Each cluster will recruit an average of 15 patients, assessed at baseline and 6 months (n=240). In phase 2, clusters in the control arm will receive the implementation strategy and evaluate the intervention on an additional 15 patients per cluster, while sustainability in active arm clusters will be assessed qualitatively. Change in activation over 6 months, measured using the Patient Activation Measure will be the primary effectiveness outcome, while secondary effectiveness outcomes will explore changes in chronic disease self-efficacy, coping strategies and HRQoL. Secondary implementation outcomes will be collected from patient–participants, mentors and healthcare providers using validated questionnaires, customised surveys and interviews aligning with the Reach, Effectiveness, Adoption, Implementation, Maintenance framework to evaluate acceptability, reach, dose delivered, sustainability, cost-utility and healthcare provider determinants.

Ethics and dissemination This trial has full ethical approval (2021/ETH12279). The results from this hybrid trial will be presented at scientific meetings and published in peer-reviewed journals.

Trial registration number ACTRN12622000697785.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is informed by pilot research and extensive engagement with consumers from culturally diverse backgrounds and lived experience of chronic disease management.
⇒ In addition to effectiveness, this trial includes a comprehensive evaluation of implementation outcomes, informed by established determinant and evaluation frameworks.
⇒ The mentor intervention is embedded in routine care and engages a volunteer workforce, thus enhancing the potential scalability of the intervention.
⇒ The effectiveness of the mentoring intervention may be limited by contextual factors including mentor skill, the severity and progression of chronic disease and setting. These will be explored by qualitative and process evaluations.
⇒ The degree to which any observed changes in patient activation translate to improved disease specific outcomes, including longer term outcomes, is beyond the scope of this study protocol and will require further exploration.

BACKGROUND

Chronic illness is one of the leading causes of death and disability[1] and is recognised to disproportionately burden culturally and linguistically diverse (CALD) communities. People from CALD communities are at a greater risk of developing a chronic illness, and more likely to experience adverse health effects and encounter additional challenges in accessing high-quality care compared with the wider population.[2–7] In Australia, specific migrant communities, such as those from the Middle East, South-Asia and Pacific Islands, are known to have a 1.3–2 times higher risk of physical inactivity, obesity, metabolic and cardiovascular disease risk compared with Australian-born communities.[7–10] Similarly, communities with low English proficiency are 1.5–3 times more likely to misunderstand medication regimes and discharge instructions compared with English proficient patients.[11 12] In addition, diverse conceptualisations of illness, often differing from those held by their healthcare providers (HCPs), may deter migrant community members from accessing and engaging with preventative healthcare.[13 14]

Effective chronic disease self-management largely depends on patient engagement,[15] which is contingent on their levels of *patient activation*. Patient activation is a construct that encompasses patient's knowledge, skills and confidence to manage their health condition, alongside their willingness to take independent actions.[16] A growing body of evidence indicates low-level *patient activation* is associated with more frequent utilisation of costly health services[17 18] and poorer physiological (blood pressure, HbA1c, cholesterol, weight) and behavioural (self-efficacy and health-related quality of life) chronic disease outcomes.[16 17 19] Consequently, strategies for optimising 'activation' among people from CALD backgrounds with chronic disease are needed. However, the limited research exploring self-management among CALD communities is concentrated on culture-specific programmes that are often fragmented and poorly integrated with formal healthcare services.[20 21] Further, isolated programmes targeting specific cultures are not scalable for the breadth of cultures and diversity within multicultural societies, such as Australia.[13] Thus, there is a need for interventions that optimise self-management to be responsive and adaptable to the heterogeneity of cultural presentations in the Australian healthcare context.

Integration of cultural mentors or 'Natural Helpers' (NH; those who identify with the same cultural background with a lived experience of the condition of interest) into chronic disease management services may be a feasible and scalable means of improving patient activation among members of CALD communities.[22–25] Previous research indicates that the adoption of peer and cultural mentors alongside health promotion activities may improve consumer knowledge and understanding, treatment attendance, adherence and coping skills.[21 26–31] In addition to facilitating patient activation, the integration of cultural mentors into chronic disease management systems has potential to inform and improve a patient's HCPs' cultural competence and responsiveness. From the medical education literature, there is evidence that role models in clinical practice facilitate learning of adaptive communication skills,[32] thus the integration of NH into chronic disease management has potential to enhance clinical service delivery and support patient activation in CALD community members.

Research into the feasibility, acceptability, and efficacy of NH (cultural mentors) within the Australian healthcare context is lacking.[31] However, our team conducted pilot research to evaluate the acceptability of NH within the context of chronic pain management in Australia[33] and embedded six mentors in three clinics treating musculoskeletal pain. It found patients from Arabic, Vietnamese, Assyrian and mixed culturally diverse communities who received NH mentored care demonstrated greater and clinically meaningful improvements in activation at 3 months (*median change 10.3 points*) using the Patient Activation Measure (PAM), compared with patients from the same communities who received usual care alone (*median change 0; p<0.01*). Importantly, there was high acceptance of the programme with 96% of patients satisfied or highly satisfied with their care.

