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TITLE:

Effectiveness and cost-effectiveness of a Home-based Functional Exercise Program for Community Dwelling Frail Older Adults Provided by Professionals and Volunteers: Protocol of a Pragmatic Randomised Controlled Trial

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Abstract

Between 2020 and 2050, the world's population aged 80 years and over will triple, drastically increasing the prevalence of frailty and associated healthcare costs. Multimodal exercise programs have proven to be an ideal countermeasure for frailty but the current Flemish standard of care does not include them. The purpose of this study is to investigate functional outcomes and cost-effectiveness of the homebased exercise program ACTIVE-AGE@home delivered by professionals or volunteers.

A pragmatic randomised controlled trial will be conducted. Participants will be randomized into three parallel groups using permuted block randomization. There will be two intervention groups: in one group the intervention is delivered by professionals and in the other by trained volunteers. Both groups will be compared to a control group receiving usual care. Participants (n=195) are community-dwelling frail older adults (>70 years). The intervention is a 24-week program that consists of three one-hour visits per week and contains aerobic, strength, balance, flexibility, coordination and dual tasking exercises, accompanied by goalsetting and motivational interviewing. The Timed Chair Rise test is the primary outcome. Functional ability, cognition, loneliness, self-management, subjective health, health care utilization and meaningful activities will be measured in all groups at 0, 24 and 48 weeks. Time and expenses invested by professionals or volunteers will be kept in diaries for trial and model-based cost-effectiveness analyses, expressed in incremental cost per QALY (quality-adjusted life year). Statistical analysis will be blinded to group allocation and outcome assessors will be blinded to the maximal extent possible.

Ethics and dissemination

Ethics approval has been obtained. Results will be disseminated in publications and other relevant platforms.

Registration details

NCT05946109

Strengths and limitations:

+ This is the first study that entails a guided, homebased multimodal exercise program (ACTIVE-AGE@home) consisting of personal goalsetting and motivational interviewing, exercises based on daily activities and cognitive challenges, to counteract adverse health outcomes in community dwelling frail older adults.
+ The innovative ACTIVE-AGE@home intervention was developed according to the British Medical Research Council guidelines (1) and had a strong patient and public involvement.
+ This robust pragmatic RCT will generate a lot of differentiated evidence on functional and psychosocial outcomes and cost-effectiveness of the multimodal exercise program ACTIVE-AGE@home.

- The sample size of community dwelling frail older adults aged 70 or over (n=195) might cause a challenge for the researchers and recruitment stakeholders.
- Participants will know if they participated in the intervention or the control group, potentially jeopardizing the single blinded assessment during post- and follow up measurements.

INTRODUCTION

The population is ageing rapidly. It is expected that worldwide between 2020 and 2050, people aged >60 years will increase with 50% whereas people aged >80 years will triple (2). In Flanders 20,9% of the population is 65 years or older, approaching the European average of 21,1% (3). Older adults aged 85 or older make up 3,2% of the Flemish population, scoring 0,2% above European average. In addition, Flemish women and men only experience 64.4 and 64.8 healthy life years respectively (4). One of the predetermining factors for the discrepancy between healthy life years and total life expectancy is the high prevalence of frailty in Flanders (21,5%)(5). The onset of frailty rises with increasing age, independently of the assessment instrument (3). Amongst community-dwelling adults aged 80 or over, an even higher prevalence of frailty is observed in populations with specific diseases or chronic conditions (6). Since frailty has a severe impact on Quality of life (QOL) and health-care utilization, effective interventions should be developed and implemented (7).

Frailty is a clinically recognizable state in older people, resulting from age-related declines in physiological reserve and function across multiple organ systems (8,9). Frailty is, however, not inevitable or irreversible. Research has shown that people can move in and out of frailty status over time due to timely health and care interventions (7,10). In a systematic review of Sobhani et al. (2021), 21 conceptual and 59 practical definitions of frailty were identified but no consensus about one definition was reached. The authors found that frailty is characterized by physical, cognitive, psychological, nutritional and social dimensions. They also suggested to use the operationalisation which is best aligned with the goal of the research and the characteristics of the target population. In research involving community dwelling older adults, frailty is mostly operationalised in two ways: the unidimensional physical Fried Frailty Phenotype (11) and the multidimensional Rockwood Frailty index (12). In line with the recommendation of Sobhani et al. (2021) the researchers adopted the Fried Frailty Phenotype for this study.
Regardless of the definition used, frail older adults struggle to cope with (minor) stressors like new medication, infection, illness or surgery and experience adverse health outcomes such as diminished mobility, falls, increased disability in activities of daily living (ADL), low performance of meaningful activities, loneliness, cognitive disorders, hospitalization, admission to a residential care centre and premature death (13–17). Also, several studies pointed out that the average additional costs associated with frailty when controlled for ageing and multimorbidity range from 1.500 to 5.000 euro per person per year (18–20). Stabilizing or reversing frailty has proven to lower hospital and ambulatory care uses (21).

Physical activity (PA) is the most effective intervention to counter frailty (22,23). A network meta-analysis reviewed 21 RCT's with PA interventions and concluded a decrease in frailty compared to placebo or usual care (SMD -0.92, 95% CI -1.55, - 0.29) (24). PA has favorable effects on all dimensions of frailty and provides fundamental improvements in risk and fear of falling, mobility, balance, functional ability, muscle strength, body composition and frailty status (25). Recent literature also provides strong evidence for counteracting depressive symptoms, cognitive impairment and chronic diseases (26). There is also evidence of a dose response relationship

between higher intensities of PA and lower levels of frailty (26,27). WHO stipulates in their PA guidelines (2020) that older adults with or without frailty, should participate in moderate and/or high intensity aerobic PA for at least 75 (when high) and 150 (when moderate) minutes per week, strength training on two occasions per week and functional exercises (strength, flexibility and balance) on three occasions per week (28). For frail older adults multicomponent exercise programs are most appropriate as a preventive and curative measure, including resistance and power training (e.g. lifting weights), functional exercises (e.g. standing from a chair), balance and gait exercises (e.g. standing on one leg, line walking)(25,26,29).

