

STUDY PROTOCOL

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Belgium program Enhancing the uptake and Effectiveness of a Multifactorial falls Prevention intervention in Older community-dWelling peRsons (BE-EMPOWERed): A study protocol

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Abstract

Aims This study protocol aims to outline a mixed-methods study of the implementation of the BE-EMPOWERed program in four primary care areas (PCAs) in Flanders. The study assesses implementation processes and outcomes, while exploring its effectiveness on clinical outcomes.

Background Despite strong evidence supporting multifactorial falls prevention interventions, their implementation in clinical practice remains limited, contributing to substantial research waste. Systematic implementation science approaches are essential to address this gap. The BE-EMPOWERed program, developed using Intervention Mapping and Implementation Mapping, aims to enhance the uptake and effectiveness of multifactorial falls prevention interventions in older community-dwelling people. The program includes a seven-week group intervention for older people, workshops for healthcare professionals (HCPs), and an implementation plan tailored to PCAs.

Methods Two-year mixed-methods study using a convergent parallel design. Qualitative data from focus group interviews and observations will assess implementation outcomes and processes, while quantitative data from a before-and-after study will evaluate the program's effectiveness on fallers, concerns about falling, balance, walking speed and muscle strength and behavior in older people using surveys and tests at multiple time points.

Discussion The BE-EMPOWERed program addresses barriers and facilitators in translating evidence into practice, aiming to reduce falls and promote active aging. This study will offer actionable insights, tools for scaling up and evidence-based strategies for future national and international initiatives. It will also contribute to implementation science by demonstrating practical methods for bridging research into practice gaps in community-based falls prevention.

Study protocol ClinicalTrials.gov (NCT06105437).

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Keywords Community setting, Implementation, Falls prevention, Aged

Background

Significant evidence-based innovations fail to reach clinical practice, with only 14% of research findings implemented within an average of 17 years [1]. These delays contribute to research waste [2]. This results in one in three patients not receiving appropriate treatments, and one in four receiving unnecessary or harmful treatments [3]. Falls prevention research exemplifies these challenges. Systematic reviews and meta-analyses confirm the efficacy of multifactorial falls prevention interventions tailored to individual risk profiles [4, 5]. However, translating these findings into practice remains challenging [6, 7].

With one-third of community-dwelling people aged 65 years and older experiencing at least one fall a year, falls represent a global health issue requiring urgent attention [8]. Barriers to implementing multifactorial interventions include resource availability, financial incentives, healthcare professionals (HCPs) motivation and integration into existing workflows. The interplay of contextual factors - spanning individual, organizational and societal levels - often determines the success or failure of interventions [9]. Despite evidence underscoring the critical role of context in implementation, most falls prevention research does not systematically examine contextual determinants and interactions, nor do they develop tailored, theory-driven implementation strategies [10–12].

To bridge this gap, implementation science offers systematic approaches to optimize intervention uptake and sustainability [2]. Enhancing the uptake, effectiveness and sustainability of multifactorial falls prevention interventions requires early assessment of contextual factors and implementation barriers and facilitators. Tailored strategies that address the specific needs of older people, HCPs, organizations and policymakers are critical to achieving long-term success [12].

The BE-EMPOWERed program, developed using Intervention Mapping and Implementation Mapping, aims to address these challenges [13]. This co-produced, contextually tailored program consists of a seven-week group program for older people, workshops for HCPs, and a six-step implementation plan and implementation guidance for primary care areas (PCAs) [9, 12–16]. This protocol outlines a mixed-method study designed to evaluate the implementation of the BE-EMPOWERed program across four PCAs in Flanders, providing actionable insights for scaling up and sustaining evidence-based falls prevention initiatives.

Methods

Aims & objectives

The study aims to implement and evaluate the BE-EMPOWERed program in four PCAs in Flanders by:

1. assessing implementation outcomes of the BE-EMPOWERed program including reach, dose, fidelity, feasibility, acceptability, implementation cost, and sustainability.
2. understanding the implementation process of the BE-EMPOWERed program from the perspectives of older people, HCPs, PCAs, and policymakers.
3. exploring the effectiveness of the BE-EMPOWERed program intervention on fallers, concerns about falling, balance, walking speed and muscle strength, and behavior in older people.

Study design

A mixed-methods study with a two-year convergent parallel design will be conducted across four PCAs. The qualitative component, comprising focus group interviews and observations, will evaluate the implementation outcomes and process. In parallel the quantitative component, a before-and-after study, incorporating surveys and tests conducted at multiple time points, will assess the intervention's effectiveness. Integration of qualitative and quantitative findings will occur during the interpretation phase using a narrative approach [17]. The results will be reported jointly in the discussion section, where quantitative statistical outcomes will be presented, followed by qualitative themes and illustrative quotes that support, expand upon, or challenge the quantitative findings [17]. This narrative integration will allow for a nuanced understanding of the program's implementation and effectiveness across the four PCAs. The Standards for Reporting Implementation Studies (StaRI Checklist) will guide reporting and the study protocol is registered on 27th of October 2023 at ClinicalTrials.gov (NCT06105437) [18]. Ethical approval is obtained from the Social and Societal Ethics Committee of Leuven University Hospitals [G-2022-5783-R4(AMD)]. All participants will provide written informed consent.