To scale this pilot research and evaluate if cultural mentors can be systematically embedded in a variety of chronic disease management settings (feasibility and generalisability) to achieve clinically meaningful changes in patient activation (efficacy), we propose a hybrid type 1 effectiveness-implementation trial.[34] The primary aim is to evaluate if patients who receive cultural mentorship from an NH achieve greater changes in their activation for chronic disease management at 6 months post treatment compared with those receiving usual care. Secondary patient-level outcomes will evaluate for changes in self-efficacy for managing chronic disease; the coping strategies adopted; and health-related quality of life. Secondary implementation aims include evaluating the mentor intervention and implementation strategies in terms of their acceptability, reach, dose delivered, fidelity, adaptation elements, sustainability and cost-effectiveness using mixed-method data.

METHODS

Design

This implementation evaluation will be conducted in two distinct phases. Phase 1 is a hybrid type-1 effectiveness-implementation cluster randomised controlled trial involving 2 parallel groups and 16 clusters (figure 1). Phase 2 is a mixed-method before-and-after cohort extension of phase 1 involving cross-over of control clusters and sustained implementation in active clusters if progression criteria are met. Both phases incorporate implementation science conceptual frameworks drawn from theoretical and applied perspectives for the research design and implementation strategy.[35]

The Consolidated Framework for Implementation Research (CFIR)[36] is a determinant framework used to

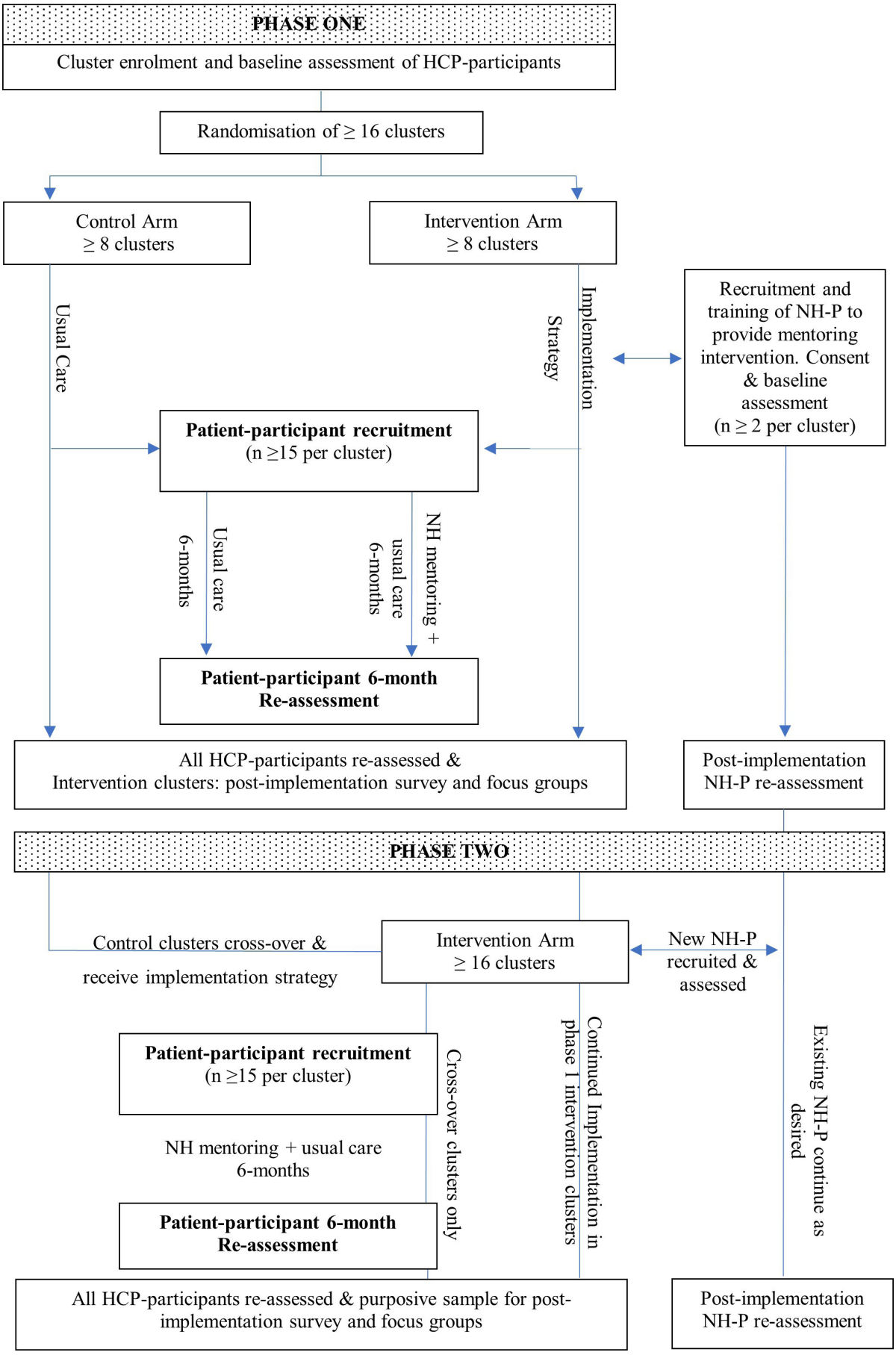

Figure 1 Flow chart describing study processes and phases. HCP, healthcare provider; NH-P, Natural Helper Participant.