Unfortunately, older adults often do not meet the requirements for health enhancing PA. According to the 2023 Health Interview Survey (HIS) in Flanders (Belgium), only 34,1% of the population between the ages of 65 and 74 engage in 150-minute moderate-intensity aerobic PA per week. For people aged over 74 this number drops drastically to 15,5%. In addition, more than 92% of the Flemish older adults do not perform exercises to improve muscular strength twice or more per week (5). The barriers for older adults to engage in PA are related to their health situation, fear of falling, specific individual PA preferences and physical and social environment (30). To motivate older adults, the emphasis should be brought to the health benefits of PA, the gains in functional capacity and long-lasting independence, lowering costs, eliminating the need for transport and offering personal guidance (30,31).

To counter PA barriers for frail older adults the home based multimodal exercise program ACTIVE-AGE@home for frail community dwelling older adults was developed according to the subsequent steps of the British Medical Research Council (MRC) guidance for the development and evaluation of complex interventions (1) (the development of the intervention will be published in peer reviewed literature in the anear future). The program offers basic functional exercises and connects to meaningful activities, goalsetting and motivational interviewing. The exercises from the ACTIVE-AGE@home program are based on daily activities like walking, cooking, playing with grandchildren and have been turned into structured exercises in line with evidence-based training principles (25,26,28,29). In this study, the program can be delivered by professionals experienced in PA or volunteers. Involving volunteers (e.g. friends, family, informal caregivers, neighbors, students, pensioners, …) holds a cost saving potential for the older adult and society. A systematic review in 2021 (32) showed that delivery of an exercise program by trained volunteers is feasible and effective in lowering frailty in community dwelling older adults.

This study aims to investigate the effectiveness and cost-effectiveness of the multimodal homebased exercise program ACTIVE-AGE@home on physical functioning, cognition, loneliness, self-management, subjective health, QOL, meaningful activities and health care utilization of community dwelling frail older adults frail older adults, when provided by professionals (study arm 1), by trained volunteers (study arm 2) compared to usual care (study arm 3).

METHOD

Design

The researchers hypothesize that the intervention will have a significant effect on functional and psychosocial outcomes of frail community dwelling older adults, but that the costs of the intervention will be lower when delivered by volunteers compared to professionals.

Therefore, a pragmatic randomised controlled assessor-blinded trial will be conducted. The RCT comprises two intervention groups: in one group the intervention is delivered by professionals and in the other by trained volunteers. Both groups will be compared to a control group receiving usual care. The duration of the intervention is 24 weeks and assessments will be done before and after the intervention (at 24 weeks) and at 48 weeks. In addition, trial and model-based cost-effectiveness analyses will be conducted, expressed in incremental cost per QALY (quality-adjusted life year). The trial is designed in line with The Geriatric ICF Core Set reflecting health-related problems in community-living older adults aged 75 years and older without dementia (33). The template for intervention description and replication (TIDieR) will be used for detailed description of the intervention (34) and the CONSORT statement will be followed for reporting on the RCT (35).

Participants

Community dwelling frail older adults, aged 70 or more, should be frail according to the Fried frailty phenotype (11), defining frailty as the presence of three or more of the following five criteria: unintentional weight loss, weakness, exhaustion (low energy level), slowness (slow gait) and low PA level (see table 1).

Table 1: Description of the Fried Frailty criteria and other exclusion criteria

Inclusion **Fried Frailty criteria** (11)		
Criteria	**Evaluation and Cutoff**	**Score**
Weight loss	*'In the last six months, have you lost more than 4,5kg unintentionally?'* • No • Yes	 No = 0 Yes = 1
Weakness	Grip strength using the Martin Vigorimeter (with the dominant hand, average of 3 measures) Cutoff • Men : 71kPa • Women : 42kPa	 Normal grip strength = 0 Lower Grip strength = 1
Exhaustion (low energy level)	Two statements from the CES-D Depression Scale *'I felt that everything I did was an effort'* *'I could not get going'* How often in the last week did you feel this way? • Rarely or none of the time = 0 • Some or little of the time = 1 • A moderate amount of time = 2 • Most of the time = 3	 Score 0 or 1 on both statements = 0 Score 2 or 3 on either of the two statements = 1

Slowness (slow gait)	Gait speed over 4,5 meter Cutoff • Men ≤173 cm → ≥ 7 seconds >173 cm → ≥ 6 seconds • Women ≤159 cm → ≥ 7 seconds >159 cm → ≥ 6 seconds	Normal gait speed = 0 Low gait speed = 1
PA	*"How often do you engage in activities that require a low or moderate level of energy such as gardening, cleaning the car, or going for a walk?."* • More than once a week • Once a week • One to three times a month • Hardly ever or never	More than one a week or once a week = 0 One to three times a month or hardly ever or never = 1
Exclusion		
Life expectancy less than 12 months Receiving oncologic treatment Diagnosed with Parkinson or Multiple Sclerosis Having had a stroke in the preceding 6 months Participated in exercise therapy in the preceding 6 months Contra-indications for exercise as established by a physician Cognitive impairment is present (Mini Mental State Examination score <23/30) (36) Unable to understand instructions in Dutch		

Recruitment

To recruit frail community dwelling older adults the TIBaR model of recruitment for 'hard-to-reach' older people for research will be adopted (37) (see table 2). This model consists of four basic principles: providing trustworthy companions (T), offering meaningful experiences or incentives (I), removing barriers (B) and being responsive to needs of the older adults (R). Flemish older adults will be recruited through local newspapers, pharmacies, general practitioners, (home) nurses, occupational therapists, informal caregivers and local government. Flyers and e-mails will be distributed but personal contact with local professionals and the target population is preferred.

Table 2: TIBaR model of recruitment for hard-to-reach older adults (37)

TIBaR model of recruitment in ACTIVE-AGE@home			
Build up trust	Offer incentives	Identify individual barriers	Be responsive
Trusted environment (e.g. Local service centers, general	Making participation meaningful	Interviews/ conversations with (possible) participants	Plan intake conversations and

practitioners office, …) Warm referral: tailored information. Collaboration with existing projects. Primary care providers.	Offer tangible materials (e.g. flyer, exercise book, …). Enable social interaction	Interviews/Focus groups with healthcare providers Interviews/ conversations with family, friends, local residents…	practice sessions together. Offer a confidant. ACTIVE-AGE@home telephone always available.

Screening and enrolment

After registration the blinded assessor contacts the older adult to make an appointment for the eligibility screening and, if eligible, baseline assessment at the home of the participant. Before the screening the informed consent form (ICF) is explained. If older adults agree and sign, eligibility screening can start. Older adults who are eligible will be randomized within one week of baseline assessment and intervention starts within two weeks (see also Figure 1).

