

STUDY PROTOCOL

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AUDACE: a study protocol for the realist mixed methods evaluation of the BCM2.0 occupational therapy and assistive device programme for older people aging in place

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Abstract

Background We present the protocol for the AUDACE realist mixed methods evaluation of the BCM2.0 occupational therapy and assistive device programme. The BCM2.0 ("Bien chez moi 2.0") programme provides occupational therapy sessions and assistive devices to support older people who want to age in place. We designed the AUDACE evaluation to improve understanding of the programme and its effectiveness, and to promote a favourable context for the professional empowerment of occupational therapists as primary care providers.

Methods We involved home care occupational therapists at every stage of the protocol design to ensure that the tools, training, and organisational structures put in place for the evaluation could also form the basis of their routine practice, harmonising their practices, ethos and processes. We designed a realist mixed methods evaluation to answer the following question: "How, for whom and why do assistive devices, integrated with occupational therapy support, enable older people to remain at home, and under what conditions?" Interrelated components addressed different research sub-questions: (1a) To describe the evaluation population, interventions, and contexts: a descriptive quantitative study using baseline data from all BCM2.0 beneficiaries. (1b) To describe the frailty process in older people receiving the programme: a qualitative study using semi-structured individual interviews with a biographical dimension. (2) To explore the enrolment process: focus groups with occupational therapists, following a realist approach. (3) To assess effectiveness: a prospective cohort study with up to 12 months follow-up of all BCM2.0 beneficiaries. (4) To identify barriers and facilitators to implementation: multiple nested case study in five areas, using a realist approach. (5) To build a learning community to clarify ethical considerations: communities of practice meetings.

Discussion The inclusion of occupational therapists in the design and implementation process ensured that the evaluation met their needs. This led to the development of a participatory action research protocol that improved the quality of the evaluation and supported the professional development of occupational therapists.

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Background: Occupational therapists and the use of assistive devices to support older people aging in place

Respecting older people's preferences to live in an environment that supports their autonomy is fundamental to healthy ageing [1]. Most older people prefer to age in place in their own homes rather than move into institutional care such as nursing homes [2]. This can be challenging for people at risk of frailty and frail people, as they are most at risk of losing their autonomy [3]. Healthcare systems need to meet the needs and preferences of older people in their chosen place of residence and ensure that they can live there with dignity. Among the innovative ways to support older people to live longer at home, activities and technologies that enable them to remain independent are of growing interest [4, 5].

However, these technological approaches raise concerns about whether they are consistent with older people's preference to live at home [6] and whether they achieve their stated goals [7]. To ensure that technology benefits individuals and society, it should simplify and support people's lives, foster collaboration between all stakeholders through an integrated ecosystem, and provide older people with clear, trustworthy, transparent and easy-to-understand information about innovations in care and health [8]. Support from informal carers and health professionals is needed to ensure that assistive devices meet these conditions, enable ageing in place and improve outcomes [9–14].

Occupational therapists can help to meet the growing need for primary care providers who are able to support older people who use assistive devices at home: the occupational therapy approach to care emphasises the development, recovery, or maintenance of activities that are meaningful to the person [15]. It is highly compatible with a Goal-Oriented Care (GOC) approach that supports and empowers older people. This approach focuses on the person's goals as the basis for care decisions, in consultation with all stakeholders. It starts with eliciting the person's goals, which enables care goals to be set and their achievement to be evaluated. Such an approach would ensure that the person's goals are elicited and remain at the centre of the care plan, in a process underpinned by the person's context and values [16]. In addition, their position as primary care providers puts them in a unique position to identify and manage frailty,

as they can intervene early in a person's frailty trajectory [17].

The non-profit organisation “Ergo 2.0”, led by occupational therapists, launched in 2024 the “Bien chez moi 2.0” (BCM2.0) programme to provide monthly occupational therapy sessions and the installation of assistive devices to support older people who want to age in the place of their choice. Ergo2.0 approached the authors (the “research team”) to evaluate the BCM2.0 programme: this was the start of the AUDACE evaluation (AUtonomie à Domicile grâce à un Appareil Connecté et à un suivi Ergo). The next section provides a detailed introduction to the Ergo2.0 programme and explains why a co-constructed evaluation is necessary. We then describe our collaborative approach with occupational therapists to co-create the AUDACE evaluation of the BCM2.0 programme. Next, we describe the protocol we designed for our realist mixed methods evaluation. Finally, we discuss the strengths and limitations of our approach.

The BCM2.0 programme: why a co-constructed evaluation is necessary

The BCM2.0 programme was launched by the occupational therapist-led non-profit Ergo2.0 in response to a call from the Walloon regional health agency (AViQ) for programmes to prevent or delay the entry of older people into nursing homes through the use of assistive devices [18]. This programme provides monthly occupational therapy sessions and the installation of assistive devices to support older people who want to age in the place of their choice. The initial assessment sessions (two and a half hours in total) are followed by one hour of follow-up every month for as long as necessary. In addition to the sessions, assistive devices are installed according to the needs of the person and informal caregivers. The programme proposes wearable pendants and wristbands to detect falls (accelerometers) and wandering (GPS tracking), and an AI-driven, self-learning lamp that can detect falls and provide assistance (local video analysis and voice recognition). All assistive devices allow the person to contact a 24/7 emergency helpline (button press and voice recognition). Occupational therapists can access data from assistive devices and helpline reports, which they can then use for clinical purposes. An overview of the programme is provided in Fig. 1a. The programme is open to people aged 65 and over living at home in the Walloon and Brussels regions who are considered frail or

