

Protocol for a Mixed-Methods Process Evaluation of BetterBrains: A Person-Centered Online Intervention to Delay Cognitive Decline in Adults at Risk of Dementia

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Abstract.

Background: The BetterBrains Randomized Controlled Trial (RCT) will evaluate the effectiveness of an online, person-centered, risk factor management, coaching intervention in community-dwelling, healthy adults at risk of cognitive decline. Multi-component interventions are challenging to evaluate due to program complexity and personalization to individual needs and contexts. This paper describes a multi-level process evaluation conducted alongside the BetterBrains RCT.

Objective: To understand how and why the BetterBrains intervention was effective or ineffective at reducing cognitive decline in healthy adults whilst considering the context in which it was implemented.

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Methods: 1,510 non cognitively-deteriorated community-dwelling adults aged 40–70 years old at risk of cognitive decline will be recruited and randomly assigned to the intervention or control group. All BetterBrains intervention participants, coaches, and the research team will be included in the evaluation. A mixed-methods design will be used, guided by The Framework for Implementation Fidelity and the program logic model. Data will be sourced from interviews, focus groups, surveys, BetterBrains coach notes, participant weekly check-in surveys, and audio recordings of intervention coaching sessions. Quantitative data will be analyzed via descriptive and inferential statistics and qualitative data will be analyzed using content and thematic analysis.

Results: The process evaluation will provide information about contextual and influencing factors related to the implementation of BetterBrains and the RCT outcomes.

Conclusion: Understanding how BetterBrains was implemented and its associated impacts will inform the translation of the program into community and clinical settings, providing easy access to online, personalized dementia prevention services.

Keywords: Chronic disease prevention, cognitive decline, implementation, process evaluation

Trial registration: ACTRN 12621000458831. Registered on the Australian New Zealand Clinical Trials Registry (<https://www.anzctr.org.au>)

INTRODUCTION

Dementia, of which Alzheimer's disease (AD) is the most common form, is the second leading cause of death in Australia [1]. It is estimated that approximately 40% of all dementia cases can be attributed to potentially modifiable factors [2]. These modifiable risk factors are well established and include hypertension, low physical activity, poor diet quality, anxiety and depressive symptoms, low cognitive engagement, and poor sleep [2–7]. Despite multiple epidemiological and clinical studies implicating these risk factors in late-life cognitive decline, there are several major challenges in reducing disease burden with behavior modification. These include 1) the implementation of innovative solutions that are effective in changing behaviors; 2) doing so as early as possible during the lifespan to favorably modify disease onset and cognitive decline and; 3) designing an appropriately designed cost-effective dementia prevention model to reduce overall healthcare costs and promote quality of life [8].

To date, there are several multi-component behavior modification interventions to delay the onset of cognitive decline that have been trialed, e.g., the Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER) and Maintain Your Brain (MYB) [9, 10], yet few utilize a person-centered, online coaching approach tailored to an individual's specific risk factors [11, 12]. Currently, there no published person-centered dementia-prevention interventions administered online that target personal risk factors of dementia in healthy adults aged 40–70 years with no cognitive deterioration at time of recruitment. The BetterBrains intervention seeks to address this by

developing, testing, and evaluating a person-centered, evidence-based, risk factor management, behavior change intervention to reduce the cognitive decline in adults (40–70 years) with a family history of dementia, and for whom there was an modifiable risk factor for dementia.

Multi-component, person-centered coaching interventions are complex interventions, comprising several interacting components. When the effectiveness of a complex intervention is evaluated, the active components that influence the overall intervention outcomes are generally unknown. A process evaluation is important in understanding the active ingredients of an intervention and the mechanisms of impact. The core of a process evaluation is to assess how a strategy or intervention is implemented, its impact and how, why, and for whom the intervention is most effective [13]. Specifically, a process evaluation considers how complex interventions bring about change and how these outcomes influence intervention fidelity. The process evaluation also seeks to understand potential moderators on the implementation process and also the impact of contextual factors and participant engagement on intervention outcomes. This evaluation will provide new evidence on the effects, causality, and replicability of the BetterBrains intervention for adults aged 40–70 years at risk of cognitive decline.

Process evaluation aims and objectives

We aim to systematically evaluate the implementation fidelity of the BetterBrains intervention and identify barriers and enablers to participation in, and delivery of, the intervention. This paper outlines the process evaluation plan that will be guided by the

Framework of Implementation Fidelity [14] to best understand the primary and secondary outcomes of the BetterBrains randomized controlled trial (RCT) [15].

Specifically, the process evaluation objectives will be to: 1) assess the degree to which BetterBrains was implemented as planned; 2) identify barriers and enablers to implementation by interviewing the BetterBrains coaches, research team and participants; and 3) explore the intervention context, acceptability and usability, from the perspectives of the BetterBrains coaches and participants.

METHODS

BetterBrains RCT design

The BetterBrains RCT protocol has been described previously [15]. Briefly, the trial is a prospective, blinded endpoint 24-month RCT to test the effectiveness of the BetterBrains intervention program. BetterBrains is an online, person-centered, risk factor management, behavior change and coaching intervention—to delay memory decline in community-dwelling healthy adults aged 40–70 years, with a family history of dementia, and who have an identified modifiable risk factor for dementia. The control group receives usual care, defined as monthly BetterBrain Blogs on information relating to non-modifiable elements of cognitive decline such as ‘*Debunking the cognition and aging debate*’ and ‘*Navigating the Healthcare system with early-onset dementia*.’