See attachment 3

Figure 1: Enrolment in the study and randomisation in three groups.

Randomisation and blinding

A computer algorithm will be used to generate the random allocation sequence. Participants will be randomized in a 1:1 ratio, using permuted block randomization with blocks of variable sizes (3-6-9) into one of the three parallel groups. Randomization will be done centrally by an interactive web response system (IWRS). Once the participants are found eligible for the trial, they can be randomized via the IWRS by the Principal Investigator (PI) or qualified person to whom this study task has been delegated. This will generate a unique study randomization number and the treatment arm label (A professionals, B volunteers, C control) to which the participant is randomized. An accountability log with the corresponding label will be kept by the PI or delegated person to ensure that allocation was successfully performed. Participants will be scheduled to receive their randomisation within one week of eligibility assessment.

The statistician will be blinded to group allocation. Outcome assessors will be blinded to the maximal extent possible. Participants will of course be aware of the intervention received. Regarding this, participants will be asked not to communicate with the assessors about the intervention received. The professional or volunteer supervisors will not be involved in the assessments, and vice versa.

Interventions

In this pragmatic randomised controlled trial two intervention groups will be compared to a control group receiving usual care. In one intervention group the intervention is delivered by professionals and in the other by trained volunteers. In table 3 the ACTIVE-AGE@home program is elicited through the Template for Intervention Description and Replication (TIDier) (34)

ACTIVE-AGE@home is a multimodal, homebased exercise program for frail community dwelling older adults, delivered by professionals or volunteers. The program is based on five innovative aspects. First, the program entails personal goalsetting (linked to meaningful individual and social activities) and motivational interviewing during the entire program. Second, functional exercises were built out of daily activities (e.g. walking, standing from a chair, carrying objects, …) and aligned with evidence-based training principles to effectively improve muscle strength, aerobic endurance, balance, flexibility, motor ability, coordination and cognition. Third, cognitive challenges (e.g. dual tasking) are added to improve executive functions and memory. Seven types of cognition (mental tracking, working memory, long term memory, recognition memory, verbal fluency, executive functioning, reaction time) are stimulated by counting, calculating, remembering, naming, recognizing, speaking and/or responding quick and correctly while performing the exercises. Fourth, the program is delivered at the homes of the older adults and uses only those materials at hand such as grocery bags, chairs and towels. Fifth, personal guidance is offered by a professional or a volunteer throughout the entire program to enhance motivation and safety. A personal referral is made to relevant individual or group PA possibilities at the end of the program.

The frail participants are visited three times per week during 24 weeks, resulting in 72 sessions in total. Each session is 1 hour in duration. A session consists of 10 minutes warming-up, 45 minutes exercises and 5 minutes of cooling-down. There are 8 to 9 exercises in each training session. The workload will increase weekly with approximately 10%. There are three main periods of eight weeks where workload and complexity of exercises will be gradually increased within the period. After eight and sixteen weeks new exercises will be introduced but at a lower workload and with less complexity in the first week of that period for supercompensation effects. Three goalsetting conversations, based on the CLEVER-protocol (38) will be held in the first and second week of intervention and 6 motivational interviews will be spread out over the remaining 22 weeks. Goalsetting or motivational interviewing takes about 10-20 minutes per session and replaces 2 or 3 exercises.

Table 3: TIDieR - Template for Intervention Description and Replication ACTIVE-AGE@home (34)

See attachment 2

Professional led program

The exercise program is supervised by professionals with a bachelor- or master's degree and specific knowledge and experience regarding PA interventions and (frail) older adults e.g. physiotherapists, occupational therapists, personal trainers or physical education teachers. The professionals will receive an 8h training course and 4 hours (3x 1h20m) on the job training to gain more knowledge and practice regarding ageing, frailty, training and safety principles and goalsetting and motivational interviewing in the ACTIVE-AGE@home program. The professionals need to show sufficient knowledge and application of the evidence-based safety and training principles after the training course (pass / fail).

Volunteer led program

The exercise program is supervised by volunteers e.g. informal caregivers, students, (parttime) working people or pensioners. A relevant background is not mandatory. The volunteers will receive an 8h training course and 4 hours (3x 1h20m) on the job training to gain more knowledge and practice regarding ageing, frailty, training and safety principles and goalsetting and motivational interviewing in the ACTIVE-AGE@home program. The volunteers need to show sufficient knowledge

and application of the evidence-based safety and training principles after the training course (pass / fail). During the remaining 23 weeks a coordinator will accompany the volunteer on seven training sessions in the home of the older adult, to provide coaching and support.

Care as usual

In the third group, frail older adults receive care as usual in Flanders. PA and lifestyle interventions are not part of the standard frailty management in Flanders for community dwelling frail older adults (5,39). Only when they are admitted to a geriatric department or a residential care facility a structural screening, evaluation and possibly physiotherapy is provided. In some cases, the general practitioner will detect onset of frailty due to underlying comorbidities and prescribe physiotherapy (40). Local government, health- and care services or health insurance companies promote general health enhancing activities for older adults e.g. healthy foods, exercise and sometimes also fall prevention. Utilization of these services by frail older adults are limited and provide challenges such as accessibility (e.g. location) and affordability (e.g. costs), (41).

Regardless randomization in the intervention or control groups, all participants in the three arms will receive the same monthly newsletter with tips and tricks to obtain good health in older age.

Outcome measures and data collection

Outcome measures

Outcomes were chosen in line with WHO's vision on Healthy Ageing (functional ability and intrinsic capacity) (42,43) and the Geriatric ICF Core Set reflecting health-related problems in community-living older adults aged 75 years and older without dementia (Spoorenberg et al., 2015). Older adults will receive assessment of primary, secondary and explanatory measures at baseline (T0), after the intervention of 24weeks (T1) and at 48weeks (T2). A blinded assessor will administer 4 physical performance tests and 9 questionnaires at T0, T1 and T2 (see table 4).

Table 4: Measurements of participants at base line (T0), after intervention of 24weeks (T1) and follow-up of 48weeks (T2).