a) Occupational therapist support and assistive device

b) Sharing data with primary care providers

c) Participation in evaluation

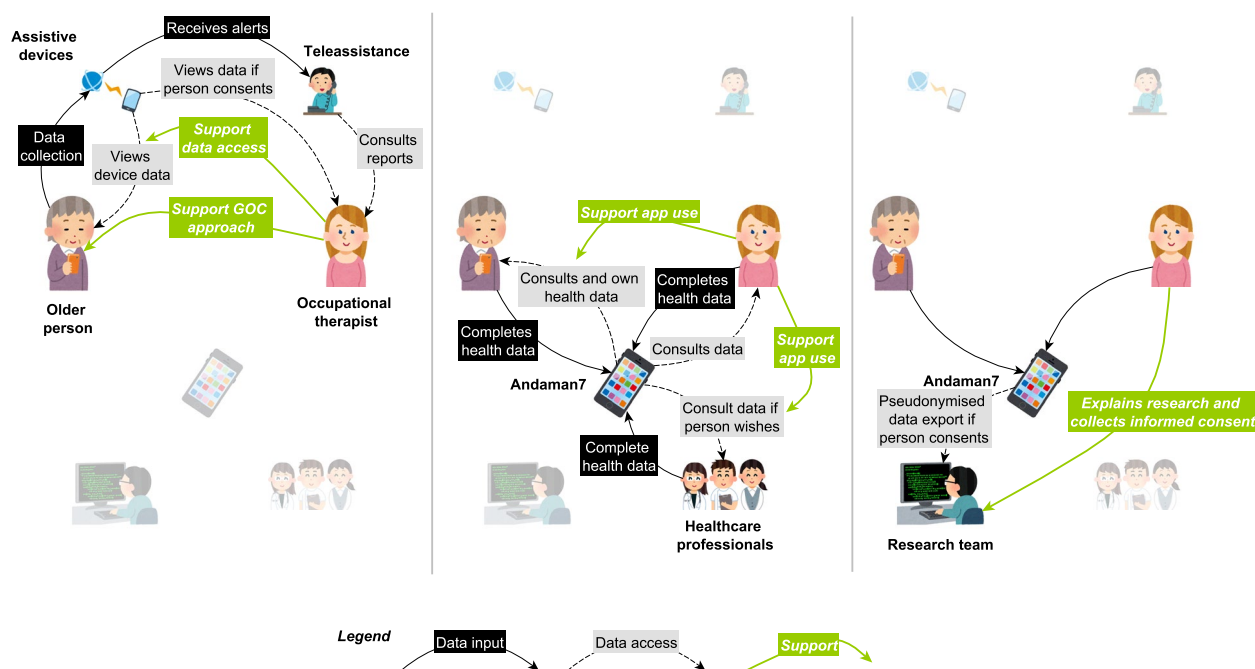


Fig. 1 Overview of the Ergo2.0 programme and how the AUDACE evaluation is integrated into it

at risk of frailty. The risk of frailty is defined as having at least one loss of intrinsic capacity measured by a trained occupational therapist using the ICOPE screening tool [19]. Up to 3,900 persons are also eligible for full reimbursement (sessions and assistive device) by the Walloon region of Belgium under the AViQ project, if they already receive some specific autonomy-related benefits. People benefiting from other programmes of this project are excluded from the BCM2.0 programme.

Scientific evaluation is essential given the current scarcity of evidence on the effectiveness of such programmes. Further research is needed to understand the impact of these programmes on occupational performance [20], quality of life [11, 14, 20], and user experience [21], with a focus on specific populations such as frail older people in primary care [5, 17, 22]. In addition, research has shown that assistive devices for older people living alone can help improve their physical and mental well-being [14], and technological innovations for dementia care, fall detection, and assisted living can help older people age in place [21]. However, the evidence for the beneficial effects of GPS tracking alarms on the health and well-being of older adults and on social care provision remains weak [23], and the use of alarm pendants may lead to unanticipated and adverse outcomes [24]. Research on technology-based programmes should address complexity by focusing on the people involved, including professional identities, and by putting in place mechanisms to

ensure that lessons learned during implementation can be used to adapt subsequent steps [25].

The actual implementation of this programme faces a significant hurdle: in Belgium only 9.8% of occupational therapists working in the healthcare sector work in home care [26]: There is therefore an opportunity to develop this aspect of the profession [27]. This shift to home care may be easier for the newer generations of occupational therapists: they have been trained in a biopsychosocial paradigm, which is particularly suited to the challenges of home care, whereas previous generations have been trained in a more biomedical paradigm. They need to construct their professional skills and identity as primary care providers in order to find their place in the Belgian primary care landscape, especially as occupational therapy sessions are hardly reimbursed by the Belgian health insurance system.

We co-constructed this evaluation with occupational therapists to achieve several goals: (a) to improve in-depth understanding of the programme and its effectiveness, while ensuring that the outcomes and processes examined would be meaningful to older people, their informal caregivers, home care occupational therapists, and funding healthcare authorities; (b) to support Ergo2.0 in promoting a favourable context for the professional empowerment of occupational therapists as primary care providers that respects the GOC principles. The next section describes our collaborative approach

with occupational therapists to cocreate the AUDACE evaluation of the BCM2.0 programme.

Approach: Cocreating a favourable context for the empowerment of home care occupational therapists through evaluation

The research team involved both aspiring and established home care occupational therapists in every step of the design of the AUDACE protocol to ensure that the evaluation was tailored to their needs and to secure their commitment as participants. We call the combination of the research team and the expert occupational therapists from Ergo2.0 who were involved in the design of the protocol the “design team”. The design team ensured that the tools, training, and organisational structures put in place for the evaluation could also form the basis of GOC-inspired routine practice by home care occupational therapists, harmonising their practices, ethos and processes.

The design team began by defining the domains to be assessed in the evaluation. These domains were derived from the programme objectives as described by Ergo2.0. An initial programme theory was drafted to describe the expected programme mechanisms, and a probing of the scientific literature and consultation with the funding healthcare authorities was undertaken to incorporate their goals and priorities. The resulting person-level domains identified were older people’s life goals and their realisation, occupational performance, frailty and pre-frailty status, sense of security for the person and their informal caregivers [11–13, 20, 28], falls and apprehensions regarding falls, satisfaction and health-related quality of life, burden on informal caregivers, unplanned hospital use, and nursing home admission [29]. The design team also identified programme-level domains that need to be assessed: factors that facilitate or hinder programme implementation, ethical considerations, and better description and understanding of the intervention and target population.