The BetterBrains intervention

The key inputs, impacts and intended outcomes of the BetterBrains intervention are summarized in Fig. 1. Modifiable risk factors for cognitive decline and their associated evidence-based management strategies have been categorized broadly into four modules (see Fig. 2). The modifiable risk factors targeted are: cardiovascular (excessive alcohol use, smoking, physical inactivity, high cholesterol, obesity, diabetes and hypertension—‘BetterHearts’ module); low social or cognitive engagement (social isolation, lack of cognitive stimulation—‘BetterMinds’ module); poor sleep (daytime sleepiness, disrupted sleep, excessive use of sleep medications—‘BetterSleep’ module); and poor mood (high levels of depression, anxiety and/or stress—‘BetterMood’ module).

Intervention delivery and dosage

The intervention will be delivered by allied health professionals (e.g., psychologists, dietitians) hereby termed “BetterBrains coaches” experienced in community linkage, behavior change strategies, and motivational interviewing. BetterBrains coaches provide coaching and psychoeducation to intervention group participants via online video or telephone coaching sessions. These coaching sessions will incorporate positive health messages and person-centered care to optimize engagement and participation in personalized cognitive decline prevention strategies. According to the intervention protocol, intervention group participants will receive a minimum of six coaching sessions, which is the equivalent of at least 3 h over an active intervention period. These sessions will be completed at weeks 0, 2, 6, 24, 26, and 30 to review progress and goal action plans. Additional coaching sessions will be available to participants upon request at any time across the 12 months. In conjunction with these sessions, all participants (intervention and control) receive monthly blogs (BrainBlogs). Intervention participants also receive information sheets, weekly alerts about their goals and strategies through the website and mobile app, and are able to communicate with the BetterBrains coach as required, using a secure messaging system on the BetterBrains platform (see Fig. 3).

The monthly BrainBlogs will be written by research experts in the BetterBrains team, to provide easy-to-understand non-modifiable information about dementia (Supplementary Material 1). Information sheets relate to a targeted risk factors as discussed in a BetterBrains coaching session and will be sent to intervention participants when deemed appropriate (e.g., needing a practical outline to complete a goal or additional education). Information sheets will be developed by BetterBrains coaches or will use evidence-based resources from credible organizations (e.g., Heart Foundation Australia, Dementia Australia).

BetterBrains RCT data collection

Several outcomes will be reported for the RCT. The full list of RCT outcomes and assessment tools has been detailed previously [15]. The primary outcome of the trial is favorable cognitive performance at 24 months, defined as the absence of a decline in one or more of the following areas using the Cogstate Brief Battery in both the intervention and control group at

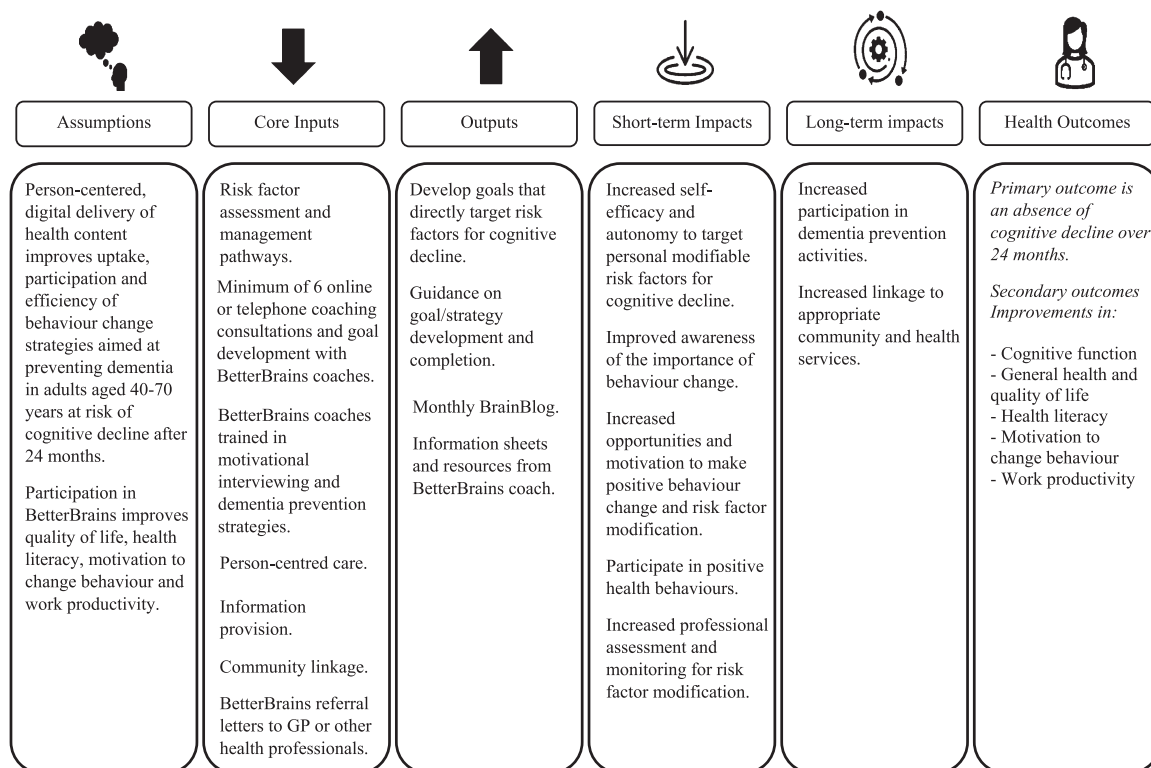


Fig. 1. BetterBrains program logic.