identify implementation barriers and facilitators arising from our pilot study. Specifically, the barriers and facilitators to implementing the intervention identified in the pilot analysis were matched to the Expert Recommendations for Implementing Change[37] list of strategies to inform the study implementation strategies. A combination of the CFIR, the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) evaluation Framework[38] and the Practical, Robust Implementation and Sustainability Framework (PRISM)[39] extension of RE-AIM guided the choice of implementation outcomes and the determinants of the implementation outcome. Specifically, the RE-AIM[38] framework guided outcomes selected (table 1) to evaluate the implementation strategy, while the CFIR[36] and PRISM[39] extension informed the strategy for understanding contextual factors that may influence the implementation outcome. This included the design of HCP–participant (HCP-P) and NH–participant (NH-P) postimplementation surveys and semistructured interview guides, with specific questions canvassing organisational, environmental and participant characteristics that characterise the context within which the intervention was implemented. Further, to capture the adaptations and modifications to this highly contextualised intervention, the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS) model[40] was selected. Specifically, the 'adaptable elements' of the implementation strategy (table 2) have been planned according to the FRAME-IS components and will be recorded as such. Finally, the need for practical, contextualised approaches to advance health equity for vulnerable communities supported the adoption of a pragmatic trial design, underpinned by the Pragmatic-explanatory continuum indicator summary trial framework.[41] This guided the selection of heterogeneity of clinical settings and conditions as participating clusters, adoption of authentic participant eligibility criteria, flexible intervention delivery, application by the full range of practitioners, and the use of usual practice controls.[42] The trial design is guided by the Consolidated Standards of Reporting Trials: extension to cluster randomised controlled trials[43] (online supplemental file 1) and the Standards for Reporting Implementation Studies Statement[44] (online supplemental file 2). This study was approved by South Western Sydney Local Health District Human Research Ethics Committee (2021/ETH12279) and registered prospectively on the Australian and New Zealand Clinical Trials Registry (ACTRN12622000697785). Any modifications to the trial protocol will be updated online.

Cluster recruitment

A minimum of 16 clusters will be randomised. Eligible clusters will be clinics that provide healthcare for patients with chronic and complex conditions across participating public hospitals located in highly multicultural regions of Australia. Participating clusters will include, but not be limited to, diabetes, musculoskeletal, pain, rheumatology, cancer, lymphoedema, respiratory and cardiac care clinics.

Participants

Three levels of participants will be recruited: HCP-P, NH-P and patient–participants (P-P). In the active arm, HCP-P and NH-Ps will interact to provide culturally informed treatment of the P-P.

Healthcare provider participants

HCPs, from any discipline, will be eligible for inclusion if they are clinicians in a clinic of interest during the implementation period and anticipated to be exposed to the NH mentoring programme. HCP-P will be recruited before randomisation, or before exposure to the project.

Natural helper–participant

Prospective NH-P are community members intrinsically motivated to help others willing to be trained and volunteer with the health service in participating clusters. They will be recruited from the clusters and existing consumer and multicultural health networks, according to piloted strategies. NH-P will be eligible for inclusion if they have: a lived experience of the condition of interest for a specific clinic; self-identify with the target community identified for mentoring by the clinic based on language, ethnoculture or other cultural identification; and have completed the multicultural health mentor training programme.

Patient–participants

Consecutive patients attending clusters during the recruitment period will be assessed for eligibility by treating HCPs and provided with study information. Eligibility includes (1) aged≥18 years, (2) commencing active treatment with a participating cluster for a condition of interest of that clinic, (3) self-identification with a CALD community targeted for cultural mentoring by the clinic, (4) no cognitive impairment identified by their clinical team that could unduly influence their capacity to give informed consent in their preferred language. Interested patients will be referred to the research team. As a pragmatic trial, prospective P-Ps will only be excluded if they have a clinical diagnosis that may impair their cognition, such as dementia, delirium or severe psychiatric disorder, or cannot give written informed consent.

All levels of participants will give written informed consent. Translated participant information sheets and consent forms will be available for participants speaking a language other than English.

Phase 1 procedure

Before randomisation, recruited clusters will be matched according to similarities in conditions of interest (where possible) or disease trajectory (where an exact clinic match is not available) into a block size of two. The matching process will be completed by agreement among the operational team after considering the list of recruited clusters and the projected trajectories of each cluster according to Corbin and Strauss' model[45] with the aim to