The design team then selected outcome measurement scales to assess the identified domains. This selection was initiated by a survey of occupational therapists who had expressed an interest in developing home care activities or who were already working in home care. This survey helped to compile a catalogue of tools – such as scales or theoretical models – that occupational therapists use routinely. From this catalogue, the design team selected tools that assessed the domains relevant to the evaluation, followed a person-centred approach in line with the principles of GOC, reflected an occupational therapy approach to care, were evidence-based, and had satisfactory and validated metrological properties. In addition, the design team proposed a limited number of supplementary tools to assess domains of interest not covered

by the above instruments. Notable scales included the ICOPE (Integrated Care for Older People, measuring loss of intrinsic capacity) [19], COPM (Canadian Occupational Performance Measure, assessing daily occupations of importance that people are unable to perform) [15], EQ-5D-5L (measuring health-related quality of life) [30], and short FES-I (short Fall efficacy scale – international, measuring concern over the possibility of falling) [31]. The use of the ICOPE as an initial screening tool to assess risk of frailty also ensured that the BCM2.0 programme was integrated into the overall approach to care for older people proposed by the World Health Organisation. We chose the COPM over the Model of Human Occupation Screening Tool (MOHOST) for assessing life goals and occupational performance because expert trainers in our team felt that the COPM was more appropriate as an introduction to model-driven practice for occupational therapists new to the approach. Finally, in cases where no existing tool was found to assess a particular domain, the design team developed bespoke questions.

Occupational therapists from Ergo2.0 chose to use the Andaman7 smartphone application as their case report form (CRF). This selection was motivated by the application’s dual functionality in both care and research. After the evaluation phase, the application can be seamlessly transformed into a professional software tool for home care occupational therapists, facilitating interoperability with other primary care providers and hospital information systems. Importantly, the person-centred ethos is respected, as the person retains ownership of the data and has the autonomy to decide whether to share it with other healthcare professionals [8], as shown in Fig. 1b. The application is free to the user, is installed on the person’s smartphone, and Andaman7 has no access to the data in normal use situations. In addition, the developers of this application have previous experience of working with research teams on clinical trials, such as data extraction, pseudonymisation, and transfer. The research team will have full access to the pseudonymised data. UCLouvain researchers and Ergo2.0 members will establish a joint data ownership agreement within six months of the end of the study. This joint ownership agreement will define the terms for the protection and use of the data. The involvement of Andaman7 was limited to providing technical advice on the design of the CRF during the planning phase of the study. They will not be involved in data analysis, interpretation, report writing or the decision to submit the report for publication. The device data was only used by the occupational therapists for clinical use, but not by the research team for research use.

The design team organised training sessions for occupational therapists who were interested in participating in the BCM2.0 programme. This group was quite heterogeneous as it consisted of professionals with different

levels of skills required to use the Andaman7 application or to support the use of the assistive device. The occupational therapists were trained in various paradigms (biopsychosocial or biomedical) at the time of their studies, and came from very different professional backgrounds (hospitals, nursing homes and very few from home care). The aim of these sessions was to achieve consistency of skills within this group and covered enrolment, selecting appropriate assistive devices, supporting older people in the use of assistive devices and the Andaman7 application, and using the selected scales to assess outcomes. A structured approach based on the Canadian Model of Occupational Performance and Engagement (CMOP-E) [15] was provided to all trainees. This model was chosen to complement the use of the COPM, the scale associated with this model. Guidance on engaging with other primary care providers or organisations to recruit participants for the evaluation was also essential. Advice was given on client recruitment and building referral networks, critical skills for any self-employed primary care provider who needs to carve out a place for themselves in their local primary care landscape. Due to the limited home care experience of the participating occupational therapists, most of whom still worked in institutional settings, the development of these skills was crucial.

The integration of the AUDACE evaluation into the BCM2.0 programme from the participant's perspective is shown in Fig. 1c. All participants are asked by their occupational therapist to consent to take part in this evaluation when they enrol in the BCM2.0 programme. Participants have the right to refuse to take part in the evaluation and still benefit from the programme. The inclusion criteria for participants in the AUDACE evaluation are the same as those for the BCM2.0 programme described in the first section (in summary people aged 65 and over living at home in the Walloon and Brussels regions and considered to be at risk of frailty). These criteria are assessed by the occupational therapist at the start of the programme. Recruitment started in March 2024, and is expected to end in March 2025. The monthly occupational therapy support sessions provide an opportunity to assess the research outcome scales. For people who have consented to participate in the evaluation, data will be extracted and pseudonymised by Andaman7 before being transferred to the research team for analysis at regular intervals. In the next section, we describe the protocol we designed for our realist mixed methods evaluation.

Methods: a realist evaluation with interrelated components

A realist mixed-methods evaluation was chosen as the BCM2.0 programme is a complex intervention involving multiple interacting components, diverse populations

and different stakeholders' perspectives, as well as significant contextual factors. Traditional experimental designs are inadequate for capturing how outcomes emerge from the interactions between assistive technologies, professional practices, and living environments.. The realist approach has been shown to be effective in evaluating complex interventions such as the BCM2.0 programme [32]. While a conventional evaluation may measure differences on quantitative criteria, a comprehensive realist evaluation allows an examination of what works, for whom, in what context and why [33]. Realist evaluations allow the use of both quantitative and qualitative data. Quantitative data analysis aims to determine whether success has been achieved, to what extent, and in what contexts. Qualitative data analysis allows a deeper exploration of how success was achieved or failure occurred [34]. Following the RAMESES II standards [35], the realist approach begins and ends with an initial theory that postulates the mechanisms by which an intervention (or, in our evaluation, a programme) in a particular context produces changes in the individuals who benefit from the intervention, and why. Data collection and analysis allow researchers to refine their initial theory in a cycle shown in Fig. 2a.

