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Perspectives of general practitioners and memory clinic patients on ageing and cognitive decline to inform the design of a decentralised antihypertensive dementia prevention trial

Alexandra Hurden [a,b], Isabella Cotter [a], Loren Mowszowski [c,d], Sharon Naismith [c,d], Craig S. Anderson [a,b,*]

[a] The George Institute, Sydney, Australia
[b] Faculty of Medicine, The University of New South Wales, Australia
[c] Brain and Mind Centre, The University of Sydney, Sydney, Australia
[d] Faculty of Science, School of Psychology, The University of Sydney, Sydney, Australia

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ABSTRACT

Background: The global burden dementia is growing each year. Clinical trials investigating approaches to preventing dementia have been occurring for decades, but they are particularly challenging including the requirement to include large numbers of healthy 'at-risk' people who need to be followed up for a long period of time. Community and consumer involvement in trial design helps to ensure that the methods are acceptable to the involved stakeholders, the design and operation of clinical trials are suitable and applicable to the target population, and that key areas of concern are identified and addressed at an early stage. Objectives: To gain insights from samples of memory clinic patients without dementia and general practitioners on the acceptability of, and attitudes towards, the proposed design of a decentralised antihypertensive dementia prevention trial. Topics addressed included the assessment of cognition, antihypertensive medication use, and motivation to participate in research. Methods: Two focus groups (total $n = 7$) with memory clinic patients and individual interviews with GPs ($n = 5$) were conducted. Transcripts were analysed using qualitative thematic framework analysis. Results: The proposed design was acceptable, with some possible barriers identified regarding computer use, GP time restraints, and concerns about medication interactions. Additional themes included the importance of communication and social connectedness in research participation and perceptions of ageing in medical settings. Future directions of research into larger studies and consumer-led research practices were discussed. Conclusion: The proposed trial design was agreed to be acceptable with some operational considerations, which were incorporated in the trial design.

1. Introduction

An estimated 47 million people are currently living with dementia worldwide, with 10 million new diagnoses made every year. The number of people affected is expected to exceed 130 million by 2050 [1,2]. As no treatment for any form of dementia is available or imminent, prevention is key to reducing its incidence and burden [1]. The Lancet Commission on dementia has further emphasised the importance of modifiable preventative factors for this disease, with blood pressure (BP) control being the most important [3]. The link between hypertension and the risk of Alzheimer's disease (AD), the most common form of dementia, has been well-established in cohort studies with over 15 years of follow-up [4,5]. With the average age of onset of dementia in the United States being 83.7 years old [6], much of the current research on preventative measures for dementia and cognitive decline focuses on older adults.

In a Dutch survey, general practitioners (GPs) were hesitant to prescribe antihypertensives (BP-lowering medication) to adults older than 80 years of age due to the frailty being common and insufficient support regarding benefits of intensive control in clinical guidelines [7]. Doctors tend to be conservative in their use of antihypertensive agents in older people because of concerns the treatment will cause harm [3]. However,

* Corresponding author at: The George Institute, Sydney, Australia
E-mail address: ahurden@georgeinstitute.org.au (C.S. Anderson).

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systematic reviews of randomised controlled trials (RCTs) show that intensive BP lowering does not increase the risks of falls or worsen cognition, and even reduces the likelihood of orthostatic hypotension [8]. Reviews of relevant RCTs have shown variable results to date, due mainly to having insufficient statistical power to reliably answer these key questions, and none have reduced BP in normotensive individuals despite comparable relative risk reductions to those hypertensive [9, 10]. Thus, a compelling case exists to undertake a RCT to reliably determine whether BP lowering can prevent dementia.

When designing an RCT, it is recommended that consumer and community members are consulted to ensure the protocol and procedures are acceptable to the public and that the is incorporation of the patient's viewpoint is considered [11]. Additionally, as any proposed RCT would need a large sample size to achieve the necessary statistical power, consulting stakeholders should aid in appealing to potential participants and reinforce acceptability to health professionals involved [12]. Given the acceleration in digital literacy driven by the COVID-19 pandemic and the increased equity in trial participation, in addition to the opportunity to reach large numbers of people with fewer resources required [13], a decentralised RCT design was chosen to test the impact of BP lowering on incident dementia and cognitive decline.