Table 1 Study outcomes and timepoints

Outcome	Description	Timepoint			
		BA	6A	P1 end	P2 end
Effectiveness outcomes: Patient–Participant					
*The Patient Activation Measure[46]	A reliable and valid[46 47] 13-item self-reported questionnaire that assesses a patient's knowledge of their health condition and confidence in managing health-related tasks.	X	X		
Self-Efficacy for Managing Chronic Disease (SEM6S)[47]	A 6-item self-reported validated questionnaire[48–52] evaluating an individual's confidence managing fatigue, discomfort, pain, emotional distress or any other symptom associated with managing a chronic condition. Respondents rate their confidence on a 0–10 NRS across 6-items, to yield a mean self-efficacy score out of 10. Higher scores are associated with higher self-efficacy.	X	X		
The Brief COPE[53]	A reliable and valid 28-item questionnaire that assesses an individual's situational coping efforts.[53–58] Responses are scored on a 4-point Likert Scale and scores are summated across coping subscales: problem-focused, emotion-focused and avoidant coping.	X	X		
EQ5D-5L[59]	A valid and reliable 5-item quality of life scale measuring the domains of mobility, self-care, usual activities, pain or discomfort and anxiety or depression.[59–61] Each subscale is rated on a 5-level rating, ranging from 'no problems' to 'unable to do'. In addition, a 0–100 VAS captures a respondent's current health status, with a higher score corresponding to the 'best imaginable' health status. A health utility score is derived from completion of the EQ5D-5L.	X	X		
Implementation outcomes: all levels of participants					
Reach	1. HCP screening logs (% patients meeting inclusion criteria subsequently recruited)			X	X
	2. Electronic Scheduler (% appointments attended out of those scheduled).			X	X
Acceptability	1.The Client Satisfaction Questionnaire[70]—An 8-item questionnaire evaluating P-P satisfaction with healthcare.			X	X
	2. Programme coordinator records (% P-P withdrawing from mentoring)			X	X
	3. Interviews or focus groups with P-P and HCP-P (intervention perspectives)			X	X
Dose	NH-P log-books (number of sessions, frequency, and duration of mentoring sessions)			X	x
Fidelity	1. NH-P log-books (% of core components received by each individual P-P)			X	X
	2. Audit checklists coding core components observed by bilingual audit team.			X	X
Context	HCP-P attitudes towards cultural responsiveness and patient-centeredness: 1.The Cultural Competency Assessment Instrument[62]—A 3-item questionnaire evaluating cultural awareness and cultural sensitivity.	X		X	X
	2. Patient-centred care competency scale[63]—A 17-item questionnaire appraising one's perceived competence with person-centred care activities.	X		X	X
Costs	1.Payroll; cost-centre expense registries (direct programme costs)			X	X
	2.Admitted patient data collection; Emergency Department Data Collection; National Hospital Cost Data; EQ5D5L (P-P health utilisation costs)			X	X

Continued

Table 1 Continued

Outcome	Description	Timepoint BA	6A	P1 end	P2 end
Sustainability	1.The Clinical Sustainability Assessment Tool[71]—A 35-item questionnaire exploring organisation's capacity for sustainability (HCP-P)			X	X
	2. Interviews/ survey's with NH-P and HCP-P.			X	X
	3.The number of intervention clusters continuing beyond phase 1.				X
	4.NH-P well-being sustainability via the CASP-19 scale[72]—A 19-item questionnaire evaluating overall well-being in older adults.			X	X

6A, 6-month assessment; BA, Baseline Assessment ; EQ5D-5L, EuroQOL-5D; HCP, Healthcare Provider ; HCP-P, HCP participant; Key, *Denotes primary outcome measure; NH, Natural Helper; NH-P, Natural Helper Participant; NRS, Numerical Rating Scale; P1, phase 1; P2, phase 2; P-P, patient participant; VAS, Visual Analogue Scale.

ensure relative balance in outcome expectancies for the diverse chronic disease clusters. Consenting HCP-P will complete baseline assessments of cultural responsiveness and patient centeredness (table 1). When a cluster pair is ready for randomisation, the chief investigator will notify a senior researcher (JN) not involved in data collection or intervention who will liaise with the study biostatistician. The study biostatistician (JD), who is independent of the implementation team and outcome assessors will allocate cluster pairs by block randomisation (figure 1)

Table 2 Key implementation strategies and adaptable elements

Intervention component	Implementation strategy	Description	Adaptable elements
Service restructuring around NH integration	Service readiness and needs assessment (plan strategy)	A local needs assessment with key service stakeholders conducted preimplementation to identify readiness, patient needs and resources to support implementation.	Individualisation of service resources
Effective cultural mentoring	Education and training of cultural mentors	NH mentors will complete 16 hours of preimplementation training including concepts of peer mentoring, behaviour change skills and practice of operational elements.	Individualisation of NH–mentor resources specific to the context
	Expert shadowing	Three expert-shadowing/joint mentoring sessions will be delivered during the provisional period by an experienced multicultural health officer or experienced past NH mentor.	Tailored mode of supervision, specific to the setting and the NH mentor preferences
	Audit and feedback	Observation checklists and feedback on performance will occur weekly for the provisional phase and then monthly until the end of the active treatment phase.	The format of feedback delivery will be tailored to the preferences of the NH mentor
	Ongoing training and creation of an NH learning collaborative	Monthly sessions will be held using a flexible format for NH mentors to engage with other mentors and support staff. Updates of community programmes and resources will also be provided. Repeated training sessions will be scheduled to support onboarding and/or revision for existing NH mentors at regular time intervals	Attendance at the learning collaborative sessions will be optional and tailored to the needs and availability of individual NH mentors
Effective NH-Clinic Relationship	Develop tools for quality monitoring	Debriefing resources will be created to foster quality NH-HCP debriefing	Debriefing resources will be tailored to align with the clinic and mentoring structures
	Provide ongoing consultation and support	Monthly meetings to identify potential challenges and support adaptation as necessary	

NH, Natural Helper.

to immediate implementation (active arm) or delayed implementation (control arm) and notify the senior researcher within 48 hours. Thereafter, the chief investigator will advise participating clusters of their allocation. Active clusters will receive the multifaceted implementation strategy that includes the recruitment, training and guided incorporation of the NH programme in their service. Thereafter, consecutive patients attending any cluster will be assessed for eligibility until an average of 15 P-P per cluster consent. All P-P from a single cluster receiving the same treatment, according to the cluster's random assignment.