baseline, 12- and 24-months post-intervention completion (Table 1). The battery will test: 1) processing speed (measured using the Cogstate Detection test); 2) learning (measured using the Cogstate One Card Learning test); 3) working memory (measured using the Cogstate One Back test); and 4) subjective cognitive concerns (measured using the Cognitive Function Instrument total score). These tests have been developed for online, unsupervised assessment [16–18] and are sensitive to AD cognitive change [19, 20]. Secondary outcomes will measure: quality of life (RAND-36) [21], motivation to change (Motivation to Change Health Behaviour for Dementia Risk Reduction) [22], and health literacy (Health Literacy Questionnaire) [23]. Universal health care is available in Australia via the Medicare scheme. Medicare Benefits Schedule (MBS, information relating to interactions with health professionals and healthcare networks) and Pharmaceutical Benefits Scheme (PBS, information regarding pharmaceutical prescriptions) data will be collected for all participants who provide consent. This data will determine the number of Medicare-funded healthcare visits (GP

and other health professionals) a participant attended during the BetterBrains program.

The process evaluation plan

A convergent parallel mixed-method study will be conducted simultaneously alongside the RCT [15]. RCT data will be combined with data collected specifically for the process evaluation. The BetterBrains logic model (Fig. 1) outlines each of the components of the intervention to guide the evaluation.

Overview and purpose of the logic model

The logic model details the assumptions, inputs (core intervention components), outputs (products of intervention activities), short- and long-term impacts (specific changes in participant behavior), and health outcomes (fundamental change occurring as a result of the intervention). The core components of the intervention are: 1) risk factor assessment and management pathways; 2) online consultations with





| | Risk Factor | Risk Assessment | Intervention Strategy Options | Example Goal | |
|----------------------------|---|--|---|--|--|
| Poor Cardiovascular Health | Hypertension | BP >140/90 or SR diagnosis | Medication review with GP; reduce dietary salt intake/saturated fat/ increase fibre; increase adherence to MIND diet; increase physical activity; regular heart health check-ups with GP; referral to allied health professional | Attend GP for review | BetterHearts  |
| | Type 2 diabetes | SR current diagnosis | | Medication adherence | |
| | High cholesterol | SR current diagnosis | | Attend dietitian appointment | |
| | Atrial fibrillation | SR current diagnosis | | Attend session with the exercise physiologist | |
| | Obesity | BMI ≥ 25kg/m ² | Increase steps/day; engage with community fitness groups and gyms (e.g., YMCA); reduce sitting time | Work up to 6000 steps/day OR maintain at 10,000 steps/day | |
| | Physical inactivity | Total IPAQ met-mins <150/week | | | |
| | Smoking | SR current smoker | GP smoking cessation plan; nicotine patches, smoking support groups | Reduce/cease smoking | |
| | Excessive alcohol use | SR daily alcohol intake | GP alcohol cessation plan; engage with Alcoholics Anonymous | Reduce daily alcohol consumption | |
| Low Stimulation | Low educational attainment | < 12 years formal education | Increase engagement in enjoyable cognitively stimulating activities or courses e.g., U3A, TAFE, online classes, volunteering, language classes | Complete craft course through U3A each week over the next 6 weeks. | BetterMinds  |
| | Social isolation (small social network) | Relationship total network size < 10 | Increase social engagement with friends/family and community groups (e.g., volunteering, U3A) | Social contact with friends/family > once/week | |
| | Monolingualism | English as only spoken language | Learn a new language (e.g., online courses, Duolingo, in-person courses) | Attend language class once a week/fortnight for 12-months | |
| Poor Mood | Depressive/ anxiety symptoms | DASS depression > 7; DASS anxiety > 6; DASS stress > 10; HADS anxiety ≥ 8; HADS depression ≥ 8 CES-D ≥ 16 | Referral to, and engagement with, specialist mental health services (e.g., mental health care plan) through GP; cognitive behavioural therapy with psychologist; yoga; exercise | Complete 15 min/day of yoga over the next month. | BetterMood  |
| | High levels of stress | | | | |
| Poor Sleep | Daytime sleepiness | ESS ≥ 11 and/or ISI ≥ 8, reports disruption to work/social/family life & >60 min difference between ASPQ questions 7 and 8 | Improve sleep hygiene; referral to GP to determine presence of sleep disorders; referral from GP to sleep study or specialist; CPAP therapy (for sleep apnoea); mindfulness for sleep (e.g., body scan) Gradual withdrawal or rationalisation of sleep medications by GP | Complete CPAP therapy each night as directed by specialist over the next 3 months. | Better Sleep  |
| | Sleep disruption/Insomnia | | | | |
| | Excessive use of sleep medications | Requires sleep medication 2 or more times p/week | | | |
| | Sleep apnoea | Positive score on 2/3 BSA categories | | | |

Fig. 2. BetterBrains intervention.