BE-EMPOWERed program

The BE-EMPOWERed program was developed using Intervention Mapping and Implementation Mapping in line with the Medical Research Council (MRC) framework [14, 15, 19]. Intervention Mapping involves iterative steps integrating theory, evidence and clinical practice to design, implement, and evaluate the program [14].

Implementation Mapping expands on the fifth step (i.e. implementation planning) of Intervention Mapping, guiding researchers in the systematic development of tailored implementation strategies.

A multidisciplinary stakeholder group of 21 professionals, including physiotherapists, geriatricians, pharmacists, occupational therapists, registered nurses, policy makers, researchers and older people, was involved throughout the development process. Stakeholders were selected through purposive sampling mainly based on their expertise in falls prevention and implementation projects. The stakeholder group met five times between October 2020 and October 2023.

The BE-EMPOWERed program was co-produced with one PCA in Flanders, which formed a local stakeholder group with HCPs and organisations. This group met quarterly during the development phase. The program consists of three key components: (i) a seven-week group program for older people, (ii) two workshops for HCPs focusing on multifactorial falls prevention interventions and motivational interviewing, and (iii) a six-step implementation plan tailored to each PCA, supported by a trained implementation facilitator. A detailed description of the falls prevention intervention and implementation strategies is provided in Fig. 1 and described in detail elsewhere [13].

Group program for older people

Adapted from the Australian program 'Stepping On' [20], this seven-week intervention empowers older people to incorporate falls prevention interventions into daily life using a small-group learning environment [20, 21]. Stepping On has shown positive outcomes, i.e., increasing levels of independence, enabling a proactive approach to health and a 30% reduction in falls in a randomized controlled trial [20, 22]. Stepping On was adapted to our context by aligning interventions with participants' personal goals to enhance motivation, adding two booster sessions for continuity (every three months), and linking group sessions to local initiatives, such as the Flemish Otago Exercise Program. Falls prevention brochures from the Center of Expertise for Falls and Fracture Prevention Flanders were integrated. Trained HCPs (e.g., occupational therapists or physiotherapists) will facilitate sessions after completing a two-day training and receiving monthly telephone coaching from researchers.

Workshops for HCPs

The workshops for HCPs will focus on the multifactorial falls prevention interventions and motivational interviewing to empower older people. Networking and collaboration among HCPs will be a central focus. Each 2,5 h workshop will be facilitated by a trained expert in falls prevention and motivational interviewing.

Implementation plan and guidance for PCAs

The implementation plan follows frameworks such as the MRC framework and the PDCA cycle (Plan, Do, Check, Act) [23, 24]. The six-step plan includes: (i) enabling support, (ii) mapping the baseline situation, (iii) defining objectives and priorities, (iv) planning implementation, (v) executing the plan and (vi) evaluating, adjusting and working towards sustainability. It allows tailored implementation of the BE-EMPOWERed program in the different PCAs. Implementation facilitators will receive one-day training in implementation guidance and monthly telephone coaching from the researchers.

Setting

The BE-EMPOWERed program will be implemented and evaluated in four PCAs in Flanders, Belgium, one of which was involved in the program co-production and feasibility testing. Flanders has 60 PCAs, which are geographically defined networks of primary care providers. Three additional PCAs will be selected using purposive sampling with selection criteria based on motivation, sustainability, collaboration with local partners, geographic diversity and size of the PCA. This approach allows us to observe differences in implementation and underlying dynamics. Invitations will be sent to all 60 PCAs.

Sample

Older people attending the group program

Older people will be eligible if they are 65 years or older, live in the community, are cognitively intact, can walk independently outside with or without a walking aid, speak and understand Dutch, and meet at least one of the following falls-related criteria: a falls-related injury in the past year, two or more falls in the past year, self-reported gait or balance problems, or concerns about falling. Recruitment will be conducted through flyers, advertisements, e-mails, newsletters and referrals by HCPs. The recruitment will last for one year. Trained group leaders will screen participants for potential cognitive problems; those with suspected cognitive impairment will be excluded. Eligible participants will provide written informed consent before baseline data collection by the research team. Each PCA will have one trained group leader delivering three to five different group programs, with ten to fourteen participants per group. The PCA involved in the co-production will have two group leaders. In total, the study aims to include approximately 200 older people. The structure of the repartition of the program among the areas and the group leaders is represented in Fig. 2 below.