Intervention (active clusters)

Immediate implementation clusters will receive strategies associated with implementing the NH programme (implementation strategies) before the intervention (NH-mentoring) is delivered to consenting P-Ps.

Implementation strategy

The strategies adopted for embedding the NH programme during intervention have been informed by pilot data and described determinant and adaptation frameworks. Table 2 provides an outline of key implementation strategies and the elements adaptable to each setting. The strategies will be delivered by the implementation team comprising the primary investigator (BB), a clinical specialist physiotherapist and postdoctoral research fellow, and multicultural health officers with expertise in community engagement, health promotion and cultural adaptation. The implementation team who is not blinded to the intervention will use the implementation strategies to support participating clinics and NH mentors to embed the NH programme, using a multifaceted approach that includes a restructuring plan for HCP-Ps to integrate the mentor, education and practical training of NH mentors, and provisions for fostering reciprocal relationships between mentors and HCPs.

NH-mentoring intervention

NH–mentors, trained by the implementation team, will deliver the mentoring intervention to consenting P-P within active clusters for up to 6 months. NH–mentors will be matched with P-P according to similarities in chronic diseases and cultural identification. An iterative model of mentoring has been adopted for this project via a combination of research synthesis, stakeholder engagement, pilot testing and refinement phases. While it is designed to be flexible and adaptable to different settings and diverse cultural backgrounds, six core components characterise the intervention (table 3). P-P will receive ongoing mentoring for their chronic condition in a format (face to face, virtual or phone), frequency and duration collaboratively determined by the patient, treating HCP and NH–mentor for up to 6 months.

Intervention (control clusters)

Control clusters will deliver usual clinical care to patients attending the service with interested consecutive eligible P-P screened for eligibility, informed about the study, and referred to the research team.

Phase 2 procedure

Phase 2 will follow phase 1 (figure 1) if progression criteria have been met. This includes achieving adequate recruitment rates (≥ 50% of eligible patients recruited), intervention acceptability (≥ 70% of patients satisfied or highly satisfied), outcome acceptability (≥ 80% of outcome measures completed) and minimal loss to follow-up (less than 20%). Adverse events or problems will be reviewed by the research and consumer panel to determine if they should prevent progression.

In phase 2, clusters randomised to the intervention in phase 1 will continue the programme. While no new patient–participants will be recruited into these clusters, process outcomes and HCP-P and NH-P outcomes/perspectives will be captured to explore sustainability. Simultaneously, the previously assigned control clusters will receive the implementation strategies as described in phase 1 to embed the NH programme in their service. Thereafter, new consecutive P-Ps will be recruited (n=15 per cluster), consented and complete baseline assessments before matching with an NH for mentoring up to 6 months.

Outcomes

The outcome assessment approach incorporates both effectiveness and implementation outcome evaluations across the three levels of participants (table 1). Demographic characteristics of all levels of participants will be collected at baseline only, while effectiveness and process measures will be collected at multiple time points.

Primary effectiveness outcome

P-P change in activation from baseline to 6 months post treatment, evaluated using the PAM,[46] is the primary effectiveness outcome. The PAM, available in 22 languages, is a 13-item self-reported questionnaire that assesses a patient's knowledge of their health condition and confidence in managing health-related tasks across five response options (0: 'not applicable', 1: 'strongly disagree' through to 4: 'strongly agree'). Responses are transformed to achieve a standardised metric ranging from 0 to 100 (0=lowest activation; 100=highest activation) and classified into one of four levels of activation (level 1≤47.0 characterised as not believing activation is important, through to level 4≥67.1, characterised as taking action but requiring support in maintaining positive behaviour change). In a recent review of the psychometric properties of the PAM, the 13-item version was reported to have high internal consistency reliability (Cronbach's alpha values between 0.8 and 0.9), good to excellent test–retest reliability (intraclass correlation coefficients between 0.76 and 0.98), satisfactory content and face validity, and significant correlations with measures of self-efficacy and locus of control (moderate to strong correlation coefficients).[47] A four-point improvement in