BetterBrains coaches and goal setting; 3) person-centered care; 4) information provision; and 5) community linkage.

Theoretical framework

To determine which BetterBrains components were implemented as planned, BetterBrains will be evaluated using a modified version of The Framework for Implementation Fidelity [14]. This is because complex person-centered coaching interventions that target collective behaviors are known to require adaptations, both pre-defined and pragmatic, by intervention developers and implementers to meet contextual needs [24, 25]. Adaptations may

be deliberate or accidental and include additional components, deletions or substantial modifications of an intervention component as well as minor or major modifications to an existing intervention component (e.g., the intensity of an intervention component, cultural modifications). Adaptations may lead to either intervention improvement or threaten the underlying theory of change of the intervention (how inputs and outputs are anticipated to impact outcomes), impacting overall intervention effectiveness [26]. Here we investigate how well the fidelity-adaptation balance is reached during the implementation of BetterBrains by systematically analyzing subcategories of the BetterBrains components that may have been adapted (Table 2).

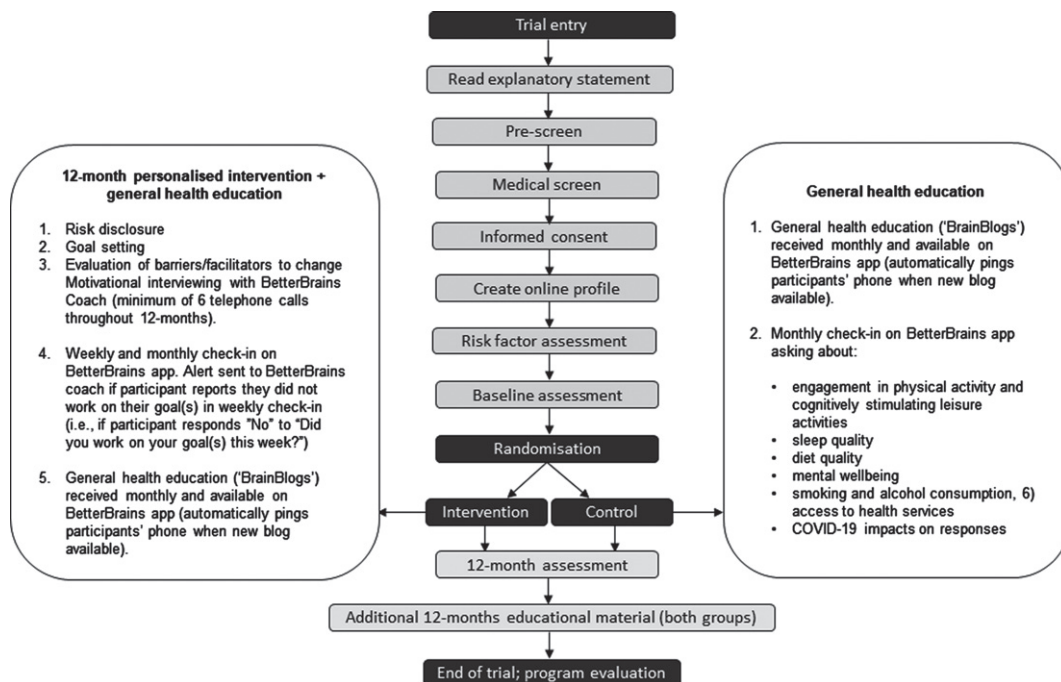


Fig. 3. BetterBrains trial figure.

Table 1
 Schema of the BetterBrains RCT data collection mapped to the evaluation objectives

| Data source | Objectives | | | | |
|--|--|---|---|--|---|
| | Assess the degree to which BetterBrains was implemented as planned (fidelity). | Explore the context, impact, and consequences of conducting the intervention. | Explore intervention acceptability and usability. | Identify barriers and enablers to intervention implementation. | Explore how the intervention may be improved for future implementation and use. |
| Participant experience survey | | ✓ | ✓ | | ✓ |
| Electronic database exports (BetterBrains coaches) | ✓ | ✓ | | | |
| Electronic database exports (research team) | ✓ | ✓ | | | |
| Rochester Participatory Decision-Making Scale | ✓ | | | | |
| Motivational interviewing coding | ✓ | | | | |
| BetterBrains coach competencies post-training | ✓ | | | | |
| BetterBrains coach observation competencies | ✓ | | | | |
| Participant focus groups | ✓ | ✓ | ✓ | ✓ | ✓ |
| Semi-structured interviews (BetterBrains coaches) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Semi-structured interviews (research team) | ✓ | ✓ | ✓ | ✓ | ✓ |

Table 2
Specific descriptors of adaptation for the BetterBrains intervention

| Questions to identify adaptations to BetterBrains | |
|---|--|
| What | What content delivered in the intervention changed in any way? If so, how? Was any subject or domain suppressed? Which one? Why? Was any topic added? Which was it? Why? |
| How | Was any core component of the intervention adapted (e.g., person-centered care, risk factor assessment and management, community linkage, online coaching, and information provision). If so, which one? How? Why? |
| How frequently | Was any form of the BetterBrains intervention adapted? (e.g., quantity of participants, length of online sessions, information provided to participants). If so, why? |
| By whom | Was any BetterBrains coach not trained? Why? Were any core components of the project adapted whilst training the BetterBrains coaches? Why? Were the core components of BetterBrains (MI, online sessions, community linkage, risk factor management pathways, information provision) replaced by others? Why? |
| Specifications relating to the context | Was there any change in the number of minimal telehealth sessions completed? Why? Were there any changes to the method of communication between the BetterBrains coach and participant? Why? Were there any changes in content and manner in which information was provided to participants? Why? How? |