HCPs attending the workshops

HCPs in the selected PCAs who work in community settings and speak and understand Dutch fluently will be

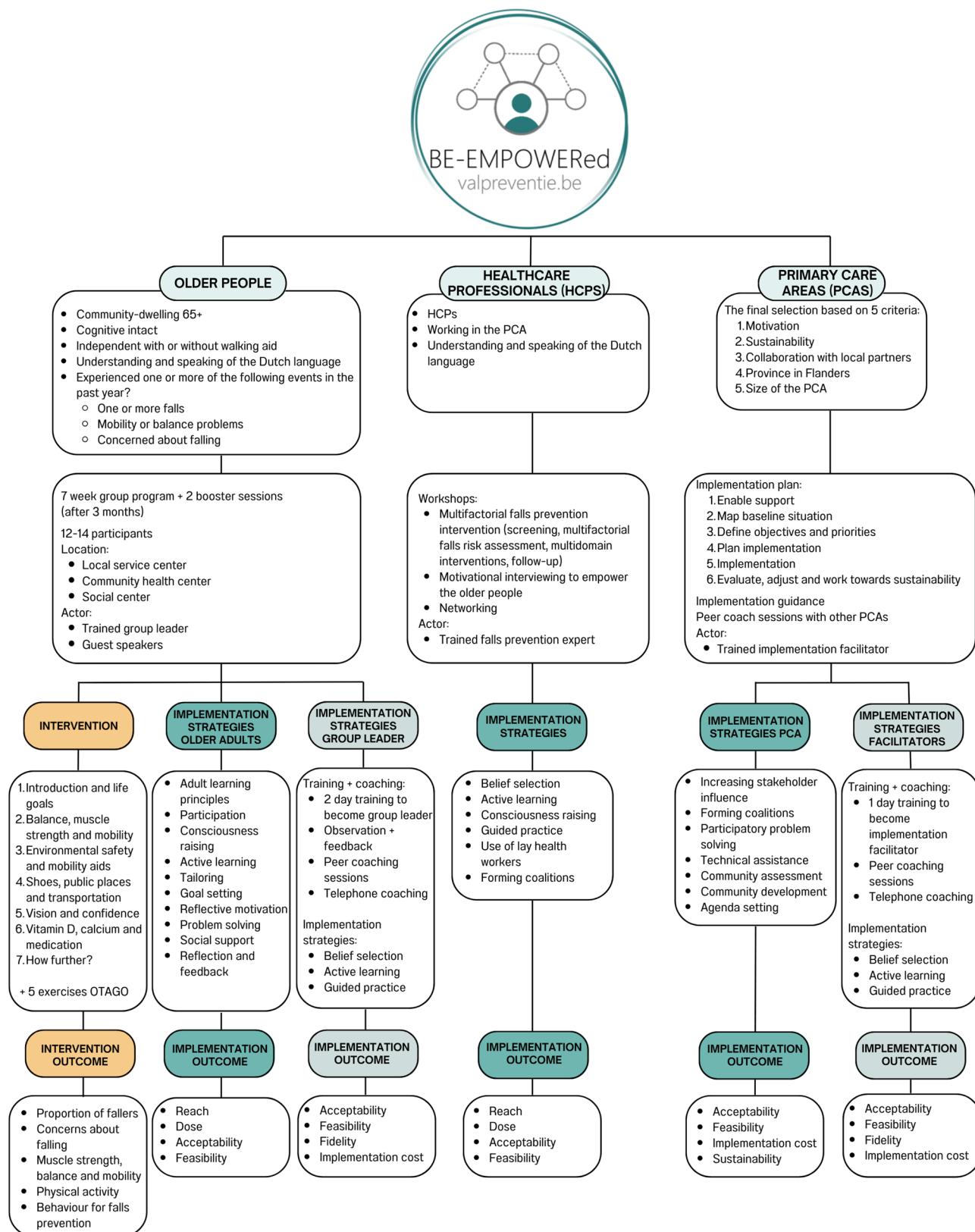


Fig. 1 BE-EMPOWERed program (intervention and implementation strategies)