Table 3 Core intervention components

Core component	Description	Fidelity assessment
Clinic surface adaptations	Fostering a culture whereby mentoring is considered suitable and appropriate for patients from the target community will be fostered by: ► Display of patient-facing resources, adapted to each setting in key languages ► HCPs and clinic staff endorsement of the mentoring programme in routine discussions with prospective patient–participants ► Scheduling mentoring sessions alongside clinical appointments where possible.	Monthly clinic observation using checklists evaluating visible display of materials, coscheduling of appointments and review of mentor and HCP log books for evidence of relationship verification (coded as 0=did not occur; 1=occurred).
Relationship verification	Patient and NH acceptance of a match will be ascertained by the NH coordinator and clinic staff independently after the first visit to verify both parties' desire to continue the mentoring relationship.	Patient and NH semistructured interviews that enquire about relationships between patients and NHs.
Briefing and debriefing processes	Briefing and debriefing between HCPs and NHs before and after mentoring sessions is considered important for integrating mentoring with clinical care. To facilitate communication, NHs will be encouraged to: ► Complete session templates highlighting the focus of the session and core topics discussed. ► Note challenges encountered ► Appraise a patient's progress ► Raise suggestions and/or provide cultural reflections on a patient's actions/behaviours to support the HCPs understanding of the patient experience.	Questions in semistructured interviews conducted with NHs and HCPs will enquire about the occurrence and utility of debriefing following each mentoring session. NH and HCP logs will be compiled to cross-check dates and signatures for debriefing occurrence for each patient and each session.
Mentoring topics	While the content of mentoring discussions will be unscripted and guided by participant needs minimum content guidelines include discussion of: 1. Emotional well-being 2. Chronic disease management progress 3. Advice grounded in a NHs experience adopting the behaviour change or navigation of common challenges managing chronic disease (eg, task grading, pacing, habit formation) 4. Strategies to problem-solve challenges and manage set-backs 5. Community participation	A purposively designed checklist will audit for the core elements of the peer mentoring intervention that align with critical attributes identified in Dennis' conceptual model of peer mentoring and informed by our pilot research.[73] A checklist will code the occurrence of key elements as 0,1 (0 did not occur, 1 occurred) and collate for each mentor to achieve a % fidelity for each observed session. HCP survey's and focus groups will explore HCP perspectives of NHs' social competency including willingness to talk openly about disability and life experiences, motivation and commitment to participation.
Communication and behaviour change techniques	The NH training programme encompasses a range of techniques associated with promoting behaviour change and chronic disease self-management.[74] Core techniques include: ► Active listening ► Non-judgmental communication ► Feedback on behaviours (descriptive, non-judgmental and specific) ► Problem solving and action planning ► Displays of empathy/emotional support.	A purposively designed checklist will audit for the presence of communication and behaviour change techniques, coded as 0,1 (0 did not occur, 1 occurred) for each mentor to achieve a % fidelity for each observed session.
Mentoring dose	The number of and frequency of mentoring sessions will be flexible in line with a patient-centred care approach and for supporting adaptability to the different settings. The minimum parameters established include three sessions within 3 months of individual contact and a minimum duration of 3 months exposure. Beyond this minimum dose, the format and method of mentoring may be extended as desired and encompass varying modes of delivery including individual and group sessions, as determined suitable by the target clinic. The effective duration for peer mentoring cited in the literature is variable ranging from 6 weeks to 6 months,[75] thus the minimum duration encompasses these periods and allows for partnerships to continue for as long as 6 months depending on the clinic and the patient–NH relationships.	HCP and NH logs will be used to verify the occurrence of the minimum dose. Records of the number, duration of, frequency and overall length of the mentorship will be recorded to explore patterns between the relationship between dose and outcomes.

HCP, Healthcare Provider; NH, Natural Helper.

the PAM has been cited as a clinical meaningful improvement in activation.[14]

Secondary effectiveness outcomes

P-P secondary outcomes will be collected at baseline and 6 months post treatment to evaluate a participant's change in self-efficacy, coping styles and health-related quality of life over the treatment period, using outcomes described in table 1. Self-efficacy will be measured using the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEM6S), a brief questionnaire with good test–retest reliability, good internal consistency and moderate correlation with other self-efficacy measures including the PAM.[47–52] Coping will be measured using the Brief Coping Orientation to Problems Experienced Inventory.[53] While the Brief COPE has been reported to have good to excellent test–retest reliability,[54 55] good internal consistency for the three subscales (alphas ranging from 0.54 to 0.91)[55 56] and moderate correlation with psychological health measure,[55 56] further research is needed to understand the variable factor structure across the different versions of the Brief COPE, including translated versions.[57 58] The EuroQOL-5D (EQ5D-5L), a widely used health-related quality of life measure, has been demonstrated to have moderate to excellent test–retest reliability, moderate to strong correlations with quality-of-life instruments, functional measure and symptoms measures.[59–61] All questionnaires have been explored for use in a variety of chronic conditions and the final selection of instruments was pragmatically determined based on the availability of translations in key languages using established methodology.[50–61]

Secondary implementation outcomes

Data from implementation outcomes aligned with the RE-AIM[38] and associated PRISM extension[39] evaluation frameworks will inform further implementation research (table 1). This includes measures of reach, acceptability, intervention dose, intervention fidelity, contextual factors influencing implementation success (HCP-P cultural responsiveness[62] and patient-centeredness[63]) and sustainability.

A within-study cost-utility analysis (CUA) will compare the cost of NH-mentored care to usual care. The main outcome is quality of life, expressed as quality-adjusted life years (QALYs) and measured using the EQ5D-5L.[59] Total costs for each P-P will be determined from the intervention costs and cost of health services over the intervention period for the active group; and the cost of health service utilisation for the control group. Direct intervention costs, including the implementation strategies, will include staff, reimbursements and programme materials derived from sources outlined in table 1. Healthcare utilisation costs will be estimated from datasets specified in table 1, using the National Efficient Price Determinants 2022–2023. The fixed and variable costs associated will be aggregated to form an estimate of the total cost per use. The total cost per use will be multiplied by the number of services rendered, which then will be averaged over the groups to obtain an estimate of the cost per NH-mentoring session per patient. Labour costs will be attributed to the staff member and the cost of intervention and usual care (based on time and location) to determine a total intervention cost for each participant, including infrastructure. A cost-utility ratio will be calculated based on EQ5D-5L as the change in total programme and health service cost per change in QALY in the active and control groups.