Table 3
Specific descriptors of fidelity for the BetterBrains intervention

| Specific descriptors of fidelity for capacity-building in BetterBrains | |
|--|--|
| What | Development of knowledge and abilities relating to: 1) risk factors promote cognitive decline; activities to reduce the risk of cognitive decline; 2) participation in behavior change; 3) community linkage; 4) action plans and communication strategies; 5) participatory evaluation |
| How | Online sessions that incorporate MI to develop goals and strategies targeting personal modifiable risk factors for cognitive decline according to risk factor management pathways. |
| How frequently | 1 × 45 min initial online session and at least 5 × 30 min online sessions with a BetterBrains coach. |
| To whom | Healthy adults (40–70 years) screened to be at risk of cognitive decline. |
| By whom | Facilitators trained on the principles of MI and an allied health discipline (e.g., psychology, dietetics) and an understanding of behavior change for cognitive decline. |
| Specifications relating to the context | BetterBrains coaches are guided based on a risk factor management pathway, as separated according to module (BetterHeart, BetterMind, BetterMood, and BetterSleep) and the corresponding risk factors for each. BetterBrains coaches are also guided by participants' physical, social, and economic capabilities, including eligibility for Medicare or private health care rebates to access local medical and allied health professionals as required to optimize community engagement. |

Table 3 outlines the descriptors of fidelity for the BetterBrains intervention. Table 4 summarizes the data sources that will be used to assess intervention fidelity. Potential moderators and adaptations to implementing the BetterBrains intervention are also important to consider as part of this evaluation and are further described in Table 5.

Participants

BetterBrains intervention group participants, BetterBrains coaches, and the research team will be included in the process evaluation.

BetterBrains intervention group participants

The RCT will recruit 1,510 community-dwelling healthy adults aged 40–70 years who are living in Australia with a first- or second-degree family history of dementia. Participants must also be planning to live in Australia for the 24 months following recruitment, be fluent in English, have access and be able to use a computer, be willing to commit to a series of online tests over 24 months, have no signs of current cognitive impairment or brain injury, report no alcohol or substance abuse within the last 24 months and have no history of myocardial infarction or unstable severe cardiovascular disease in the last

Table 4
Mapping of the survey, focus group, and interview questions of the BetterBrains intervention to the Framework for Program Fidelity

| | Data source | | | | | | | Timing | | | | |
|---|-------------|--------------|------|-----------|--------------|-------------|------------|----------------------|--|------------------|-----------------------------|----------------------------|
| | Survey | Data exports | RPAD | MI coding | Competencies | Focus group | Interviews | External researchers | Themes | Pre-intervention | During intervention (0–12M) | Post-intervention (12 + M) |
| <i>Evaluation of adherence</i> | | | | | | | | | | | | |
| Content | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | Extent intervention active ingredients are implemented as planned.* | ✓ | ✓ | ✓ |
| Frequency/duration | | ✓ | ✓ | ✓ | | | | | Frequency of implemented intervention active ingredients | | ✓ | ✓ |
| Coverage/Reach | ✓ | ✓ | | | | ✓ | ✓ | | Characteristics of intervention completers versus non-completers. | | ✓ | ✓ |
| <i>Potential moderating factors</i> | | | | | | | | | | | | |
| Participant responsiveness (dose received) | | ✓ | | | | ✓ | | | Participant engagement with intervention website, app, and completion of set goals. | | ✓ | ✓ |
| | ✓ | | | | | ✓ | ✓ | | Participant and BetterBrains coach satisfaction with intervention implementation and outcomes. | | | ✓ |
| Intervention complexity | | | | | | | | ✓ | Complexity of BetterBrains | | | ✓ |
| Comprehensiveness of intervention description | | | | | | | | ✓ | Specificity of BetterBrains intervention description. | | | ✓ |
| Strategies to facilitate implementation | | | ✓ | ✓ | ✓ | ✓ | ✓ | | Strategies used to support intervention implementation. | | ✓ | ✓ |
| | | | | | | ✓ | ✓ | | Perspectives of BetterBrains coaches and research team | | | ✓ |
| Quality of delivery | ✓ | ✓ | ✓ | ✓ | ✓ | | | | Intervention delivery quality | | ✓ | ✓ |
| Recruitment | | | | | | ✓ | ✓ | | Provided recruitment information. | | | ✓ |
| | | | | | | ✓ | ✓ | | Barriers to continued intervention engagement. | | | ✓ |
| Context | ✓ | ✓ | | | | ✓ | ✓ | | Environmental factors that affected intervention implementation. | | ✓ | ✓ |
| | | ✓ | | | | ✓ | ✓ | | Response of external community professionals | | ✓ | ✓ |

*Active ingredients relate to person-centered care, online coaching, information provision, risk factor management and community linkage. M, months; MI, motivational interviewing; RPAD, Rochester Participatory Decision-Making Scale.