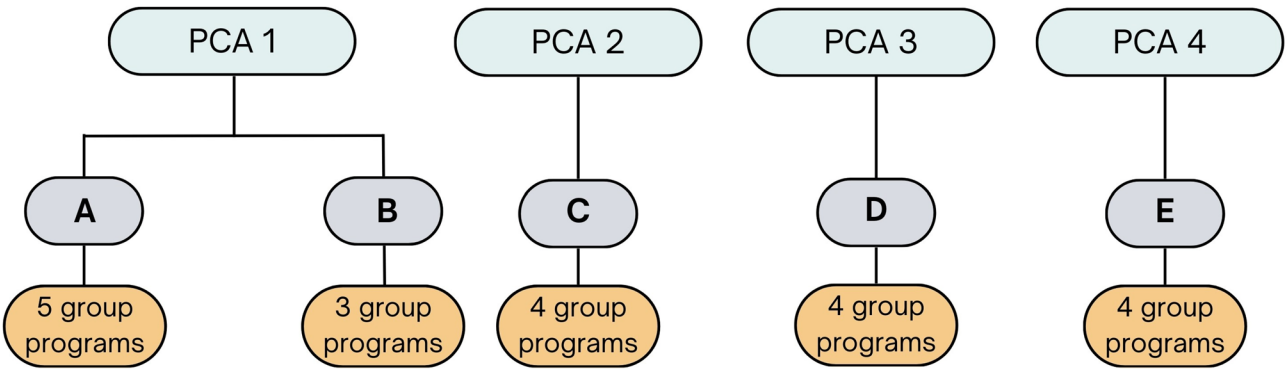


Fig. 2 Repartition of 20 programs given by five group leaders (A to E) among the four primary care areas (PCA 1 to 4)

eligible. Recruitment will mirror the strategies used for older people. The recruitment will last for one year and a half. In each PCA, experts will be trained to deliver the workshops. Each expert will conduct at least two sets of workshops. Each workshop can accommodate up to 25 HCPs, with some participants attending only one workshop, while others will attend both. Figure 3 shows the structure of this training program.

Data collection

Figure 4 illustrates the BE-EMPOWERed study’s progression over five years. The initial timeline depicts the overall study flow, including the development, preparation,

implementation according to the implementation plan and guidance, and evaluation phases. The second and third timelines detail the data collection processes for the workshops for HCPs and the group program for older people.

Aim 1 and 2: program’s implementation outcomes and process

This study will examine various implementation outcomes, including: reach, dose received, fidelity, feasibility, acceptability, sustainability, behavior of HCPs and implementation cost [25]. Experiences with the implementation process and the intervention will be gathered

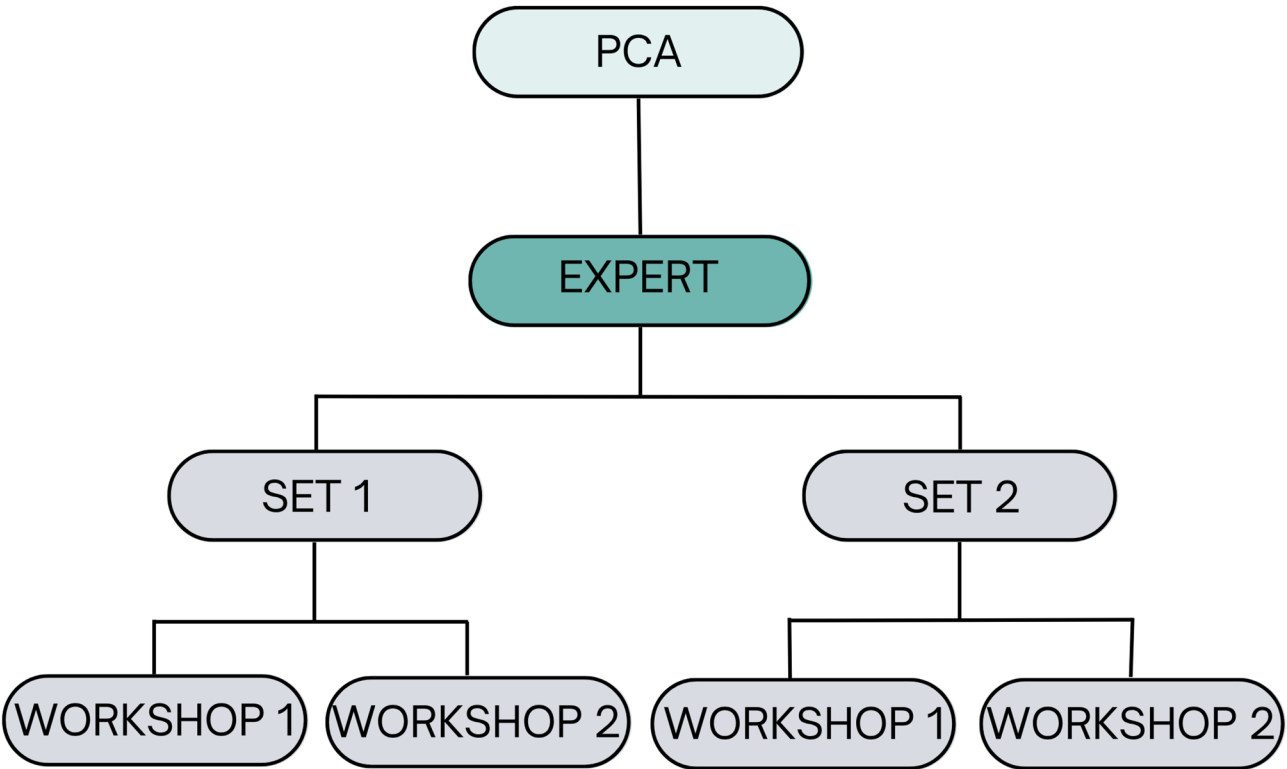


Fig. 3 Schematic representation of the training of the healthcare professionals (HCPs) in a primary care area (PCA) by an expert, during two workshops of two modules each