OUTCOME	ELIGIBILITY	T0 (BASELINE)	T1 (24WEEKS)	T2 (48WEEKS)
EXCLUSION CRITERIA				
Exclusion questions	X			
Mini Mental State Examination	X			
FRAILTY PHENOTYPE OF FRIED				
Unintentional weight loss	X		X	X
Handgrip strenght (weakness)	X		X	X
Center for Epidemiologic studies - Depression Scale (exhaustion)	X		X	X
Gait Speed (slowness)	X		X	X
Physical Activity	X		X	X
DESCRIPTIVE OUTCOMES				
Age	X			
Gender		X		
Height		X		
Weight		X	X	X

BMI		X	X	X
Race/ethnicity		X		
Marital status		X		
Educational level		X		
Household composition		X		
Income		X		
Medication use		X		
Fall risk		X		
Charlson Comorbidity Index		X		
Medical history (Health Interview Survey))		X		
PRIMARY OUTCOME MEASURE				
The Timed Chair Rise		X	X	X
SECONDARY OUTCOME MEASURES				
2-minute step in place stress test		X	X	X
Montreal Cognitive Assessment		X	X	X
Trail making Test		X	X	X
Rey Auditory Verbal Learning Test		X	X	X
Fatigue resistance grip strength		X	X	X
Timed Up and Go (Balance)		X	X	X
iMTA MCQ (health utilization)		X	X	X
MOS 36-item-short-form health survey (Health related quality of life)		X	X	X
EXPLANATORY OUTCOMES				
De Jong Gierveld 11-item loneliness scale		X	X	X
Engagement in meaningful activities scale		X	X	X
Self-Management Abilities Scale – Short Form2		X	X	X
Activities of Daily Life (Health Interview Survey)		X	X	X

Primary outcome

Timed Chair Stand (TCS)

In the TCS test, participants are asked to stand upright from a seated position in a chair (height 43 cm) with their arms folded across their chest and return to a seated position as many times as possible within 30 seconds (44). The TCS measures lower body strength and relates to important Activities of Daily Living (ADL) like walking up stairs and getting out of a chair or bed (44,45). The test is frequently used in older adults with fall-risk or frailty and is a reliable and valid instrument (Reliability: ICC 0.84 – 0.92, r = 0.93;) (46,47).

Secondary outcomes - Physical outcomes

Two Minute Step Test (TMST)

In the TMST participants need to march in place as many times as possible within two minutes, lifting the knees to a benchmark on the wall placed at the height of the exact middle between the patella and the iliac crest. The score is the number of times the right knee passes the benchmark in two minutes (44). The test measures aerobic capacity and relates to ADL e.g. walking in and around the house, climbing stairs and shopping. The test is a valid and sensitive alternative to the 6 minute walk test with a test-retest reliability coefficient of 0.90 (44,48).

Timed Up and Go (TUG)

The TUG test is measured by the number of seconds the participant needs to get up from a seated position, walk 8 feet (2.44 m), turn, and return to the seated position. The purpose of the TUG test is to assess functional mobility, more specific agility and dynamic balance. These are important in tasks that require quick displacement such as getting on and off public transport or getting up to answer the phone (44,49). The TUG has been proven to be a reliable The TUG has been proven to be a reliable (ICC ≥ 0.83) (50) and valid instrument to test functional mobility and balance in frail older adults (49,51,52).

Fatigue resistance grip strength test

In the Fatigue resistance grip strength, the Martin Vigorimeter is used to measure muscle fatigability (53). The subject is seated with both feet on the ground, the shoulder in neutral position and the elbow flexed in 90°. The participant holds the large bulb of the Martin Vigorimeter in the dominant hand by enclosing it on one side with the thumb and on the other side with four fingers. The participant is instructed to push the large pear as hard as possible and to maintain this force as long as possible (54). A good to excellent inter- and intra-observer reliability is observed (ICC values ranging from 0.77 to 0.94). Hand grip strength is seen as an indicator of overall body strength for frail older adults and other populations (53–55). Lower body strength leads to adverse health outcomes e.g. falls, disability and a higher risk of frailty (56).

Secondary outcomes - Cognitive outcomes

Montreal Cognitive Assessment (MOCA)

The MOCA is a global cognitive test developed to screen for mild cognitive impairment (57). It can also be used as a repeatable measure to evaluate treatment response. In our study the MOCA will be used to evaluate the effect of the intervention on the cognitive function. The total score for the MOCA ranges from 0 to 30 points assessing following domains: visuo-constructional/executive function skills, verbal memory, attention/working memory, language/executive function, conceptual thinking and orientation (58). The MOCA is a reliable and valid instrument demonstrating adequate to excellent internal consistency and construct validity; an adequate to excellent test-retest reliability, and adequate to excellent inter-rater and intra-rater reliability in community dwelling older adults (58). Feeney et al. observed a standard error of measurement of 1.5 points, with estimates of minimum detectable change of 4 points at 95% level (59). This is supported by Kopecek et al, indicating that changes of at least 4 points are necessary to assume a reliable change (60).

Trail Making test (TMT)

The Trail Making Test is a widely used neuropsychological test, originally part of the Army Individual Test battery (61) and then included in the Halstead-Reitan Neuropsychological Battery (62). The TMT consists of two parts, namely TMT-A and TMT-B. In TMT-A, the subject is asked to connect the encircled numbers (1 to 25) in consecutive order as quickly as possible. In TMT-B, encircled numbers and letters must be connected in a numerical and alphabetical order, but alternating between numbers and letters (1,A,2,B,3,C etc). The score represents the time to complete each part (63). TMT-A score is associated with measures of visual scanning, graphomotor speed, and visuomotor processing speed, while TMT-B performance reflects more executive functions such as working memory and inhibition control (64,65). The TMT has an adequate test-retest reliability (r = 0.70) (66) and has also demonstrated an adequate construct validity (62,65).

Rey Auditory Verbal Learning Test (RAVLT)

The Rey Auditory Verbal Learning Test (RAVLT) is a neuropsychological assessment designed by Rey (1958) to evaluate verbal episodic memory (67,68). A list of 15 words (LIST A) is presented orally, after which the participant is asked to recall as many words as possible. This procedure is repeated over 5 trials. Then the participant listens to an interference list of 15 different words (LIST B) and is asked to recall as many words as possible from list B. Immediately after the interference list, the participant should recall the words from LIST A again. After a 20-minute delay, the participant is once again asked to retrieve the words from list A (69). Outcomes measures used are the total number of words retrieved in 5 trials (=Sum trail 1-5), and the number of words recalled immediately and following the 20 min-delay. Different studies have demonstrated the construct, criterion, convergent and divergent validity (70–72), and reported a good internal consistency (Cronbach's alpha = 0.80) (71). When alternate forms are used the RAVLT is a reliable instrument for repeated neuropsychological assessment (73). The total score (= the sum of scores across the five acquisition trials) and the delayed recall score are the most reliable measures (69,73,74).