Qualitative methodology

Individual interviews will be conducted with a purposive sample of P-P, selected for variability in outcomes, to answer implementation research questions, while a combination of post-implementation surveys and focus groups will be conducted with NH-P and HCP-P. Interviews and/or focus groups will be conducted face-to-face, by phone, or virtually, according to participant availability and pandemic restrictions. A bilingual member of the research team experienced in qualitative interviewing or an investigator and National Accreditation Authority for Translators and Interpreters (NAATI) accredited interpreter will conduct interviews for participants preferring to speak a language other than English. A semistructured interview guide, mapped to the CFIR determinant framework and designed with consumer input will be used to explore participants' experiences with the programme, including perceived benefits, challenges and recommendations for improvement. Sampling will be continued, alongside qualitative analysis, until there is a sufficient repetition of information (codes) for a deeper engagement with the data[64] or the maximum number of available participants is reached.

Data analysis

Sample size

Using parameter estimates derived from a multilevel analysis of pilot data, we estimated sample size in a simulation study that showed 240 patients (15 patients over at least 16 clusters with equal allocation into intervention and control groups) would be sufficient to find an improvement in the PAM of 6.5 points between intervention and control clusters, achieving 81% power, assuming 5% statistical significance and 20% loss to follow-up. These calculations have been based on pilot data that showed a 10-point higher PAM for those exposed to the NHs, which exceeded the minimally important difference of four points.[14] In the simulation, we assumed conservative variance parameters estimated from the pilot data by variance+1.96*SE (variance), which gave random intercept variance (clinic)=121, residual variance=239, co-variance of the premeasurements and post measurements=111. Fixed effect parameters were intercept=64.7, phase coefficient=7.1, time coefficient=10.2, time × phase interaction coefficient=6.5.

Effectiveness analysis plan

Planned analyses will be performed by the blinded study biostatistician (JD). Descriptive data will include

summaries of potentially confounding variables. For the primary hypothesis, data analysis will be completed using the intention-to-treat principle with P-P analysed according to their cluster assignment, regardless of the level of protocol compliance. A 2-multilevel model will be used to model PAM at 6 months, with a random intercept of clinic, fixed effects of allocation, time, and an allocation by time interaction as the main variables of interest. The coefficient of the allocation by time interaction will provide the difference in the changes of PAM from pre to post between the allocation groups. The analysis will be adjusted to control for covariates that may be related to level of activation (eg, education, age, English proficiency and gender).

For the secondary patient-related hypothesis, similar 2-level multilevel models, adjusted for potential confounders, will model secondary continuous outcomes. The coefficient of the allocation by time interaction will provide the difference in secondary outcomes between the allocation groups from pre to post.

Exploratory analysis on P-P outcomes will include a per-protocol analysis of the primary and secondary P-P outcome measures, including only P-P for whom treatment fidelity criteria were met. For the intervention clusters, fidelity criteria stipulated a minimum of three sessions of NH mentoring occurring within 3 months, in addition to routine care. For control clusters, similar minimum dose criteria were adopted (at least three consultations with a HCP over the study period). Exploratory analysis of P-P outcomes from control clusters in phase 1 will be evaluated against P-P outcomes collected in phase 2 when these clusters are exposed to the intervention. Comparability of the two cohorts will be descriptively reported for baseline variables and outcomes. Multilevel models will be used to compare the change in outcome scores (PAM, SEM6S, Brief COPE and EQ5D) from baseline to 6 months, with a random intercept of clinic, predictor variables of time, allocation and an interaction between time and allocation.

Implementation and mixed-method analysis

Implementation outcome analysis of measures of acceptability (patient satisfaction: CSQ-8) will be evaluated via between-group comparisons using linear models. A within-study CUA will compare the NH programme at the completion of phase one to usual care. The main outcome is quality of life, expressed QALYs. Results will be reported as incremental cost-effectiveness ratios (ICER) derived from total direct costs (table 1). To assess the difference in QALYs between groups, ordinary least squares (OLS) will be used, controlling for a set of covariates (gender, age, education and English proficiency) and baseline PAM. A log transformation will be applied if the fitted model violates the OLS normality assumption. Back transformation will be performed using the smearing estimator approach to produce a difference in costs to inform the ICER. For all regression analyses, mean differences between groups, variance and p-value associated with mean difference, goodness of fit (R-squared) will be reported. One-way and two-way sensitivity analyses will determine the impact of changes in input variables to facilitate determination of parameters with the highest influence on the outcomes, and prioritise areas for future intervention.