Implementation and study flow

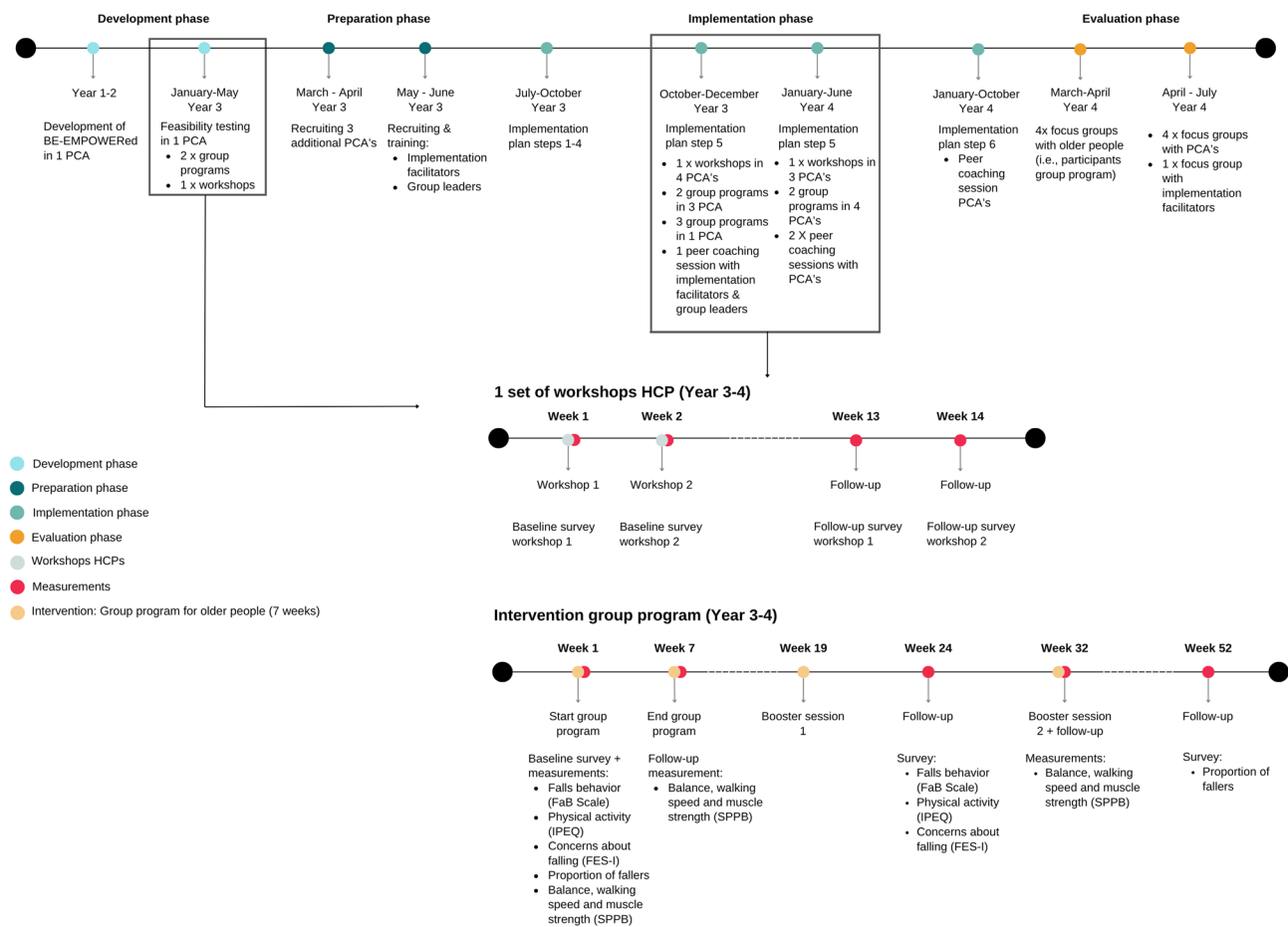


Fig. 4 BE-EMPOWERed study flow

from older people, implementation facilitators, and local stakeholders from the PCAs. Measurement tools include participant lists, fidelity checklists, observations, meeting minutes, focus group interviews, surveys and self-reported costs. Table 1 summarizes the outcomes, time points, and data sources for each outcome.