Secondary outcomes - Quality of Life evaluation

Medical Outcomes Study 36-Item Short Form Health Survey (MOS SF-36 / SF-36)

Health related Quality of Life will be measured by the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) (75). The SF-36 questionnaire is widely used to monitor general population health status, evaluate the efficacy of interventions, monitor health status in patients with chronic disease and determine the relative burden of various diseases (76). Also, a strong inverse association between (pre)frailty and quality of life in community-dwelling older people was detected by the SF-36 (77). The SF-36 includes a multi-item scale that assesses eight health concepts: limitations in physical activities due to health problems (1 item), limitations in social activities because of physical or emotional problems (2 items), limitations in usual role activities because of physical health problems (4 items), bodily pain (2 items), general mental health due to psychological distress or low well-being (5 items), limitations in usual role activities because of emotional problems (3 items), vitality due to low energy and fatigue (4 items) and lastly general health perceptions (5 items). In addition to the scale scores, a Physical Component Score and a Mental Component Score can also be calculated. The SF-36 is suitable, reliable and valid for use in frail older adults (78–80). The SF-36 also allows to calculate utilities (with 1 = perfect health and 0 = dead) allowing the calculation of Quality Adjusted Life Years (QALYs). People with mental or physical problems and/or aged over 75 may need assistance of an interviewer (81).

Secondary outcomes – Psychosocial outcomes

De Jong Gierveld 11-item loneliness scale (DJGLS)

The De Jong Gierveld loneliness scale is an appropriate scale for the assessment of loneliness among older adults (82). This scale consists of 11 items, 6 items are formulated negatively and 5 items are formulated positively. Participants can respond with 5 possible answers ("yes!", "yes", "more or less", "no", "no!"). Cut points can be used to classify people into not lonely, moderately lonely, or strongly lonely (83). The scale's developers note that this scale can be used as a unidimensional measure for overall loneliness or can provide information about two subscales: the emotional and social loneliness (83). Most studies confirm this two-factor structure (78,84) nevertheless some studies conclude that the scale is unidimensional (85,86). The 11-item De Jong Gierveld loneliness scale proved to be a valid and reliable instrument for overall, emotional and social loneliness with Cronbach's alpha >0.8 (78,83,87)

Secondary outcomes – Activities of Daily Living outcomes

Engagement in Meaningful Activities Survey (EMAS)

The Engagement In meaningful activities survey (EMAS) is a 12-item questionnaire with statements about the meaningfulness of activities in one's life (88). Each item can be scored with rarely (=1), sometimes (=2), usually (=3) and always (=4). The sum of the 12 items ranges from 12 to 48. People perceive their activities as low, moderate or high when they score respectively less than 29, between 29 – 41 or more than 41. Standard deviations for the EMAS in community-dwelling older adults are 36.4 (6.2). EMAS is a valid instrument, available in Dutch, with moderate reliability (89–91).

Self-Management Abilities Scale – Short Form2 (SMAS-S)

The Self-management abilities scale short form (SMAS-S) is a questionnaire designed to measure six self-management abilities in older adults based on five dimensions of well-being specified in the social productions function (SPF) theory (92,93). These consist of the ability to ensure multifunctionality, maintain variety in resources, keep a positive frame of mind, invest in resources for longer term benefits, self-efficacy and taking initiative (94). SMAS-S is a shorter version from the originally developed SMAS-30 and consists of 18 items (93,95) (94). Having a shorter instrument makes it more feasible to assess self-management abilities in a broader number of people, especially among frail older adults (95). SMAS-S has a good internal consistency, all subscales are .63 or higher (Cronbach's alpha) and total reliability of the SMAS-S is .90 (94).

National Health Interview Survey – (HIS)

Every five years a national Health Interview Survey (HIS) is held in Belgium. This cross-sectional population survey includes questions on health status, lifestyle, use of health services and socio-demographic characteristics and is administered in a representative sample of the Belgian population (5). In the ACTIVE-AGE@home study, questions regarding Activities of Daily Living (ADL) are adopted from the HIS.
The respondent is asked to indicate if they have difficulties performing daily activities and/or household tasks. The 7 daily activities and 7 household tasks are read out loud, answers are given by selecting a predefined 4-point scale ranging from 'no, no difficulties', 'yes, a few difficulties', 'yes, a lot of difficulties' of 'not possible to perform'. When a question is not applicable 'does not apply' can be noted as well.
Activities of Daily Living are getting in and out of bed, sitting down or standing up from a chair, getting (un)dressed, taking a bath or shower, washing your face or hands, eating with knife and fork or using the toilet. Household tasks are preparing meals, using the telephone, doing groceries, taking medication, doing light chores, doing heavy chores and handling money.

Secondary outcomes – Health economic outcomes

Trial and Model-based cost-effectiveness analyses will be conducted, expressed in incremental cost per QALY (quality-adjusted life year). Therefore, the MOS SF-36 (to enable calculation of the QALYs) and the iMTA-MCQ (to measure resource use) will be used. Volunteers and professionals also register time and expenses made for every training session in a field log.

iMTA Medical Consumption Questionnaire (iMTA-MCQ)

To measure medical costs experienced by frail older adults the Dutch version of institute for Medical Technology Assessment - Medical Consumption Questionnaire (iMTA-MCQ) will be used. The iMTA-MCQ is not related to a specific disease and measures medical consumption through 36 questions covering the past 3-month period. Formal (physician, dietician, …) and informal (family, …) care

services are registered as well as out-of-pocket expenses (96). For the purpose of this study one question was excluded from the iMTA-MCQ regarding the consultations with an occupational physician. Despite the widespread use of the iMTA-MCQ in older adults (97–101) and other populations (102–105) the validity and reliability of the iMTA-MCQ still needs to be established (96,103).

The model will be designed to associate the frailty at the end of follow up with further expected healthcare expenses beyond the duration of the trial.

During the intervention volunteers, professionals and participants are also required to fill in a log after each training session to signal adverse events and measure adherence, motivation and fidelity to the intervention protocol.

Adverse events reporting

An adverse event is an unexpected medical problem that occurs between pre-testing (0w) and follow-up testing (48w) of the intervention (106). These events can be mild, moderate, or severe, and may be linked to the intervention or not. Professional and volunteer trainers will be assigned to complete a log after every training session. This log will register the adverse events as well as intensity, feasibility, pleasantness and training progress. After the intervention (24 weeks), participants will be asked to note possible adverse events related to the intervention themselves.