The initial programme theory underpinning the AUDACE evaluation was developed through iterative discussions between the research team and key stakeholders from the BCM2.0 programme. It was also informed by a targeted, realist-oriented literature review focusing on security, ageing in place and assistive technologies.

At baseline, the programme theory hypothesises that the combination of assistive devices and occupational therapy support acts primarily through mechanisms related to perceived security: admission to a nursing home is often associated with a need for reassurance in the context of a sense of frailty and vulnerability, or repeated falls [36]. When older people experiencing loss of autonomy receive personalised occupational therapy support and appropriately selected connected devices, their sense of security and reassurance — as well as that of their informal caregivers — increases. This enhanced sense of security is expected to influence behaviours, decision-making and care trajectories, enabling older people to continue living at home under acceptable and safe conditions.

To find a theoretical framework to frame this concept, we conducted a more targeted search on Medline via PubMed using the BeHEMOTH tool and framework (Behaviour of interest; Health context; Exclusions; Models or Theories). This is a tool and procedure outlined by Booth and Carroll to systematically identify theories and models in the literature [37]. At the beginning of the evaluation, the theoretical model proposed by Hanson et al. [38] seemed the most compelling to initiate our empirical

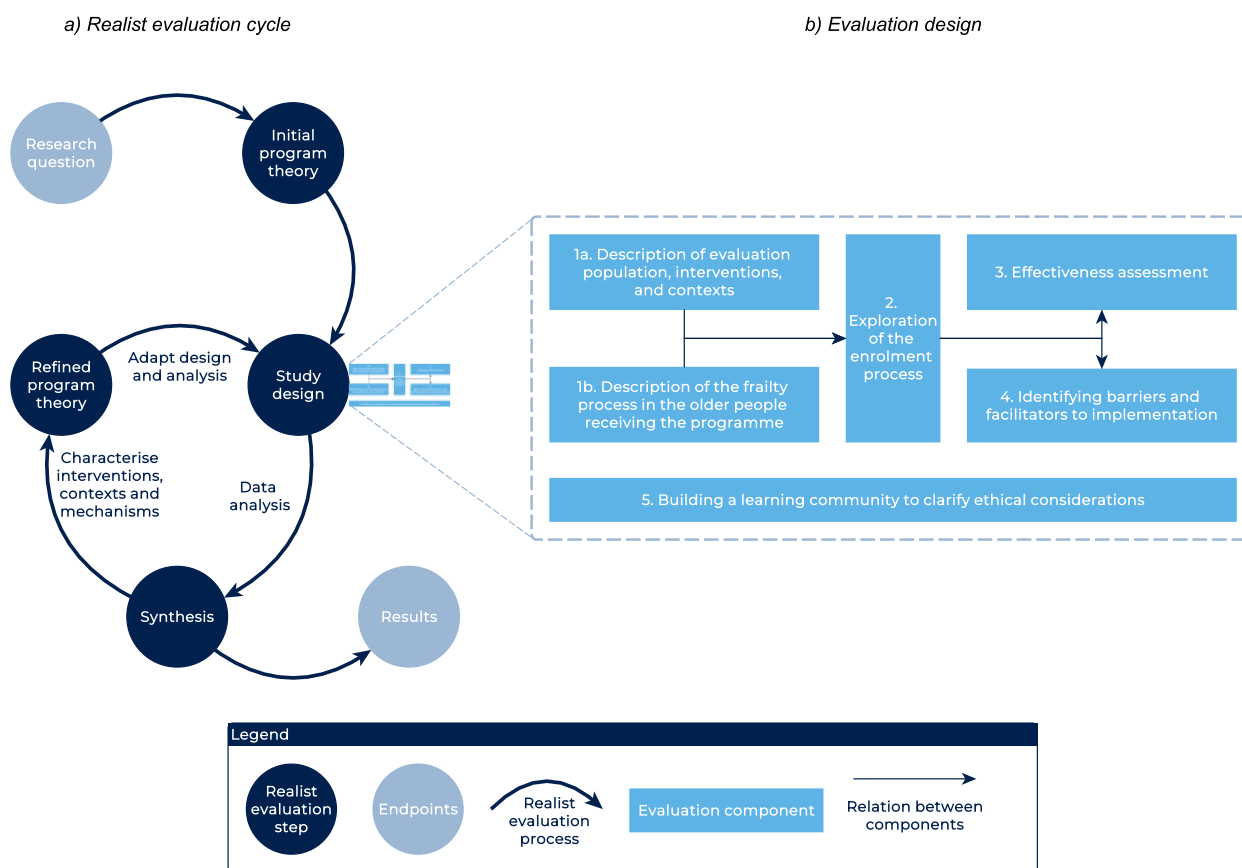


Fig. 2 Realist evaluation cycle, evaluation components and their interrelationships

research. It serves to validate Haddon's thesis regarding the paradigm shift in the evolution of injury prevention from a biomedical construct to an ecological concept. The theoretical model is underpinned by a socio-ecological paradigm that emphasises the interaction between three dimensions – the individual, the physical environment, and the social environment – operating across five levels: intrapersonal, interpersonal, organisational, community, and societal. Drawing on this socio-ecological and injury-prevention models, the programme theory assumes that outcomes do not result from technology alone, but from interactions between individual characteristics, physical home environments, social support systems and organisational contexts. In this perspective, occupational therapists play a central mediating role by translating technological solutions into meaningful, acceptable and ethically appropriate supports aligned with older people's goals and life context.

Based on this initial theory, the evaluation therefore seeks to test, refine and explain how different context–mechanism–outcome (CMO) configurations influence programme functioning and effectiveness across diverse populations and settings. The research question guiding the overall evaluation was as follows: How, for whom and why do assistive devices, integrated with occupational

therapy support, enable older people to remain at home, and under what conditions? To answer this question, we designed a realist mixed methods evaluation with inter-related components, each addressing a different research sub-question [33]. These components are summarised in Table 1. Figure 2b shows how the components are inter-related, and how they fit into the realist evaluation cycle. The methodology for each component is detailed in the following section, and the study schedule is available in Table 2.