In the context of designing a decentralised dementia prevention trial that utilises BP lowering in an older adult population, this study aimed to gather insights from a sample of memory clinic patients without dementia, including some individuals with a history of caring for someone with dementia, alongside a sample of GPs, on the acceptability of the proposed RCT design. Topics for discussion cover the remote nature of the decentralised RCT, recruitment via mailed letters, involvement of GPs, use of antihypertensive medications, and motivations and barriers to participating in such a trial. The topics of cognitive decline, experiences with peers and medical professionals, and ageing were also investigated.

2. Methods

2.1. Participants

A two-sample, formal, semi-structured interview trial was conducted in July 2022, with a group of memory clinic patients participating in focus groups of up to four people, and a sample of GPs interviewed individually. The sample of patients ($n = 7$) was recruited through the Healthy Brain Ageing memory clinic at the Brain and Mind Centre, University of Sydney, Australia. The clinic provides comprehensive medical, mental health and neuropsychological assessment for individuals aged ≥50 years. Individuals are referred by a medical practitioner, for assessment of cognitive concerns (see [14] for a description of the clinic and methods). Potential participants were informed about the opportunity during regular clinic visits, with clinic staff completing screening. Inclusion criteria were: (a) aged >60 years, (b) experiencing memory concerns and/or having experience as a carer for someone with dementia, and (c) not having dementia or other severe cognitive impairment. The GP sample ($n = 5$) was recruited through a metro Sydney public health network newsletter. Eligible participants had experience in general practice for a minimum of five years in Australia.

2.2. Interviews

For the patient sample, informed consent was obtained on the day of each focus group, prior to the interview. Sixty-minute interviews were held on-site at the memory clinic, with experienced moderators in attendance with members of the research team. The location was familiar to the participants. Interviews were recorded using audio recording computer software and portable voice recorders, then manually transcribed after the interview.

GP participants submitted e-consent forms and were interviewed individually by the researcher via teleconference software (Zoom or Microsoft Teams) due to constraints on participant availability. Interviews were recorded in these applications and then manually transcribed following the session. All participants received financial reimbursement for their time.

As part of the interviews, the design and feasibility of a future antihypertensive dementia prevention RCT was discussed. Details given to participants for consideration included:

- Participants would be contacted about joining the study via mail, with contact details provided by the electoral roll.
- During the trial, participants will be asked to take 1 antihypertensive (blood-pressure lowering) tablet per day. This tablet can be taken on top of any pre-existing medications, including other antihypertensives, and safety of starting this medication would be assessed with a clinician prior to commencement of participation. Prescriptions would be dispensed and posted to the participants in a six-monthly supply. The proposed medication has been shown to be safe for use for blood pressure, and this trial will investigate any effects on memory and cognitive function. A nominated GP for each participant would be informed of the involvement in the trial for monitoring of any adverse effects and usual care.
- Participants would be asked to complete a short series of online cognitive tests every 6 months over the period of 5 years. If significant issues with cognition are found in these tests, they will be referred for further testing and to specialists. This testing is an online program that requires an email address and password to login, along with access to a computer, phone, or tablet.
- A subset of the study would be asked to record their blood pressure periodically to demonstrate the effectiveness of the drug. This could be done at home or at a doctor's office or pharmacy.

Preliminary findings from these interviews were intended for use in informing the design of a pilot trial. Interview guides also included questions on the topics of seeking medical advice for mild cognitive concerns, experience within the primary care health sector, knowledge of, and attitudes towards, ageing and cognitive impairment, and motivations towards health-seeking behaviours related to cognition.

Table 1
Key themes and operationalised questions for the patient focus groups.