Data management and analysis

Sample size

Physical capacity, measured by the timed chair rise (TCR) is the primary outcome of this study Based on the major clinically important improvement (i.e. 2) (107) (intervention group improves by 2 more rises from a seated position to a standing position than the control group), and a population standard deviation of 3.2, coming from our pilot study with process evaluation, a sample size of 54 participants per study-arm provides 90% power at the 0.05 level of significance. To allow for dropouts it is planned to recruit 65 participants per study arm, resulting in 195 frail community-dwelling older adults to be recruited.

Data management

The assessor will register data from baseline, T1 and T2 measurements in a secure web application for databases called REDCap. A detailed and pseudonymised Case Report Form (CRF) will be created per participant so blinded extraction and analysis can be carried out. The assessor will be adequately trained to collect and register sociodemographic data and administer the four physical performance tests and nine questionnaires.
Participants and the deliverers of the intervention (professional trainers, volunteers and volunteer coordinator) also register proceedings of every training session in their own pseudonymized log on REDCap. The CRF of the assessor and the logs of the participants and deliverers are strictly separated by disabled user rights. Participants and volunteers first register their findings in a paper log which is collected at 12 and 24 weeks. A designated and blinded researcher will then enter the data in REDCap.
All digital data will be securely stored in a secure cloud-based repository at Vrije Universiteit Brussel, which is encrypted and password-protected and can only be accessed by the Principal Investigator (PI) and/or its representatives. Offline copies of data and the informed consent forms will be separately archived in a locked cabinet in a room only accessible by the PI (access with key card).

The collected data from the target population applies to physical and mental health and, following the European law, it will be kept in secure storage for 25 years after final contact with the research participant. All other data will be kept for at least 5 years.

Quality assurance

An independent partner with no link to the collection of the data will be responsible for fidelity and quality assurance. The intervention groups will be monitored at different times throughout the study in both intervention arms (arm1: intervention provided by professionals and arm2: intervention provided by trained volunteers) by means of video-recordings and live observations. The recordings and the observations will be evaluated by two researchers independently from each other by completing a checklist with predefined quality indicators. The quality assurance plan is compiled out of three major steps: (a) developing a set of critical indicators of the intervention in a focus group (108) with the original developers, (b) collect data to measure the indicators by video recordings and life observations and (c) evaluate the indicators on a five-point Likert scale. When a score lower than 4 on the Likert-scale is marked, feedback will be given to the trainer.
Data regarding the quality assurance will be securely stored in a secure cloud-based repository at University of Ghent, which is encrypted and password-protected and can only be accessed by the responsible of the quality assurance. Offline copies of data will be archived in a locked cabinet in a room only accessible by the responsible researcher at University of Ghent (access with personal key).

Statistical analysis

Before statistical analysis of primary outcomes, secondary outcomes and explorative outcomes, data will be coded to permit blinding to group allocation, afterwords data will be cleaned.
The effect of the intervention over time on outcome measures will be investigated with intention-to treat analyses. For the primary outcome variable, analysis of covariance (ANCOVA) will be used with the measurement at 24-weeks and at 48 weeks as outcome and baseline values as covariates to provide an unbiased estimate of the mean group difference. Comorbidity will be considered into the analysis as a covariate. Mean differences will be reported with 95% Confidence Intervals. P values less than .05 will be considered statistically significant, and all the tests will be 2-sided. A similar approach will be applied for the other study outcomes that will be treated as continuous variables.

The health economic evaluations concern incremental analyses in terms of incremental costs over incremental effects between the alternatives. Therefore cost-utility analyses will be conducted. The thresholds suggested by the Belgian Health Care Knowledge Centre will be applied, expressed in Gross Domestic Product (GDP) per capita ≈40,000€/Quality Adjusted Life Year (QALY). This threshold represents a willingness-to-pay, as society, for one adjusted QALY gained. There is, however, no "hard" cut-off in determining interventions to be cost-effective or not. The investigators will conduct threshold analyses which look for a tipping point for one or more specific input parameters that lead to an incremental cost-effectiveness ratio above or below the threshold. Additionally, probabilistic sensitivity analyses will be conducted and presented in cost-effectiveness acceptability curves indicating at each possible threshold the likelihood whether one of the intervention arms is cost-effective compared to the alternative. Both trial and model based economic evaluations will be made.
In the trial-based economic evaluation, the effects are expressed in utilities, derived from the national values of the MOS-SF-36. QALYs will be calculated using the area under the curve method. The cost-effectiveness of the intervention will be expressed in incremental cost per QALY. The incremental cost per QALY will be calculated as a ratio of (Expected Cost ACTIVE-AGE@home - Expected Cost standard care) / (Expected Outcome ACTIVE-AGE@home - Expected Outcome standard care). The robustness of the results will be analyzed by probabilistic sensitivity analyses on the cost as well as on the outcome. Bootstrapping with replacement will be employed utilizing @Risk

and MS Excel®, using a minimum of 1000 iterations to obtain 2.5% and 97.5% percentiles of the incremental cost-effectiveness ratio (ICER) distribution. All bootstrapped ICERs will be presented on a cost-effectiveness plane to determine the robustness of the ICER, and to determine the probability that ACTIVE-AGE@home is cost-effective at various willingness-to-pay thresholds. A cost-effectiveness acceptability curve will be used to depict the probabilities of acceptable ICERs.
In addition to the trial-based evaluation a model based evaluation will be performed to account for the expected costs and health outcomes in both intervention and control groups beyond the follow-up period of the trial. A probabilistic Markov model will be developed compliant to the commonly used guidelines. The rationale of the model is based on the association between frailty and healthcare resources and cost, and on the expected outcome of reduced frailty in the intervention arms compared to the control arms. The investigators assume a cycle of 1 year in the model and applying a lifetime horizon. Lifetime incremental costs and QALYs will be the input for the ICER calculation. Discount rates of 3% for costs and 1.5% for utilities will be applied, which is in line with the Belgian guidelines. Non-parametric bootstrapping will be applied for both costs and outcomes to test the robustness of the results. These iterations will be presented in cost-effectiveness planes. Probabilities to be cost effective for the different willingness-to-pay thresholds will be presented in cost-effectiveness acceptability curves.