Component 1a: Description of evaluation population, interventions, and contexts

To answer the question “What form of intervention is being delivered to what type of population?” we will use a descriptive quantitative study using baseline data from all older people benefiting from the “BCM2.0” programme and who have consented to participate in the AUDACE evaluation. We expect to produce a classification of the types of interventions provided by occupational therapists and a description of the population benefiting from the programme.

Pseudonymised data will be collected by re-using scales and questionnaires collected by occupational therapists in routine care using the Andaman7 application:

Table 1 Summary of the evaluation components

Component 1a: Description of evaluation population, interventions, and contexts	
Research question	What intervention is delivered to which population?
Population	All older persons enrolled in the BCM2.0 programme who consented to the AUDACE evaluation
Methods	A descriptive quantitative study using baseline data
Expected result	A classification of OT-delivered interventions and a description of the beneficiary population
Start – end	2024–03–04 – 2025–03–04
Component 1b: Description of the frailty process in the older people receiving the programme	
Research question	What is pre-frailty, and what marks the transitions from robustness to frailty?
Population	Around 30 older persons enrolled in BCM2.0 who consented to the AUDACE evaluation
Methods	Qualitative study using semi-structured biographical interviews
Expected result	A pragmatic definition of pre-frailty and an exploration of turning points between robustness and frailty
Start – end	2024–03–04 – 2025–09–04
Component 2: Exploration of the enrolment process	
Research question	How does the enrolment process work, from identification to the first home visit?
Population	Occupational therapists in the BCM2.0 programme
Methods	Focus groups using a realist approach (seeking CMO configurations)
Expected result	A detailed account of the enrolment process, including what works, what does not, and why
Start – end	2024–06–01 – 2025–09–04
Component 3: Effectiveness assessment	
Research question	How effective is the programme, and which individual characteristics influence its success?
Population	All BCM2.0 participants who consented to the evaluation
Methods	Prospective cohort study with up to 12 months of follow-up
Expected result	Which interventions work for which populations
Start – end	2024–03–04 – 2025–09–04
Component 4: Identifying barriers and facilitators to implementation	
Research question	What barriers and facilitators affect programme implementation?
Population	Three older persons per area, along with their primary care providers
Methods	Multiple nested case study in five areas using the same realistic approach as in Component 2
Expected result	Identification of implementation factors and mechanisms explaining what works, for whom, and why
Start – end	2024–10–01 – 2025–09–04
Component 5: Building a learning community to clarify ethical considerations	
Research question	What ethical issues affect programme implementation, and how are they reflected in the support provided?
Population	OT representatives, older persons, informal caregivers, primary care providers, and health authorities
Methods	Community-of-practice meetings informed by interim findings from other components
Expected result	Development of best practices with a focus on ethical issues
Start – end	2024–10–01 – N/A

Andaman7 staff will extract participant data, pseudonymise the data using a confidential mapping table, remove indirectly identifying data such as address, and encrypt and transfer to UCLouvain where they will be stored in a secure storage accessible only to the research team. The data will be accessible for two years after the end of the evaluation (until the end of 2027) and archived for 20 years on a secure storage, as required by law.

Data will be collected on the following domains: Risk of frailty (ICOPE), occupational goals on which occupational therapy sessions were focused and satisfaction and performance scores associated with these occupations (COPM), type of assistive device installed, presence and burden of informal and professional caregivers in general and for each (instrumental) activity of daily life (I)ADL, concern about the possibility of falling (FES-I) and occurrence of falls in the last six months, health-related quality

of life (EQ-5D-5L) mapped to Belgian utility scores, use of hospitalisation (planned and unplanned) and institutionalisation in a nursing home in the last six months, and access to reimbursement for occupational therapy sessions and installation of the assistive device.

A manual classification of occupational goals will be performed to better describe the type of intervention provided. This analysis will allow us to classify the types of interventions provided by occupational therapists and the different sub-populations benefiting from the programme. Summary descriptive statistics for the measures of interest will be produced for each of these groups. The enrolment period will start as soon as the BCM2.0 programme is launched, from 2024–03–04, and will end on 2025–03–04. We will conduct the analysis at the end of the enrolment period, but an interim analysis will be conducted at the halfway point (2024–09–01) to discuss the

Table 2 Time schedule of participant enrolment, interventions, assessments, and visits

	Enrol- ment month	Month- ly visit	Six-month assessment	12-month assess- ment
BCM2.0 usual care				
Eligibility check and enrolment	X			
Assistive device installation	X			
ICOPE	X			
Caregiver presence and burden			X	X
EQ-5D-5L	X		X	X
Use of hospitalisation	X		X	X
Nursing home institutionalisation	X		X	X
FES-I	X		X	X
Occurrence of falls	X		X	X
Access to reimbursement	X			
COPM	X	X	X	X
Sense of security			X	X
Use of assistive device			X	X
Collection of informed consent				
To participate in research	X			
To participate in the interview	X			
	03/2024	10/2024	03/2025	09/2025
AUDACE evaluation				
Inclusion period start	X			
Inclusion period end			X	
Follow-up period end				X
Component 1b interview start	X			
Component 1b interview end				X
Component 4 interview start		X		
Component 4 interview end				X

interim results with the occupational therapists, to check the accuracy of the data collected, and to inform discussions for the learning community meetings.

Component 1b: Description of the frailty process in the older people receiving the programme

This component will address the following questions: “What is pre-frailty according to the older person? What are the turning points between robustness, prefrailty and

frailty?” We will conduct a qualitative study using semi-structured individual interviews with approximately thirty older persons living at home to describe in depth the older people who receive the programme. This component will aim to (a) develop a pragmatic definition of pre-frailty, and (b) explore the turning points between robustness, prefrailty and frailty.