Theme	Question(s)
Attitudes towards dementia and cognitive decline	Are you concerned about cognitive decline/ memory loss in yourself or family members? Do you undertake any activities to keep your brain healthy? Would you say this is prioritised more, less or the same as activities to maintain your physical health? Would you be interested in monitoring your memory as you age? What sort of feedback/information would be helpful for you to receive?
Online cognitive testing	In our study we intend for participants to complete a short series of online cognitive tests over the period of 5 years. Would you have any concerns about this? Would you participate in cognitive testing if it was online? Would you face any barriers in accessing this kind of content? How motivated would you be to participate in cognitive testing every six months for 5 years? (Participant rating: 0 = not motivated; 5 = undecided; 10 = extremely motivated)
Medication use	Are there any barriers to you accessing or taking daily medication? Would you be comfortable committing to taking this medication for the foreseeable future?
Benefits and outcomes.	Although the medication used in this research is low-risk and has been shown to be safe, there is always some side effects possible. Are there any possible side effects that would make you unable or unwilling to participate?

Examples of how the key themes were operationalised as questions can be found below in Table 1.

2.3. Data analysis

Interview transcripts were analysed in NVivo using qualitative thematic framework analysis [15]. Key themes and sentiments were grouped together for each sample, and then exported with the relevant references for further consideration. Themes were ranked by the saturation of references, how many individuals' references matched this theme and/or the prioritisation of the theme by said individuals. Primary data analysis was conducted by two members of the research team to ensure all themes were covered.

2.4. Ethics

This project was approved by The University of Sydney Human Research Ethics Committee (project no. 2022/434).

3. Results

3.1. Participant characteristics

The mean age of the seven participants in the focus groups was 72.86 (SD = 5.34), with a mean length of education of 16.71 years (SD = 2.29). For six of the participants, their socioeconomic status was estimated by referencing their residential postcodes against the 2016 Australian Bureau of Statistics' Index of Relative Socio-economic Advantage and Disadvantage (IRSAD). All six scores were in the 80th percentile or higher, with a mean score of the 95th percentile (SD = 0.84). Residential data for one participant was unavailable. Of the memory clinic patients, all seven participants from the memory clinic had current or previous memory complaints. Cognitive data were available for all participants (MMSE, $M = 29.14$, SD = 1.21). Six participants also had a history of caregiving to someone with dementia. All were aged over 60 years, with English as their primary language. Participants included six females and one male.

All GPs met the inclusion criteria of having practised as a GP in Australia for over five years. All five GP participants were recruited through the Central and Eastern Sydney Public Health Network (CESPHN), which services about 1.5 million people. Referencing the postcodes included in the CESPHN against the 2016 Australian Bureau of Statistics' Index of Relative Socio-economic Advantage and Disadvantage (IRSAD) found a mean score of the 85th percentile (SD = 16.01).

3.2. Patient focus groups

3.2.1. Ageing and dementia prevention

Participants were first asked about their views on what is 'normal' ageing and cognition compared to mild cognitive impairment and dementia. The majority understood the difference between natural changes due to ageing and the development of impairments and diseases. All participants had concerns about memory due to having cognitive complaints themselves and/or a history of caring for a family member with dementia. All participants were taking part in activities that they perceived would maintain brain health, such as not drinking alcohol, reading, memory exercises, and playing social sports. A common perception was that healthcare professionals viewed cognitive and functional decline as inevitable and dismissed mild memory concerns. Participants were positive and highly motivated towards dementia prevention research.

3.2.2. Antihypertensive medications and GP involvement

The proposed RCT to evaluate use of antihypertensive treatment was met with hesitation from most participants. Worries included that there would be severe side-effects that impacted daily functioning (e.g., dizziness, instability) or an increased risk of developing low BP by using the medication when they were not currently being treated for hypertension. Having previous experiences with appointments feeling rushed and/or short, participants felt their GPs would be too time-poor to add BP measurements into their usual appointments, where this would solely be for research purposes and not part of the individual's usual care. Participants, however, were able to identify both practice nurses and pharmacies as alternate avenues for BP measurements during the trial.

An element of the proposed RCT was to involve the participant's GP to monitor and report any side effects of using the antihypertensive medication. Concerns raised regarding the involvement of GPs included the participant potentially lacking a regular GP, along with the increased difficulty in recent years of finding GPs that do not charge private fees more than what is covered by Medicare, the universal healthcare rebate system in place in Australia. Other concerns included how the GP would contact the research team, whether the GP would be informed of the participant's trial involvement, and whether this would add a burden to already time-poor GPs.