To ensure the fidelity, a researcher will observe one session per seven-week program using a fidelity checklist adapted from the Australian 'Stepping On' program [27, 28]. The checklist evaluates adherence to the intervention protocol, the group leader's delivery and participants' engagement. Additional file 1 contains the adapted fidelity checklist from 'Stepping On'. Observations will involve active participation by the researcher, using the fidelity checklist to assess adherence to the intervention's core elements [25, 29].

Acceptability, feasibility, sustainability, and stakeholder experiences will be assessed through focus group interviews using a Grounded Theory Approach [29, 30]. Two focus groups will be organised per PCA. One focus group will involve the coordinator or staff member, implementation facilitator, and PCA falls prevention local

stakeholder group. The second focus group will include one or two older people from each program organized in the PCA, selected through purposive sampling by group leaders. Participants will be invited and informed about the focus group via email. Topic guides will be developed collaboratively and adapted iteratively as new insights emerge. Additional file 2 contains the developed topic guides. Focus groups will be audio-recorded, transcribed verbatim and pseudonymized. The first author is experienced in conducting focus group interviews and will conduct the focus group interviews, with an observer present to take notes on non-verbal cues and other observations. The research group under supervision of an experienced qualitative researcher and co-author, will review and discuss the transcripts, providing methodological feedback. The research group is composed of experts in qualitative research, ethics, falls prevention, geriatrics, and implementation science [29].

To evaluate changes in HCPs' professional behavior related to falls prevention and motivational interviewing, a baseline and follow-up questionnaire will be administered for each workshop—initially at baseline and again

Table 1 Overview data collection aim 1: implementation outcomes and aim 2: implementation process

	Definition [25, 26]	Measurement tool	Time points	Data sources
Aim 1: Implementation outcome				
Reach	The number, proportion, and representativeness of individuals who participated in the group program and workshops	Participant list group program older people and workshops healthcare professionals (HCPs)	After every session After every workshop	Group leader Falls prevention expert
Dose received	The quantity of intervention implemented	Participant list group program older people and workshops HCPs	After every session After every workshop	Group leader Falls prevention expert
Fidelity	How closely the group program adhered to the original protocol	Fidelity checklist	Observation of 1 session per group program	Researcher
Implementation cost	The expenses associated with carrying out the implementation effort	Self-report of costs of group program, workshops	For 2 years	Group leader Primary care areas (PCAs)
Feasibility	The practicality of implementing the BE-EMPOWERed program within PCAs	Focus groups Meeting minutes of the peer coaching sessions with implementation facilitators and PCAs	Evaluation phase	Researcher
Acceptability	Stakeholders' satisfaction with and approval of the group program and workshops	Focus groups Meeting minutes of the peer coaching sessions with implementation facilitators and PCAs	Evaluation phase	Researcher
Sustainability	The program's ability to become integrated into the routine operations of service settings	Focus groups Meeting minutes of the peer coaching sessions with implementation facilitators and PCAs	Evaluation phase	Researcher
Behavior HCPs	The extent to which HCPs have adjusted their professional behavior regarding falls prevention and motivational interviewing	Survey (Likert scale)	Baseline and after 3 months	Researcher
Aim 2: Implementation process				
Experiences	How the older people, HCPs, group leaders, stakeholders, local policymakers and implementation facilitators experienced the group program, workshops, implementation plan and guidance	Focus groups Meeting minutes of the peer coaching sessions with implementation facilitators and PCAs	Evaluation phase	Researcher
PCAs: Healthcare professionals, PCAs Primary care areas				

Table 2 Overview data collection aim 3: clinical outcomes

Outcome	Definition	Measurement tool	Time points	Data sources
Clinical outcomes				
Behavior older person		Falls Behavioral (FaB) Scale for the Older Person [32]	Baseline and after 6 months	Researcher
Concerns about falling		Incidental and planned activity questionnaire (IPEQ) for older people [31] (REDCap, telephone or paper)		
		Falls Efficacy Scale International (FES-I 16 items) [33, 34] (REDCap, telephone or paper)	Baseline and after 6 months	Researcher
Fallers	A faller is a person who has fallen once during the study period [36]	Survey (REDCap, telephone or paper)	12 months before and 12 months after the intervention (retrospectively)	Researcher
Balance, walking speed and muscle strength		Short Physical Performance Battery (SPPB) [35]	Baseline, after 7 weeks and after 8 months at booster 2 of the group program	Group leader

three months post-workshop. HCPs will use a four-point Likert scale (strongly disagree to strongly agree) to rate statements on the multifactorial approach to falls prevention, referrals, reimbursement, motivational interviewing, and practical feasibility. Additional file 3 contains the baseline and follow-up survey for HCPs.