Eligible participants will be selected from people who benefit from BCM2.0 and have consented to participate in the AUDACE evaluation. Exclusion criteria are: not speaking French or English, or severe cognitive deficits. Participation in this component will be suggested to all study participants by their occupational therapist until data saturation. These participants will be asked for an additional specific consent. The enrolment period will start as soon as the BCM2.0 programme is launched, from 2024–03–04. We expect to reach data saturation by September 2025 at the latest.

We will use a narrative research methodology [39–42] based on individual biographical interviews. This methodology is part of a theoretically reasoned inductive approach (which allows analyses of field data to be rooted in the literature) [43, 44]. In practical terms, the study will consist of biographical interviews following an interview guide partly inspired by the OPHI-II form (an OT tool used to explore the person’s life history by exploring occupational identity, occupational skills and the impact of the environment on the person’s occupations).

Component 2: Exploration of the enrolment process

To explore the question “What is the process of enrolment (from identification, through addressing, to the first home visits)?” we will organise focus groups with occupational therapists from the BCM2.0 programme using a realist approach (looking for emergent patterns in the form of context-mechanism-outcome CMO configurations) to obtain a rich description of the process and what goes well or not in the enrolment process and why.

All occupational therapists involved in the BCM2.0 programme will be eligible to participate. We plan to organise at least six focus groups, rotating locations to be as close as possible to where the occupational therapists work. The content of the topic guide for these focus groups will include a description of the enrolment process, as well as barriers and facilitators to the enrolment process, while exploring specific topics such as challenges to collaboration and information flow, privacy and ethical issues, training of occupational therapists and other care providers, and education of older people and informal caregivers. We will start running these focus groups a few months into the programme, in June 2024, to ensure that occupational therapists have sufficient experience. We expect to complete this component by September 2025.

To complement the discussions from the focus groups about older people who were eligible for the programme but not included in the evaluation, the occupational therapists will collect the reasons for non-enrolment in a completely anonymous way in a dedicated conversation group.

Component 3: Effectiveness assessment

This component will aim to answer the questions “How effective is the programme? What are the individual characteristics that influence whether the programme is successful or not?” with a prospective cohort study with a follow-up of six to up to 12 months ending on 2025–09–30. We will enrol the same population as in Component 1b: all older people who benefit from the “BCM2.0” programme and who have consented to participate in the AUDACE evaluation. We expect to learn about the association between intervention patterns, population characteristics and the intervention's impact. However, due to the absence of a control group, we cannot estimate the intervention's causal effectiveness.

The a priori definition of a sample size is not appropriate in our situation, as this number will depend on how many people receive the programme. The 12-month enrolment period will start on 2024–03–04 until 2025–03–04. The follow-up period will end on 2025–09–30. We will conduct a primary assessment six months after baseline. Data will be collected at baseline, 6 months, and 12 months if follow-up allows.

As described in the data flow plan presented in Component 1b, pseudonymised data collected by occupational therapists in routine care will be reused. Follow-up data will be transferred to the research team in October 2025. Endpoints will be calculated as the within-subject difference in measurement between baseline and six-month follow-up for the following scales: COPM, presence and burden of informal and professional caregivers in general and for each (instrumental) activity of daily life (I)ADL, FES-I and occurrence of falls in the last six months, EQ-5D-5L and utility scores, use of hospitalisation (planned and unplanned) in the last six months. In addition, the following data will be collected at six months: the person's and informal caregivers' sense of security on a 7-point Likert scale, whether the person consulted the data output from the assistive device and shared it with other health professionals, whether the person used the assistive device, and whether and when the person entered a nursing home. If a participant withdraws from the Ergo2.0 programme or the AUDACE evaluation, the occupational therapist will collect data on the reason for loss to follow-up.

For each category of the population/intervention classification produced in component 1, all outcome means and uncertainty intervals will be estimated by a Bayesian

regression model with weakly informative priors using the stanarm R package [45]. Estimates of mean differences and their uncertainty intervals between relevant categories will allow us to discuss what works and for whom. We will provide a detailed description and discussion of the population lost to follow-up who did not complete the six-month assessment, using all available data up to withdrawal. Due to the nature of the evaluation, in which we reused data from people who benefited from the BCM2.0 programme, it was neither ethical nor possible to construct a control group. To anchor our findings in the context of the general target population we will, whenever possible, place our results in the context of publicly available data (e.g. on hospital or nursing home use). This analysis will be conducted after the end of the follow-up period, from 2025–09–04. There will be no interim analyses for this component.

Component 4: Identifying barriers and facilitators to implementation

To learn “What are the barriers and facilitators related to the implementation of the programme?” we will conduct a multiple nested case study where the unit of analysis is a local area where the occupational therapist works. Using the same realistic approach as in Component 2, we plan to identify implementation factors and strategies and explore the mechanisms of how, for whom, and why the implementation of the BCM2.0 programme goes well or not.

The local areas correspond to newly defined primary geographical zones in Wallonia (Organisations Locorégionales, $N=10$) and Brussels (Bassins, $N=5$). These zones are expected to have their own local dynamics that can either support or hinder the implementation of occupational therapy, interprofessional and interorganisational collaboration [46]. From these fifteen zones, five diverse zones will be selected. The criteria for the selection of these five zones include existing structural interorganisational and interprofessional dynamics, urban, rural or semi-urban characteristics, population density and socioeconomic characteristics. Three older persons benefiting from the programme will be recruited per area, together with the primary care providers who support them.

Data will be collected through focus groups with beneficiaries and their informal caregivers and primary care providers who (a) live or work in the primary geographical area, (b) are participating in the BCM2.0 programme and the AUDACE evaluation or, for primary care providers other than occupational therapists, are likely to be involved. Where focus groups are not possible, individual semi-structured interviews will be organised instead. The focus group topic guide is based on the Theoretical Domains Framework [47, 48], which provides an

overarching framework to guide the exploration of multiple domains that influence implementation. We will begin conducting these focus groups in October 2024 and expect to complete this component by September 2025.