Table 5
Moderators and corresponding definitions within the BetterBrains context

| Moderator | Definition |
|--|---|
| Participant responsiveness | How the BetterBrains participant engages with the intervention. This is measured by analyzing how participants use the app and website to engage with the intervention content and to interact with their BetterBrains coach. |
| Complexity | The complexity of the BetterBrains intervention – four modules, person-centered goal setting and motivational interviewing – increases the challenges of implementing the intervention with fidelity. Understanding of how the intervention works, its parts and processes all interact with the people who are responsible for implementation (BetterBrains coaches). BetterBrains complexity will be evaluated using the Intervention Complexity Scoring Tool by Ravishankar et al. [37]. |
| Comprehensiveness of policy description | This relates to the detail provided in describing the BetterBrains intervention for the BetterBrains coaches to properly complete their roles and instruct participants. This will be an important component to allow for an optimal measure of fidelity (Table 3). |
| Facilitation strategies for implementation | These are strategies employed to promote the accurate delivery of the intervention including the training, monitoring, manuals, feedback, and supervision of the BetterBrains coaches. These strategies support the BetterBrains coaches to deliver the intervention with fidelity. All strategies will be audited for their clarity, utility and implementability. The training documents including manuals, slides and handouts will be examined in connection to three factors: 1) Knowledge of modifiable risk factors for dementia; 2) Discussion and development of community linkages to address identified modifiable risk factors; and 3) Motivational interviewing. Monitoring and feedback processes will also be examined to evaluate whether they are meeting the needs of the BetterBrains Coaches. |
| Quality of delivery | Relates to how well the BetterBrains Coaches can engage with the participant. The person's motivation to change may hinder interactions between the BetterBrains Coach and participant. This necessitates high-quality engagement is needed. Further, different approaches may be needed at different phases of the intervention and this will need to be captured. A subjective view of quality engagement will be obtained via participant surveys and the online discussion forum. Objective measures of quality will also be obtained from auditing recorded telephone calls to assess the degree of motivational interviewing using the Rochester Participatory Decision-Making Scale. This tool aligns with the goals of the BetterBrains intervention as a person-centered intervention and includes items such as the clinician clearly explaining relevant issues, discussing uncertainties, clarifying agreement examining barriers and asking open-ended questions. This tool was used effectively in the process evaluation for RESPOND—a patient-centered intervention that aimed to improve older person's participation in falls prevention strategies through the telephone delivery of patient-centered education and behavior change strategies [38]. |
| Recruitment | This considers the processes and procedures used to attract and enroll adults in the BetterBrains intervention. Recruitment methods will create expectations about the intervention, impacting intervention coverage and the ability to respond to participant needs. The recruitment process will also implicate attrition, meaning data about inquiries and subsequent enrolment will be linked to intervention retention and compliance [39]. The issue for the BetterBrains participants is that attrition may be related to more unusual factors like modifiable risk factor screening and access to services. We will need to understand the factors related to this at the participant level to determine if recruitment strategies and the consent process may impact attrition. |
| Context | Considers the larger political, social, and economical environment in which BetterBrains will take place and impact intervention implementation, including COVID-19. BetterBrains will be implemented Australia-wide, across multiple contexts. Questionnaires and interviews will be used to better understand these contexts of intervention implementation. |

12 months. Participants will be randomized 1 : 1 to the intervention or control arm of the RCT according to these stratified factors: (a) age (<55 years ver-

sus ≥ 55 years) and (b) rurality (i.e., urban versus rural/regional based on classifications from the Australian Bureau of Statistics) [27]. Participants will

be notified of group allocation automatically via the BetterBrains platform. All participants in the intervention arm of the RCT (planned randomization and recruitment of 755) will be invited to contribute to the process evaluation. Invitations will be sent by email to each participant within 1 month of completing the 12-month program.

BetterBrains coaches

Five BetterBrains coaches will be allied health clinicians from a variety of disciplines (e.g., dietitians, psychologists) to promote a multidisciplinary team skill set. A senior BetterBrains coach will lead the team to develop, train, and monitor BetterBrains coach performance and promote optimal intervention fidelity [28]. BetterBrains coaches are responsible for implementing the 12-month BetterBrains intervention and communicating with participants. BetterBrains coaches will complete training in person-centered care, motivational interviewing, and evidence-based behavior change to reduce the risk of cognitive decline. Depending on the primary discipline of the BetterBrains coach, they will also have additional expertise relating to one or more of the four BetterBrains modules to complement intervention implementation. All BetterBrains coaches will contribute to the process evaluation through interviews relating to the intervention as a whole (i.e., Engaging participants through coaching sessions and messaging, website use, BetterBrains coach training, intervention implementation efficiency, BetterBrains coach competency checks). All coaches will be required to complete the evaluation and will be emailed to organize a time to complete the evaluation activities upon the completion of the BetterBrains trial and are no longer working with participants.

Research team

Distinct from the BetterBrains coaches, the research team oversees and manages the logistical and operational aspects of the BetterBrains intervention that are not related to intervention delivery. The team may communicate with participants related to matters such as intervention disengagement, technical difficulties, personal queries, adverse events, or data collection. All research team members will be invited to participate in the process evaluation through interviews to better understand experiences relating to the intervention, website use, participant enrolment, disengagement, and follow-up.