Additionally, participants felt that having an accessible method of communicating with the research team, such as a phone number or email address which participants could use as needed, was important for both motivation and safety. Within the context of a remote RCT, participants emphasised the importance of having a social connection with the researchers. A key incentive, beyond the goal of dementia prevention, was that a researcher would be actively monitoring and contacting the participant.

3.2.3. Online cognitive testing

A known concern of the proposed future RCT design was participants' access to computers to complete 6-monthly online assessments and their level of computer literacy. In the discussion, focus group participants expressed that there would large variability in the computer literacy of older adults. Participants suggested family members could facilitate these assessments, by assisting with navigating the steps or providing access to a computer and engaging with their local library or community centre where public computers are available to use and assistance from staff. One participant emphasised language as a potential barrier for migrants, where the official language of a country may be an individual's second language.

The cognitive testing component of the proposed RCT also raised the question of whether participants of the trial would want to receive results in real-time, later, or not at all. All participants expressed wanting to receive the results, should the results be relevant to their daily functioning, but only if there were interventions available to them if cognitive decline was identified. It was suggested that early diagnosis of cognitive impairment would improve their overall quality of life and enable informed decision-making regarding their declining health. Two participants expressed that receiving negative results, indicative of a decline or no improvement, would be disheartening or frightening and affect motivation to continue in the study. Select quotes can be found in Table 2.

3.3. GP interviews

3.3.1. Ageing and dementia prevention

The experience of GPs was that many of their elderly patients expressed concern about their declining health as they get older. These concerns were reduced in patients with multimorbidities that took the focus of their medical care. Many patients were reported to have either family members or friends in their age group who have dementia or cognitive decline, and so expressed concern about their own health. Most identified having patients express concern about their health and seek preventative measures was encouraging.

Similarly, it was common for either a family member or friend to notice the change in the patient's cognitive ability or daily function. GP5

Table 2
Summary of themes and key quotes from patient focus groups.

Theme	Quote(s)
Perceived healthcare professionals as dismissing health issues associated with ageing as inevitable.	[Mild memory concerns were seen as] "good enough."
Concern over side effects of hypertensive use.	"[If the symptoms meant that] you're a danger to yourself. I suppose anything that led to an issue with stability and walking or any of those things that would concern me."
Preference for higher levels of communication with the research team, for both purposes of safety and social connection.	"I think it's important that people have a face, […] maybe periodically." "[Taking the antihypertensives would] be dangerous if you didn't have somebody that you could check [with] and say, […] after taking this medicine, I always feel jittery or I don't sleep well."
Concern that GPs would not have time to support involvement and complete research activities.	"…If I get 2 min from [my GP], I'm really lucky." "[My GP] really is so busy…"
Cognitive testing results were perceived as potentially either reassuring or distressing.	"That's great, you've got a baseline while you're still [unimpaired]. [Later you can] come back and say, I'm beginning to forget a lot of things and having trouble sleeping and they can compare and see if there's been any significant change." "If I know it, then I'll be worried." "I feel hesitant in the sense that if I am not progressing then it will give me very negative feedback. That's why I would like to know, and [also wouldn't] like to know."

reported that patients who are higher-functioning and/or with professional backgrounds notice and worry more when a decline occurs compared to those who are less busy and lower-functioning. This GP also noted that in the Aboriginal and Torres Strait Islander communities in which they worked primarily, there was an increased level of support within the community for those who experience cognitive decline and dementia.

GPs were asked to describe their typical investigative process for patients presenting with mild cognitive complaints. Public health referral pathways are supplied by the local health service and used in most cases. Where the pathway was unclear or insufficient, two GPs were knowledgeable of local memory clinics, and others identified specialists, such as geriatricians, that they would refer to for further investigations. All GPs expressed that they were restricted by time and often wouldn't complete investigations as thoroughly as preferable or would lose contact with patients in the follow-up process.