The remaining implementation measures (acceptability, dose, fidelity, context and sustainability measures) will be descriptively presented to facilitate interpretation of qualitative findings and support hypothesis refinement for future research. Audio recordings of interviews and focus groups will be transcribed verbatim and imported into NVivo (V.12 produced by QSR International, Melbourne, Victoria, Australia). A rapid assessment process including data categorisation and coding by two members of the research team experienced in qualitative analysis[65] will be mapped to the RE-AIM[38] and CFIR frameworks.[36] The entire research team will meet regularly regarding interpretation of findings arising from data coding and theme generation. Broadly, these data will be used to expand on the results from the pragmatic trial to understand the implementation processes as experienced by the HCP-P and NH-P. Participants will have the opportunity during member-checking sessions facilitated by a multicultural health officer and the research team to review the trial results and interpretations of qualitative findings. Results of the mixed-method analyses will be presented via key informant narratives and tabular representation of themes with illustrative quotes.[66]

Patient and public involvement

The experiences of P-P and NH-P who participated in the pilot project (qualitative and quantitative measures) have informed the refining of the intervention, implementation strategies and outcome measures selected. The resulting trial protocol is a synthesis of input from past NH mentors, representatives of the district consumer and community participation committee, and consumers from the musculoskeletal clinical academic group consumer committee. Combined, the team has continued to ensure the experiences of patients and mentors are the focus of the outcome measures and instruments developed for this project, including their satisfaction with care, a key study outcome. Further, there are two consumer representatives in the project team and key consumer and community stakeholders will contribute to the stakeholder group monitoring trial process and issues regarding patient-P and NH-P.

Ethics and dissemination

Ethics approval was obtained from the South Western Sydney Local Health District Human Research Ethics Committee (2021/ETH12279). All levels of participants will provide voluntary, informed consent. For non-English speaking participants, an accredited interpreter or bilingual member of the research team will explain the study in detail before obtaining consent. The study will be monitored for quality and regulatory compliance

by the project steering committee comprising researcher and consumer representatives meeting quarterly. Any adverse event or complaints will be assessed by the project steering committee to decide whether additional investigation or a modification of the intervention may be indicated. Any participant experiencing an adverse event will be provided appropriate support as determined by the steering committee. The results of the trial and other evaluation findings will be presented at scientific meetings and local community forums for interested P-Ps, and submitted for publication in international peer-reviewed journals. On completion of the trial, and after the publication of the primary manuscripts, data requests can be submitted to the primary investigator.

DISCUSSION

Novel approaches are required to address some of the challenges CALD patients encounter accessing and implementing healthcare treatment for their chronic and complex conditions. The planned trial will test a patient-centred and culturally responsive approach embedded within chronic care clinics and teams. Such approaches are critical with prepandemic migration levels rising worldwide resulting in an increased volume of healthcare consumers identifying as CALD.[67 68] Australia is highly multicultural society with 30% of the Australian population born overseas.[69] Accompanying population diversity in language, religion and social background are diverse conceptualisations of health and healthcare that do not always align with those held by formal healthcare structures and the HCPs within them, contributing to observed health disparities for CALD communities.[13] As such, innovative, scalable and sustainable approaches are required to bridge cross-cultural and social divides.

The results of this study will have implications locally, but on a broader scale will enable HCPs and healthcare managers to make informed decisions regarding their potential to adopt a consumer-partnership approach to healthcare. While this trial builds on previously conducted pilot research, it is the first to systematically implement and evaluate a cultural mentor approach within formal hospital services using the described methodology and for a diversity of cultures and conditions of interest. The adoption of a hybrid effectiveness-implementation design will allow for exploration of the contextual factors that may influence the effectiveness of the mentoring intervention from which further research will be needed. For instance, the incorporation of qualitative interviews and processes evaluations will facilitate an understanding of the effect of mentor attributes and/or the effect of severity/progressiveness of the included chronic diseases. Thus, further research will be necessary to expand our understanding of settings wherein mentoring is most likely to be effective and the applicability of our findings to healthcare services beyond those involved in the study. Nonetheless, the pragmatic and flexible nature of the intervention and the hybrid methodology will allow for a critical evaluation of the factors associated with success, and how the model may be adaptable to other settings.

Finally, owing to the diversity of chronic disease clusters included in this pragmatic trial, it will not be possible to explore the association between changes in activation and disease specific outcomes in this study. Further research will therefore be needed to establish whether changes in activation observed with a mentoring intervention translate to improvements in disease-specific outcomes. Nonetheless, there is considerable research that supports an association between patient activation, chronic disease outcomes and costly utilisation of health services[16–18] supporting the choice of primary outcome measure and pragmatic trial design. Further, the qualitative components are designed to provide patient–provider and HCP participant perspectives on the perceived value of the intervention for health outcomes to inform directions for future research.

Trial status

Recruitment to the trial commenced in August 2022. At the time of protocol submission, the trial is recruiting participants.

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Contributors BB, BS and JMN conceived the study and drafted the original Ministry of Health funding proposal. BB, JMN, MJ, GS, CT, GH, SS and RB contributed to protocol and intervention revisions arising from the pilot study and draft ethics protocol. SS is a consumer representative involved in the pilot and consumer advisory committee supporting this trial. JD planned the statistical analysis and DL the economic analysis plan. JMN, CT, SD, CA-J, KR, CMS and GW provided guidance and feedback to BB regarding the study design, outcomes and planned analyses. All authors contributed to the final protocol for ethics, trial registration, preparation and approval of the protocol manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by South Western Sydney Local Health District Human Research Ethics Committee (2021/ETH12279). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement On completion of the trial, and after the publication of the primary manuscripts, data requests can be submitted to the primary investigator.

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