ETHICS AND DISSEMINATION

The procedures of this study were reviewed and approved by the Medical Ethics Committee (MEC) of UZ Brussel (O.G. 016), Reflectiegroep Biomedische Ethiek, Laarbeeklaan 101, 1090 Brussels on 17th of May 2023 (B.U.N. 1432023000089). Modifications to the study or intervention protocol will require a formal amendment by the MEC. High priority is given to safety principles and ethics during this study. Professionals and volunteers need to adhere to an ethical code of conduct during the intervention. All participants and volunteers in this study are covered by a 'no fault liability' insurance.

The research team will submit a yearly progress report regarding the scientific progress, financial plan and study results to the sponsor, being the Research Foundation Flanders (FWO). The findings of this study will be published in peer-reviewed journals and presented at conferences. Meanwhile, the results will be disseminated to the advisory board.

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Author contributions

All authors (DV, EDS, JT, EDK, EV, LA, DB, WP, DVdV, SL and PDV) contributed to the development of the study and reviewed, commented and edited the manuscript and have read and agreed upon the submitted manuscript. DV is study and volunteer coordinator and conceived the manuscript with support of EDS who is assessor. JT and EDK recruit participants, deliver the intervention and will be involved in analysis. LA, DB, WP, DVdV, SL and PDV were involved in the methodological design and planning of the study. WP is the study statistician who designed and wrote the analysis plan together with LA for health economics. DVdV and EV wrote the quality assurance plan. PDV and DVdV developed the goal-setting protocol and the motivational interviewing. DB supported the design of the intervention. SL supervises ethical and safety aspects in the study. PDV is the lead principal investigator (PI) and developed the conceptual idea of the program and has overall responsibility for the design and conduct of the study.

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Competing interests

None declared.

Patient and public involvement

The pre-trajectory of this study was based on the 'British Medical Research Council guidance' for the development and evaluation of complex interventions (1). This resulted in a strong patient and public involvement in the development of the multidmodal exercise program: ACTIVE-AGE@home.

Community dwelling frail older adults (n=25) were involved in the design of the program through in-depth-interviews to identify motivators and barriers for PA. Feasibility of the program was later tested in a pilot

study with 71 frail older adults. Finally, long term reminiscence and effect were questioned in a qualitative follow-up study with 50 participants.

Public partners and healthcare professionals were continuously involved through an advisory board. They provided feedback on the design, feasibility and implementation possibilities of the program and concurring studies. Recently, members of the advisory board were questioned in an online questionnaire and two focus groups before the start of the ACTIVE-AGE@home study.

Public partners and healthcare professionals will be involved in the cocreation of educational materials and a guideline for implementation of ACTIVE-AGE@home in practice. Participants will be consulted on the text, photos and videos used in these materials.

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Data availability statement

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Supplemental material

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Attachments

Attachment 1: Informed Consent Forms

Attachment 2: Table 3: TIDIER: Template for Intervention Description and Replication

Attachment 3: Figure 1: Enrolment in the study and randomisation

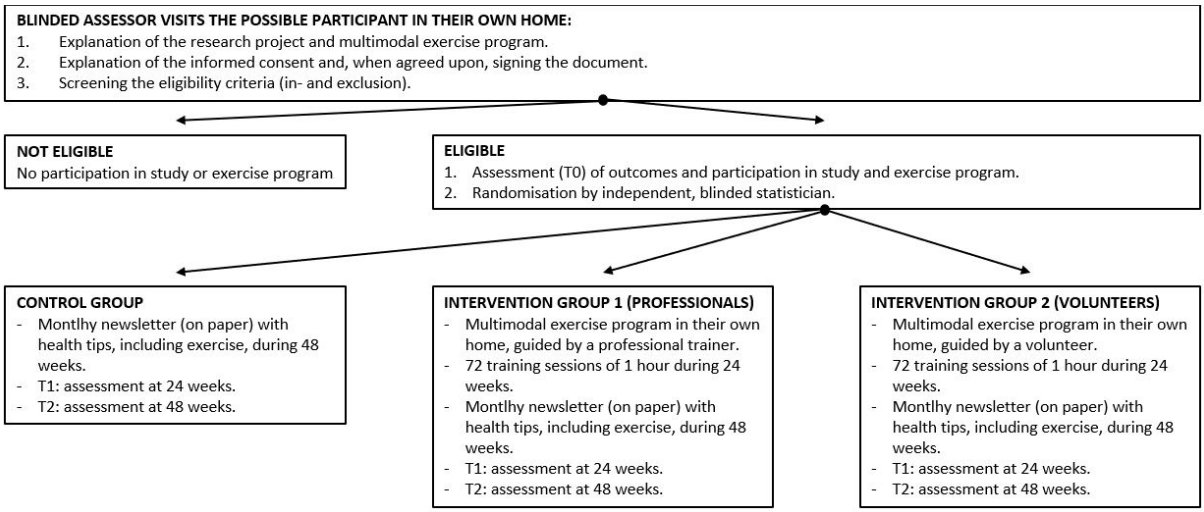

Figure 1: Enrolment in the study and randomisation in three groups.

The TIDier: Template for Intervention Description and Replication		
Brief name	**ACTIVE-AGE@home: multimodal exercise program for community dwelling frail older adults**	
Why	Between 2020 and 2050, the world's population aged 80 years and over will triple, drastically increasing the prevalence of frailty and associated healthcare costs (Hoogendijk et al., 2019; WHO, 2020; Eurostat, 2023). Multimodal exercise programs have proven to be an ideal countermeasure for frailty but the current Flemish standard of care does not include this (de Labra et al., 2015; Izquierdo et al., 2021; Sadjapong et al., 2020) (Fret et al., 2019). The ACTIVE-AGE@home program is expected to have positive effects on physical functioning, cognition, loneliness, self-management, subjective health, QOL, meaningful activities and health care utilization of community dwelling frail older adults.	
What	The ACTIVE-AGE@home intervention was developed according to the British Medical Research Council guidelines (Craig et al., 2013) and contains **five innovative aspects:** 1) **Personal goalsetting** (linked to meaningful individual and social activities) and **motivational interviewing** 2) **Structured multimodal and functional exercises** based on daily activities (e.g. walking, cooking, playing with grandchildren) in line with evidence-based training principles (Bull et al., 2020; de Labra et al., 2015; Izquierdo et al., 2021; Sadjapong et al., 2020) 3) **Cognitively demanding activities** (e.g. counting, calculating, remembering, naming, recognizing, speaking and/or responding quick and correctly) are added while performing the exercises. 4) The program is **homebased** and uses only materials available in the homes of participants (e.g. grocery bags, chairs, towels). 5) **Personal guidance** is offered by a professional or a volunteer and a personal referral is made to relevant individual or group PA possibilities at the end of the program.	
Who provided	In condition one, the exercise program is supervised by **<u>professionals</u>** with a bachelor- or master's degree and specific knowledge and experience regarding PA interventions and (frail) older adults e.g. physiotherapists, occupational therapists, personal trainers or physical education teachers.	In condition two, the exercise program is supervised by **<u>volunteers</u>** e.g. informal caregivers, students, (parttime) working people or pensioners. The participants can suggest their own informal caregiver or they can be matched with a volunteer. A relevant background is not mandatory.
	The professionals and volunteers will receive a 8h training course and 4 hours (3x 1h20m) on the job training to gain more knowledge and practice regarding ageing, frailty, training and safety principles and goalsetting and motivational interviewing in the ACTIVE-	