Preventative care that GPs suggested for elderly patients involved maintaining lifestyle, social activities, and social systems, controlling pre-existing medical conditions, and having regular check-ups with a patient's multidisciplinary team, as relevant. One GP reported a lack of knowledge of evidence-based preventative measures beyond the typical diet and exercise lifestyle advice that are protective against disease. For another GP, knowing that they had a professional interest in lifestyle medicine had attracted some of their older patients.

3.3.2. Antihypertensives and GP involvement

All GP participants expressed positive sentiments towards the proposed trial design. GPs discussed motivations towards participation, and how participation may affect health-seeking behaviours and medication compliance in patients. The primary concern raised was the risk of adverse effects when adding another antihypertensive to patients already on multiple medications, including other antihypertensives, as is common in patients of older age. Most GPs expressed a desire for some reimbursement equivalent to the tasks required of them where these tasks exceeded the limits of usual care. There was an ethical concern regarding billing research-related activities under Medicare or having the patient pay for this in mixed- or private-billing practices.

3.3.3. Online cognitive testing

Like the focus group participants, GPs identified the barrier of computer literacy, along with access to computers for cognitive testing. They were also able to identify community resources such as libraries which could be used to account for these issues. Whether the participants' GPs would be automatically notified of the cognitive testing results was also discussed. GP5 was mindful that some patients may not want to know themselves if there was nothing they could do for medical treatment. Contrastingly, GP1 stated that there are still intervention options, even if not pharmacological, and that referral to support services and informing family members and friends can greatly improve the patient's quality of life. Although all GPs expressed interest in receiving a copy of their patients' results, they acknowledged it should be the patients' choice if the GP was to receive a copy of the results. Select comments can be found in Table 3.

4. Discussion

In discussing the proposed design of a future dementia prevention trial, both GP and memory clinic patient focus group participants were generally positive in their reactions, with the primary concern raised being the safety of the antihypertensive medication and potential interactions with existing medications. Regarding the outcome measures for the proposed RCT, participants expressed interest in the idea of regular cognitive testing, with barriers identified in the use of computers for testing, and the potential for distress for participants if the results show a decline. Previous studies [16] showed that those with subjective cognitive decline may anticipate becoming distressed or feeling low self-worth if they receive concerning results. Despite this hesitation, some participants acknowledged that they would prefer to be aware and unhappy with the results than to be unaware of a decline. Opinions were mixed on the computer literacy of older adults, along with the ability to access a computer if one didn't have one in the home.

The interviews also indicated that memory clinic patients are aware of their health and cognition as they age and that many older adults

Table 3
Summary of themes and key quotes from GP interviews.

Theme	Quote(s)
GPs expressed positive attitudes towards dementia prevention trials, especially where this increases patients' health-seeking behaviour.	"They may be more proactive to come in to maybe get a blood pressure check, maybe have conversations regarding [their health]." [Having patients express concern about their health and seek preventative measures was] "very reassuring," [and that] "people really want to stay well for longer."
GPs were interested in receiving cognitive testing results of their patients and acknowledged that patients may find results frightening.	"There would be some people who would be scared of [the results]. There are people who will take [medication as advised] but they don't really want to know that they're doing worse, if there's nothing [that] we can do about it, [it would] just make them worry." "I think people just want to know what is normal."
GPs felt too time-poor in regular practice to complete comprehensive investigations for patients with cognitive complaints.	"…Oftentimes you can't do everything into the detail that you wanted in that time frame […] that's fine because you make follow up. Only [then] you might lose a patient to follow up and they don't follow through with investigation."
GPs had a strong belief in evidence-based practice.	"I try to avoid recommending things that I'm not sure of the evidence base behind [them]."

discuss these issues with their GPs. Within community interactions, however, limited discussions between peers led to a perceived lack of awareness about the commonality of these issues and concerns.

Constraints on the GPs' time for each patient's visit was identified by both groups as a barrier to quality care, in both the GP not having time for in-depth investigations and the patient wanting to discuss their concerns in detail while not going over the allocated time. This time constraint was also identified as a barrier to the GPs' participation in RCTs if their involvement were to include reporting and regular communications with the researchers. Additionally, the language used when discussing ageing and decline in health was a salient negative experience. This shows a lack of education or experience in treating dementia, in line with the GPs being unaware of evidence-based practices relating to dementia prevention. The patient experience of time-poor GPs was in line with previous findings, however, the use of a multidisciplinary team, a strategy recommended to overcome these barriers [17], was included in all the reported GPs' standard care practices.