Component 5: Building a learning community to clarify ethical considerations

Finally, to address the question “What ethical considerations are relevant to the implementation of the programme and how are these considerations reflected in the support provided?”, we intend to establish a learning community [49] to address the key ethical and privacy issues that have been raised since the start of the programme. Meetings of these communities of practice, enriched by the interim results of other components, will enable the development of best practices with a particular focus on ethical issues. To incorporate the results of this component into the overall evaluation, emerging ethical issues will be included in realist CMO configurations.

This community will include representatives of occupational therapists involved in the BCM2.0 programme, beneficiaries, informal caregivers, other primary care providers, and health authorities. Its aim will be to facilitate the sharing of experience on ethical and privacy issues. Issues discussed at these meetings will be published and disseminated to programme stakeholders via the BCM2.0 programme website and newsletters. We plan to start in October 2024 with at least two meetings per year and increase the frequency in the following years, as occupational therapists will already have to attend many meetings for the programme itself in the beginning, and the number of communities of practice meetings is likely to increase as the demand for sharing experiences during these reflective sessions increases [50]. We have not set an end date as we anticipate that the need for a learning community will continue for the duration of the programme.

Scientific advisory committee

The research team will organise meetings several times a year with a scientific advisory committee to present our evaluation protocol and results. This committee comprises Belgian researchers from a variety of backgrounds (medical doctors, occupational therapists, sociologists, ethicists, etc.) whose general area of research is older people in primary care or assistive devices. The aim of this committee will be to advise the research team on their choices, provide insight into their findings, and facilitate the implementation of the programme and its evaluation through their professional network. The research team will retain ultimate authority over the study design; the collection, management, analysis, and

interpretation of data; the writing of the report; and the decision to submit the report for publication.

Adverse event risk management

The only additional interventions that participants in the AUDACE evaluation will undergo compared to usual care in the BCM2.0 programme are pseudonymised data collection and analysis, and interviews (only for those enrolled in component 1a or 4). We identified the following risks of adverse events from these procedures: data breach and re-identification, and discussion of sensitive topics during interviews. After discussion with the ethics committee, it was decided that a data monitoring committee and stopping guidelines were not necessary to address these adverse events. We addressed these risks by developing a data security plan with our institution's data protection officer, and by ensuring that interviews were conducted only by trained care professionals.

Discussion

Implications of the cocreation process

The AUDACE evaluation was intentionally designed at the intersection of programme evaluation and professional practice development through its participatory and co-creative approach. Rather than merely observing the BCM2.0 programme, the evaluation contributes to shaping occupational therapy practices and developing a favourable context for the empowerment of home care occupational therapists. By involving these professionals in the design and implementation process we ensured that the evaluation addressed their needs: this strengthened their participation and ownership [51]. This process led to the development of a participatory action research protocol [52]. This collaborative approach not only improves the quality of the evaluation [53], but also supports the occupational therapists' professional development and fosters a culture of evidence-based practice that ultimately benefits the frail older people they serve. This interaction between programme development and research, in turn, demands flexibility from our team and the ability to adapt to constraints [54].

The participatory nature of this research created synergies not only with occupational therapists but also with other stakeholders: other primary care providers who participate in focus groups for Component 4 may also refer more participants to the evaluation. Funding healthcare authorities who have been involved in the design process can help with recruitment by ensuring that other primary care providers and the target population are aware of the programme. Members of the scientific advisory committee, with their in-depth knowledge of Belgian primary care, can also facilitate participant recruitment and programme implementation.

The dual nature of programme evaluation and professional practice development can blur the traditional distinction between evaluation and intervention, raising significant methodological concerns regarding reflexivity, reactivity, and internal validity. Rather than viewing this interaction as a source of bias to be minimised, we conceptualise it as a deliberate methodological choice consistent with the traditions of realist evaluation and participatory action research. From this perspective, professional practices are not considered to be static objects of study, but rather dynamic components of the programme itself. Supporting practice development is therefore not an activity that takes place outside of the evaluation; rather, it is one of the mechanisms through which the programme is expected to operate.

This approach is consistent with the realist assumption that complex interventions evolve through feedback loops between actors, contexts, and emerging outcomes. In such systems, attempts to isolate evaluation from implementation risk misrepresenting how the programme functions in real-world conditions.

Management of reflexivity during data collection and analysis

Several strategies are implemented to ensure analytical transparency and reflexivity throughout the evaluation process.

First, reflexive memos will be maintained by members of the research team involved in facilitation activities (e.g. training sessions, communities of practice, focus groups). These memos will document assumptions, positionality, interactions with participants, and potential influences on data production.

Second, a functional distinction will be maintained between facilitation roles (e.g. supporting occupational therapists) and analytical roles. Whenever possible, researchers directly involved in facilitation will not lead the primary coding of qualitative data generated within those same activities.

Third, realist analysis will explicitly incorporate the evaluator's role as a contextual element within context–mechanism–outcome (CMO) configurations. Rather than treating reactivity as noise, the evaluation will examine how professional support, feedback and collective reflection may themselves function as mechanisms influencing programme outcomes.

Finally, interim findings and emerging interpretations will be discussed within the scientific advisory committee to support critical distancing and triangulation across disciplinary perspectives.

Together, these strategies aim to enhance transparency, traceability and interpretive rigour while preserving the ecological validity of the evaluation.

Challenging assumptions and concepts

Given its innovative nature, key assumptions about the programme may be challenged as it progresses [55]. Our cyclical and adaptive design allows us to monitor and adapt to these findings. For example, aging in place at home is seen as evident, but may not always respect the person's preferences [6, 56]. Our design allows us to observe situations where entry into a nursing home has been chosen and prepared. Another key assumption is the definition of frailty: as there is no standard measurement [57, 58], we decided that a biopsychosocial approach to frailty was most appropriate in our context [58, 59]. This led us to select measures that considered all these dimensions of frailty, rather than being limited to its biomedical components.