Data collection and analysis

Qualitative and quantitative evaluation data will be collected during and after intervention delivery through online and in-person methods. Data will be collected by BetterBrains coaches and evaluation researchers external to the core BetterBrains research team to best prevent bias. Analysis and reporting will follow the Good Reporting of A Mixed Methods Study framework [29]. Data triangulation will provide a deeper understanding and verify quantitative data using qualitative outcomes [30].

Quantitative data

Effectiveness outcomes: Cognitive performance using the Cogstate Brief Battery, as collected during the BetterBrains RCT [15].

Participant experience survey: This 16-item survey was developed by the research team in consultation with the intervention developers and was modeled based on the RESPOND evaluation questionnaire [28]. Items relate to the reason for intervention participation, information provision, met health needs, community linkage outcomes and preferred intervention structure (Supplementary Material 2). All intervention participants will have access to the survey via the BetterBrains online platform at the 12-month follow-up assessment. Using the RESPOND evaluation, we anticipate a 65% response rate.

Electronic participant and BetterBrains coach records

BetterBrains coaches: Data will relate to BetterBrains coach caseloads, participant correspondence, data collected during the 1:1 coaching sessions, referral letters, and intervention goals and strategies. Electronic data collected and entered onto the BetterBrains database by the BetterBrains coaches during and outside of coaching sessions will be exported weekly in a.csv format (Table 6).

Research team: Electronic data entered by the research team and participants will be exported fortnightly in.csv format from the BetterBrains database. Data will relate to questionnaire data, check-in questions, participant correspondence and more (Table 6).

Rochester Participatory Decision-Making Scale (RPAD): This scale will measure the extent of person-centered care as applied by the BetterBrains coaches [31]. The scale assesses 9 aspects of participatory

Table 6
Data exported throughout the BetterBrains intervention completed by the BetterBrains coaches and research team

| | BetterBrains coaches | Research team |
|--|----------------------|---------------|
| Coach caseload | ✓ | |
| Participant correspondence | ✓ | |
| Coaching session data collection | ✓ | |
| Referral letters | ✓ | |
| Intervention goals and strategies | ✓ | |
| Baseline, 12 and 24-month questionnaires | | ✓ |
| Blog interaction and feedback | | ✓ |
| Monthly and weekly participant check-ins | | ✓ |
| Participant demographic details | | ✓ |
| Participant correspondence | | ✓ |
| Monthly and weekly check-in questions | | ✓ |
| Medicare linkage | | ✓ |
| Mood risk letters | | ✓ |
| Participant disengagement | | ✓ |
| Cognitive tests | | ✓ |

decision making, with a score of '0' indicating no evidence of the item taking place, a score of '0.5' indicating some evidence and a score of '1' showing strong evidence for all items. For item 6, "Clinician's medical language matches participant's level of understanding." This item scores '-0.5' for clear mismatch, '0.5' for most aligned language and '1.0' for clear language match. The maximum RPAD score is 9. The RPAD will be measured by a researcher external to the BetterBrains team.

Motivational interview coding: The extent to which motivational interviewing was applied by the BetterBrains coach during an online coaching session will be evaluated using OARS coding: Open-ended questions; Affirmations (gestures and statements that acknowledge participant behaviors and strengths that lead to positive behavior change); Reflections (listening to the participant and then rephrasing what the participant has stated); and Summaries (synopsis of the conversation). This will be assessed by labeling a coaching session with '0' or '1' as to whether the BetterBrains coach does or does not complete these components during an online session. Scoring will be completed by external staff to the BetterBrains investigator, clinician, and research team. Scoring guidelines with provided examples have been developed to guide and assist coding.

BetterBrains coach post-training competencies: Post-training competency will be assessed by the senior BetterBrains coach using a 32-item checklist (online or in-person) within 1 week of completing the BetterBrains coaching training. This is to ensure BetterBrains coaches are aware of the core components of the intervention, have completed orientation tasks (e.g., email setup) and have a grounded understanding

of motivational interviewing (Supplementary Material 3). All coaches will complete these competencies. Each question on the checklist will be scored (low = 1, adequate = 2, and high = 3), with the highest possible score equating to 99. A score ≥ 65 will be needed to pass this competency. Failing to pass will result in the BetterBrains coach receiving additional training and re-administration of the checklist within 1 week. The BetterBrains coach must pass this competency before working with participants. Competencies will be audited every 2 months to help ensure BetterBrains coaches are implementing the program as planned and using motivational interviewing principles with participants.

BetterBrains coach observation competencies: To ensure BetterBrains coaches are implementing the BetterBrains intervention as per protocol, all coaches will be monitored by the senior BetterBrains coach every 2 months while working with participants. Observations may take place in-person or online (live or recorded). Competencies will be measured using a 46-item scored checklist (not applicable = 0, low = 1, adequate = 2, high = 3), with a total score of 138 (Supplementary Material 4). A score ≥ 130 will be needed to pass this competency. Feedback will always be provided by the senior BetterBrains coach to promote coach development and optimal intervention fidelity. BetterBrains coaches will be re-observed and re-scored within 1 week upon failing to meet minimum competency scores.