Similarly, participants identified lacking a regular GP as a potential barrier to the proposed RCT, due to the necessity for ongoing monitoring by the same GP. Evidence has shown that having a regular GP is also associated with more positive attitudes and fewer barriers to seeking and navigating healthcare [18]. Lower availability of individual GPs and increased costs were cited by participants as reasons people may not have a regular GP. Accessibility concerns around the blood pressure measurement sub-study raised suggestions of solutions such as completing these measurements when visiting the GP for usual care or when visiting the pharmacy, as these machines are available to the public. Further accessibility concerns such as medication packaging, recruitment methods, and frequency of communication were also discussed and taken into consideration for the RCT design. The presence of multiple operational concerns and issues raised have the potential to outweigh the benefits of the decentralised design. This should be taken into consideration for future trial designs.

The theme of health equity raised within the GP interviews aligns with reports of increased rates and burden of dementia within low-resource settings, such as low-income countries [1] and indigenous populations [19]. Future research may investigate ways of addressing this inequity in Australia, in addition to targeted and culturally appropriate approaches to dementia prevention.

The broad topic areas, along with the experienced moderators, ensured the direction of conversation would follow participants' key thoughts and concerns. Key limitations of this study include the sample size and sample recruitment methods. Larger sample sizes would ensure the attitudes are more representative of the general population. An accompanying survey to a larger general population sample would increase the generalisability of these results. Similarly, recruiting through a memory clinic includes a bias that the participants interviewed likely had higher motivation and interest in dementia prevention and health promotion than may be representative of the general population. As noted in the results, there was a large skew towards female participants. Due to the time constraints of this project, we were unable to reach an even distribution for sex and socioeconomic status. The GPs recruited through the GP network newsletter may also represent a subset of GPs with stronger interests in these areas and in research than those who would not have participated. Additionally, as these GPs were all located within metro Sydney, their experience may be skewed towards patients from higher socioeconomic backgrounds. A future study in which the topic of dementia prevention was not disclosed in the recruitment materials would help lessen this bias. Like the patient sample, having a larger sample size with which a survey or less personalised measure was used would also make the results more scalable.

A key difference in methodology between the samples may also introduce some bias. Focus groups can offer a broad range of perspectives in a shorter time, along with identification of points of agreement and disagreement between participants. This methodology can introduce potential for unequal participation of participants, however with the involvement of experienced moderators, this has been limited as much as possible in this study. Whilst focus groups would have been ideal for both samples, time and recruitment constraints led to a shift towards online individual interviews. As the role of the GP is much less involved than that of the participant in the proposed trial, we deemed this acceptable for this preliminary stage of perspective gathering.

4.1. Conclusion

Although limited by recruitment and representativeness, these interviews highlight issues relating to the design of decentralised RCTs, particularly where online components and safety concerns are potential barriers to participation. Some solutions are discussed by participants. These results have been used in 2022 and 2023 in the design of a novel dementia prevention trial. Memory clinic patients showed an expected concern for their cognition and ageing. Clinicians' perspectives that they are poorly equipped to provide quality care due to time restraints, lack of knowledge of appropriate referral pathways and of new evidence-based treatments, reflect existing literature on the current barriers to quality healthcare. In addition to conducting a similar qualitative study on a larger scale with a sample more representative of the general population, future research is recommended to reduce these barriers and enable equitable, accessible healthcare and health research settings.

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CRediT authorship contribution statement

Alexandra Hurden: Data curation, Formal analysis, Investigation, Project administration, Resources, Software, Writing – original draft, Writing – review & editing. **Isabella Cotter:** Conceptualization, Data curation, Formal analysis, Methodology, Software. **Loren Mowszowski:** Investigation, Methodology, Resources, Writing – original draft, Writing – review & editing. **Sharon Naismith:** Conceptualization, Data curation, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision. **Craig S. Anderson:** Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision.

Declaration of competing interest

The authors hold no conflicts of interest and received no external funding for this research.

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