Aim 3: intervention's effectiveness

Effectiveness of the intervention will be assessed using a before-and-after design, with surveys and tests administered at multiple time points (Fig. 4; Table 2). Older people will serve as their own control group. Behavioral changes will be assessed using the Incidental and Planned Activity Questionnaire (IPEQ) [31] and the Falls Behavioral (FaB) Scale for Older People [32]. Concerns about falling will be assessed using the Falls Efficacy Scale International (FES-I) [33, 34]. Physical function (balance, walking speed, muscle strength) will be assessed using the Short Physical Performance Battery (SPPB) [35]. A survey will record retrospective the proportion of fallers 12 months before and 12 months after the intervention. Group leaders, trained in administering the SPPB, will perform physical performance assessments, while researchers will collect survey data through REDCap™, paper forms, or telephone interviews. Table 2 summarizes the outcomes, time point, data sources and measurement tools employed in the study.

Data analysis

Aim 1 and 2: program's implementation outcomes and process

Quantitative data (i.e. reach, dose, fidelity, implementation cost, behavior of HCPs) will be analyzed using descriptive statistics. Continuous data will be summarized with means, medians, ranges, and standard deviations, while categorical data will be presented as frequencies and proportions. These summaries will

provide an overview of the extent and quality of program implementation.

Qualitative data from focus group interviews and meeting minutes will be analyzed following the Qualitative Analysis Guide of Leuven (i.e., QUAGOL). This process involves two main phases. First, the preparation phase includes reading transcripts, drafting descriptive, methodological and content reports, and developing conceptual interview schemes and a coding list [30, 37]. Second, the coding phase involves systematically applying codes to the data using NVivo PRO 14 (QSR International) and refining themes through iterative discussions to ensure robustness and depth of analysis. To enhance trustworthiness, triangulation will be employed. Data triangulation will combine information from participant lists, fidelity checklists, observations, and interviews. Investigator triangulation will engage multiple researchers in coding and analysis to reduce bias. Space and method triangulation will incorporate data from diverse PCAs and integrate quantitative and qualitative findings [29].

Aim 3: intervention's effectiveness

All analyses will be conducted using R Statistical Software (v4.3.1; R Core Team 2023). The full analysis set includes all older people that attended at least four out of seven of the sessions of the group program. Continuous variables will be summarized by the number of non-missing data points, mean, standard deviation, median and interquartile range. Categorical and ordinal variables will be summarized by observed frequencies and percentages relative to the total number of non-missing items. All variables will be summarized and analyzed by PCA. To account for hierarchical data structures, such as participants nested within group programs and programs nested within PCAs, statistical models will incorporate the group leader as fixed effect and program as random effect to account for interdependencies between patients in the same program. Appropriate models will be used

for each outcome, with details specified below. All tests will be 2-sided and assessed at a significance level of 5%. For outcomes with more than 5% missing data, additional variables potentially associated with missingness will be included as fixed effects in the statistical models to improve estimation accuracy. Under the assumption of Missingness At Random (MAR), these linear mixed models (LMMs) will provide unbiased estimates despite the presence of missing data. Sensitivity analyses may be conducted to test the robustness of results under alternative assumptions about missing data.

Fall status of each older person, recorded at the individual level, is a binary outcome indicating whether they experienced a fall during the twelve months before and after the intervention. The incidence of falls 12 months pre- and post-intervention will be estimated using odds ratios and their corresponding 95% confidence intervals. The likelihood of falling will be compared between the 12 months before the intervention, and after the intervention. These estimates will be derived from a mixed logistic regression model, in which the outcome represents the log-odds of an older person experiencing a fall.

Physical function (balance, walking speed and muscle strength) will be assessed using the SPPB test [35]. The test comprises three components: (i) a four-meter walk, (ii) a five-repetition chair stand without using arms, and (iii) a progressive standing balance test. Each component is scored on a scale from 0 to 4, with higher scores reflecting better performance. When combined, the total SPPB score ranges from 4 to 12. Based on established clinical cut-points, scores of 4 to 6 indicate low performance, 7 to 9 indicate moderate performance, and 10 to 12 represent the highest performance level [38, 39]. Scores will be analyzed using LMMs. All models will include fixed effects for time (baseline, seven weeks, and eight months) and group leader, as well as random effects for program and participants (nested within program). Pairwise comparisons will be conducted to assess changes over time, with conditional means and 95% confidence intervals reported.

Concerns about falling, measured using the FES-I, will be analyzed as a continuous variable (scores 22 and above indicating concerns about falling) [33, 34, 40]. Continuous score will also be analyzed using LMMs. The analysis will include fixed effects for time and group leader, and random effects for programs and participants (nested within program).