Qualitative data

Participant focus groups: Feedback from intervention group participants will be obtained through

a 90-min focus group upon the completion of the active 12-month intervention, and analyzed qualitatively [32, 33]. Participants will be invited by phone and/or email to participate. Those who consent to participate will be asked to attend an online focus group (video-recorded). Participants will be grouped according to availability and time of intervention completion. All focus groups will be led by DA, a public health specialist with expertise in qualitative research and intervention evaluation using a discussion guide, developed in consultation with the BetterBrains team. Participants will be encouraged to share their experiences and provide feedback on the BetterBrains intervention content, delivery methods, delivery mode, dose and perceived barriers and enablers to participating in the intervention (Supplementary Material 5). We anticipate conducting 4-5 focus groups with 8-10 participants (total 50 participants) to reach data saturation [34]. Quota sampling will be used to ensure representation across gender, age, and risk profiles.

BetterBrains coach semi-structured interviews: Once all intervention group participants have completed their 12-month active intervention period, all BetterBrains coaches will be invited to share their experiences and provide feedback on the intervention individually in a 45-min online or in-person semi-structured interview. Interviews will explore the design and implementation of the BetterBrains intervention, perceived intervention benefits, how future implementation may be improved and who the intervention best targets (Supplementary Material 6). All semi-structured interviews and corresponding field notes will be conducted by a trained qualitative researcher external to the BetterBrains team.

BetterBrains research team semi-structured interviews: Upon completion of the 12-month active intervention period for all participants, all research team members will be invited to participate in a 45-min semi-structured interview to better understand the experience of designing the BetterBrains website and mobile app, completion of all administrative and operational tasks for the intervention group (including any perceived challenges) and how the intervention may be better implemented in the future (Supplementary Material 7). The interviews will be conducted by a qualitative researcher external to the BetterBrains team.

RESULTS

Below we outline the proposed data analysis which will inform how the results will be presented for this evaluation.

Data analysis

Quantitative data

The process evaluation variables (i.e., intervention description, reach, content, frequency and duration, complexity and quality of delivery; participant responsiveness, use of implementation strategies and the context in which BetterBrains was implemented) will be retrieved from the BetterBrains electronic database, entered into a.csv file and then analyzed using appropriate statistical software. Descriptive statistics from data exports will be analyzed using frequency distributions, proportions, and variability over time. Linear and logistic regression and mediation analysis will be used to explore relationships between the BetterBrains evaluation outcomes and participant characteristics. BetterBrains coach competencies will be measured using the competency checklist overall score to assess the extent of competency compliance. Intervention reach will be assessed by comparing the characteristics and behaviors of intervention completers (completed 6 coaching sessions at specified time points according to protocol) versus non-completers [15] using appropriate parametric and non-parametric tests. Characteristics may include the number of people who engaged, website and app engagement rates, modifiable risk factors for cognitive decline, demographic and sociodemographic data. The effectiveness evaluation outcomes will be reported separately, as recommended by the Medical Research Council [13]. Process evaluation outcomes will then be related to primary and secondary trial outcomes (statistical analysis detailed in the BetterBrains RCT protocol [15], including overall change in cognitive decline, to better understand intervention fidelity.

Qualitative data

All qualitative data will be managed using NVivo (QSR International Pty V.12.2018). Focus group and semi-structured interviews will be transcribed verbatim by an external transcribing service. Transcripts will then be analyzed using a deductive approach to identify evaluation measures following the Conceptual Framework for Implementation Fidelity [14].

Inductive coding will be used to identify data-driven codes. These codes will be iteratively revised and subsequently clustered into sub-themes and themes in the approach outlined by Nowell et al. [35].

Qualitative data from participant forms collected during the coaching session will be analyzed through content analysis [36] by counting word occurrences related to goal and strategy development to summarize the main objectives of participant behavior change and goal completion. Coding and theme development will be performed by qualitative researchers external to the BetterBrains team.

Triangulation of results

Data triangulation for methods (quantitative and qualitative) and participants (BetterBrains participants, coaches, and research team) will be conducted through a process of comparing results. The extent to which, and in what ways, results converge, diverge, relate to each other and/or produce a more complete understanding will be summarized and presented. For example, quantitative data from the BetterBrains participant experience survey (quantitative) will be compared to the BetterBrains participant focus group (qualitative) to determine if and how the results align. BetterBrains participant focus group themes will also be compared to the BetterBrains coach interview themes (participant triangulation).

Ethical approval

Data collection to enable process evaluation was included in the ethics application for the RCT. Ethics approval was granted by Monash University Human Research Ethics Committee, Project ID: 25221.

DISCUSSION

This protocol describes the design and methods for the planned mixed-methods process evaluation for an online, person-centered, risk factor management pathway behavior change intervention called BetterBrains. Results from this process evaluation will help explain how BetterBrains was implemented, and whether coaches and participants completed the intervention. We will also report the overall context in which the intervention was implemented. These findings will help to identify the demographic, moderating, and intervention-specific factors that may influence primary and secondary outcomes in the BetterBrains RCT, as well as how findings from the trial

may be best adapted for future capacity-building and better intervention effectiveness aimed at reducing the cognitive decline associated with modifiable risk factors.

TRIAL STATUS

The trial and intervention started in July 2021 and plans to continue to June 2023.

Ethics approval and consent to participate: Monash University Human Research Ethics Committee, Reference: Project ID: 25221

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SUPPLEMENTARY MATERIAL

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