Component 1a: Description of evaluation population, interventions, and contexts

This quantitative analysis strengthens the evaluation by classifying the type of intervention and describing the population benefiting from the programme, thus providing the basis for assessing the effectiveness of the programme. The wide range of data collected ensures a holistic understanding of participants' needs and the impact of the intervention. In addition, conducting an interim analysis provides an opportunity to refine data collection and engage with occupational therapists to ensure that the evaluation remains responsive and grounded in practice.

Component 1b: Description of the frailty process in the older people receiving the programme

Understanding the transitions between robustness, pre-frailty, and frailty is of paramount importance in geriatric care, particularly in the home setting, where early intervention may mitigate or delay the onset of frailty. Focusing on pre-frailty is important, as this stage is not well studied in the existing literature [58, 60]. The development of a pragmatic definition of pre-frailty will contribute significantly to clinical practice and academic discourse.

Biographical interviews using the OPHI-II tool are a rigorous method for exploring older people's life experiences. This qualitative approach is likely to provide insights into the nuanced transitions between different stages of frailty. However, it will be essential to ensure that the sample size provides adequate saturation, given the potential diversity of individual experiences of frailty [61].

Component 2: Exploration of the enrolment process

For healthcare interventions, a particular challenge in the enrolment process is identifying and reaching those most in need. The focus on exploring the process from the

perspective of occupational therapists is a key strength, as it provides insight into the barriers and facilitators encountered in practice. The realist approach, using context-mechanism-outcome configurations, is particularly suited to unravelling the complexities of service delivery and enrolment in healthcare settings [62].

The decision to conduct multiple focus groups in different locations ensures a more comprehensive understanding of enrolment practices in different contexts. However, it will be important to ensure that these groups represent the diversity of experiences of occupational therapists in different primary care zones, as these contexts can have a significant impact on the enrolment process [63].

Component 3: Effectiveness assessment

A prospective cohort study with a follow-up of six to 12-months allows a thorough and long-term examination of the programme. The focus on key outcomes, such as changes in occupational performance, caregiver burden and health-related quality of life, is well aligned with the objectives of the programme. The Bayesian regression model used to analyse outcomes in different sub-populations provides a robust statistical approach that allows nuanced comparisons between groups [45]. However, the absence of a control group means that we cannot attribute causal outcomes to the programme. The difficulty of constructing a comparable control group from trial data or routine health records has been reported elsewhere [64]. While contextualising the results with publicly available data from populations not benefiting from the programme may mitigate this limitation to some extent, the results should be interpreted with caution. External data should be used to discuss our results in a broader context, rather than to calculate an effectiveness difference that is likely to be uninterpretable.

Component 4: Identifying barriers and facilitators to implementation

Understanding the factors that support or hinder the implementation of healthcare programmes is critical to scaling up successful interventions. By using a multiple nested case study approach, this component recognises the importance of local dynamics in shaping the success of the BCM2.0 programme [63]. The focus on inter-professional and inter-organisational collaboration reflects the growing recognition that integrated care is essential to address the complex needs of frail older adults [65].

The selection of five diverse geographical zones ensures that the evaluation captures a wide range of experiences, from rural to urban settings, and provides insights into the different challenges and support in different regions. The use of focus groups with beneficiaries, caregivers, and healthcare providers will provide valuable perspectives on the implementation process, although the

feasibility of organising these groups in all areas may be challenging.

Component 5: Building a learning community to clarify ethical considerations

The creation of a learning community to address ethical considerations reflects a commitment to ongoing reflection and adaptation within the programme. The ethical issues around privacy, consent, changes in the home due to assistive devices and the role of informal caregivers are significant and require careful consideration [66]. The learning community allows for the development of best practices that can evolve as the programme is implemented.

In addition, the intention to disseminate the results of these discussions through the programme website and newsletters underlines a transparent and inclusive approach to addressing ethical concerns. The integration of interim results from other components will ensure that ethical considerations remain grounded in the practical realities of programme delivery.

Abbreviations

AUDACE	AUTonome à Domicile grâce à un Appareil Connecté et à un suivi Ergo
BCM2.0	Bien chez moi 2.0
CMO	Context-Mechanism-Outcome
CMOP-E	Canadian Model of Occupational Performance and Engagement
COPM	Canadian Occupational Performance Measure
CRF	Case Report Form
FES-I	Fall Efficacy Scale – International
GOC	Goal Oriented Care
(I)ADL	(Instrumental) Activities of Daily Living
ICOPE	Integrated Care for Older People
MOHOST	Model of Human Occupation Screening Tool
OPHI-II	Occupational Performance History Interview-II

Supplementary Information

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Supplementary Material 1.

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Authors' contributions

All authors have made substantial contributions to the design of the AUDACE protocol. AFP and TVD drafted the article, and AL drafted the sections on Component 1 b. AL, LAI, and TdC critically revised the article. TVD obtained funding and was the principal investigator. All authors read and approved the final version of the manuscript.

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Data availability

Pseudonymised individual study data will undergo an anonymisation process with the help of an expert in data anonymity to ensure that no combination of data would allow re-identification of participants. The data will be publicly available on UCLouvain's public open data repository <https://dataverse.uclouvain.be>

Declarations

Ethics approval and consent to participate

Our protocol was approved by the Ethics Committee "Comité d'éthique Hospitalo-facultaire Saint-Luc" on 2024-03-04 under the identification numbers 2023/29NOV/477, 2024/18JAN/029 and 2024/25JAN/045, Belgian trial registration number: B4032023000129, clinicaltrials.gov identifier: NCT06819982. In the event of a major protocol modification, an amendment will be submitted to the Ethics Committee. Informed consent will be obtained from all participants in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Tatiana de la Croix also works as a home care occupational therapist and is a member of Ergo2.0. She uses the BCM2.0 programme in her work and enrolls participants in the AUDACE evaluation.