Behavior of older people regarding falls prevention interventions will be assessed using the IPEQ (i.e., total hours of planned activity per week) and FaB Scale (i.e., falls prevention behaviors). The IPEQ is a self-report questionnaire that categorizes physical activity into two types: planned physical activities, which include structured exercises and scheduled walks, and incidental

physical activities, which refer to more casual, everyday activities [31]. The FaB Scale comprises of 30 statements about everyday actions with answers expressed on a four-point Likert Scale (never to always) that is transformed into a single score per question [32]. All scores will be recoded prior to analysis to ensure high scores equal the safest behaviors and low scores the riskiest behaviors. Since the scores are a continuous variable, they will be analyzed with LMMs, using the same methodology as the SPPB test and the FES-I score [31, 32].

Discussion

The BE-EMPOWERed program aims to bridge the gap between research and real-world application, setting a new benchmark in falls prevention research. This novel approach addresses the need for a systematic, contextually adapted and co-produced strategy for implementing multifactorial falls prevention interventions. It includes not only an evidence-based intervention but also detailed implementation guidance to help PCAs and HCPs overcome challenges and make informed choices for effective program integration into their specific contexts. By tailoring the BE-EMPOWERed program to the specific cultural, social, and healthcare needs of older people, HCPs and PCAs in Flanders, the program enhances its practical applicability, relevance and sustainability. The inclusion of both clinical and implementation outcomes ensures a comprehensive evaluation, which will generate critical insights to support the scale-up of similar interventions in other settings.

A key strength of this study is its design, by examining contextual determinants, stakeholder dynamics and practical challenges, the study will provide valuable insights for guiding future implementation across diverse contexts. Additionally, the close collaboration with community stakeholders, including HCPs, policymakers and older people, ensures that the interventions are not only theoretically robust but also practically relevant and sustainable. This participatory approach fosters a sense of ownership and alignment with local needs, increasing the likelihood of successful implementation.

For the clinical outcomes, an important limitation is the design of the mixed methods study with a before-and-after design rather than a randomized controlled trial (RCT). While mixed methods approach with a before-and-after design provide valuable insights, they may not offer the same level of control over variables as RCTs, potentially affecting the robustness of causal inferences. In addition, the BE-EMPOWERed program builds on the proven effectiveness of the Stepping On intervention, its adaptation to the Flemish context may limit generalizability to other regions with different healthcare systems or cultural contexts. Also, the purposive sampling of PCAs and HCPs, may introduce selection bias,

limiting generalizability of the findings. Besides that, reliance on self-reported data for falls and behavior outcomes introduces potential recall and social desirability biases. Additionally, variability in program delivery among group leaders, despite fidelity monitoring, may influence outcomes. The study's two-year timeframe may not fully capture long-term sustainability, and the program's multifactorial nature and tailored implementation strategies to PCAs may present challenges for scaling up in resource-limited settings.

Conclusion

The BE-EMPOWERed program has the potential to deliver critical insights and tools to drive future national and international evidence-based falls prevention initiatives. By reducing falls, promoting active aging, and improving health outcomes, the program aims to reduce healthcare and societal burdens. Furthermore, the study will contribute to implementation science by providing evidence on effective strategies for translating research into practice, particularly in the context of falls prevention.

Abbreviations

PCAs	Primary care areas
HCPs	Healthcare professionals
MRC	Medical Research Council
Plan, Do, Check, Act	PDCA cycle
StaRI checklist	Standards for Reporting Implementation Studies
RCT	Randomized controlled trial
LMMs	Linear mixed models
MAR	Missingness At Random
IPEQ	Planned Activity Questionnaire
FaB	Falls Behavioral Scale for older people
FES-I	Falls Efficacy Scale International
SPPB	Short Physical Performance Battery

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12877-025-06190-3>.

Additional file 1. Fidelity checklist.

Additional file 2. Topic guides.

Additional file 3. Survey workshops HCPs.

Additional file 4. StaRI checklist

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Authors' contributions

SAV, EV, BDdC, KD, KM: study design. SAV, EV, BDdC, GB, KD, KM: development and production of BE-EMPOWERed. SAV, GB: datacollection. SAV, AB: Data analysis. SAV, KD: drafting the manuscript. EV, BDdC, JF, KM: supervision. All authors read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Research will be performed in accordance with the Declaration of Helsinki. Ethical approval was obtained from the Social and Societal Ethics Committee of Leuven University Hospitals, on 26 January 2023 [G-2022-5783-R4(AMD)]. All participants will provide written informed consent. All methods will be performed in accordance with the relevant guidelines and regulations.

Consent for publication

No personal data were included in this manuscript.

Competing interests

The authors declare no competing interests.

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