<table>
<tr><td></td><td>AGE@home program. The volunteers are also coached by a professional and receive supervision/support during 7 of 72 training sessions in the home of the older adult. Professionals do not receive additional coaching.

The professionals and volunteers are equipped with educational tools to master their role as a trainer:
1. Booklet/binder containing charts with the different training sessions.
2. Three flowcharts to determine the right intensity of the exercises. (strength, aerobic endurance, balance)
3. An online training course.
4. Instructional videos.
5. A quicksheet with dos and don’ts during training.
6. Motivation cards for goalsetting and evaluation + a step-by-step interview guide to apply the CLEVER goalsetting method.
7. Log with evaluative and motivational questions for the participant regarding the intensity, feasibility and pleasantness.</td></tr>
<tr><td></td><td>The professionals and volunteers need to show sufficient knowledge and application of the evidence based safety and training principles after the training course (pass / fail).</td></tr>
<tr><td>How</td><td>The training sessions are given one to one.</td></tr>
<tr><td>Where</td><td>Training sessions are given one to one at the participant's home.</td></tr>
<tr><td>When, how much</td><td>The frail participants are visited three times per week during 24 weeks, resulting in 72 sessions in total. Each session is 1 hour in duration. A session consists of 10 minutes warming-up, 45 minutes of exercises and 5 minutes of cooling-down. There are 8 to 9 exercises in each training session. The workload will increase weekly with approximately 10%. There are three main periods of eight weeks where workload and complexity of exercises gradually increases within the period. After eight and sixteen weeks new exercises will be introduced but at a lower workload and with less complexity in the first week of that period for supercompensation effects. Three goalsetting conversations, based on the CLEVER-protocol (De Vriendt et al, 2019) will be held in the first and second week of intervention and 6 motivational interviews will be spread out over the remaining 22 weeks. Goalsetting or motivational interviewing takes about 10-20 minutes per session and replaces 2 or 3 exercises.

<table>
<tr><th></th><th>Volume/intensity</th><th>Progression</th></tr>
<tr><td>(1) Strength exercises:</td><td>8-12 repetitions of every exercise. Strength exercises are performed at 80% of the 1RM</td><td>Low complexity
- Going from 1-3 sets</td></tr>
</table>
</td></tr>
</table>

ACTIVE-AGE@home, TIDIER table, 02/07/2024

	(Borg scale between 15-18), power exercises at 40-75% of 1RM.	- Increase repetitions - Change position - Include more power exercises - Combine exercises High complexity: - Combining exercises to ADL activity - Dual tasking
(2) **Aerobic exercises:**	Aerobic exercises are performed at a score of 12-14 on Borg scale.	Low complexity: - Increase duration: Going from 5-10 minutes to 15-30 min - Increase pace - Add small weights - Combine exercises High complexity: - Combining exercises to ADL activity - Dual tasking
(3) **Balance exercises:**	1-2 sets of exercises emphasizing static and dynamic postures Balance intensity scale (BIS): score 5: maximal effort	Low complexity: - Going from 1-2 sets - Decrease base of support - Decrease sensory input - Perturbations - Combine exercises High complexity: - Combining exercises to ADL activity - Dual tasking
(4) **Flexibility exercises**	Dynamic flexibility: 5-10 repetitions Static flexibility: 30s Feeling of stretch, not feeling pain	Low complexity: - Going from 1-2 sets - Combine exercises High complexity: - Combining exercises to ADL activity - Dual tasking

ACTIVE-AGE@home, TIDIER table, 02/07/2024

	(5) **Coordination exercises/ fine motor skills**		Low complexity - Going from 1-2 sets - Combine exercises High complexity - Combining exercises to ADL activity - Dual tasking
Tailoring	To cater to the **individual needs of the frail older adults** and the environment they live in, functional exercises and materials will be tailored and adjusted, when necessary, but with respect to the evidence-based training principles. Every 4 weeks the participants individual level of difficulty of the exercises will be determined. Progression to a next level of difficulty will be based on: – Participant's ability to complete 12 repetitions for a given strength exercise – Quality of the exercise performance – Level of effort: 12-14 (for aerobic exercise) and 15-18 (for resistance training) out of 20, a Borg Rating of Perceived Exertion pr a score 4 or 5 on the BIS-E. – The objective checklist of signals that the participant gives when he/she trains at correct intensity The training schedule is made **meaningful and goal oriented** through the following strategies: - At the end of each training session, the participant chooses the last exercise according to his/her goal. - Adapt exercise to meaningful activity: object, space, … - Remind the participant of their personal goal		
How well planned (adherence)	The **adherence or fidelity** of the participants will be monitored at different times throughout the study in both intervention arms (arm1: intervention provided by professionals and arm2: intervention provided by trained volunteers) by means of video-recordings and live observations. The recordings and the observations will be evaluated by two researchers independently from each other by completing a checklist with predefined quality indicators. Professionals and volunteers are **adequately trained** to implement the ACTIVE-AGE@home program and use the accompanying tools for adherence e.g. intensity flowcharts, goalsetting and motivational interviewing guide and personal physical activity referral scheme.		

BMJ Open

Effectiveness and cost-effectiveness of a Home-based Functional Exercise Program for Community Dwelling Frail Older Adults, ACTIVE-AGE@home, Provided by Professionals and Volunteers: Protocol of a Pragmatic Randomised Controlled Trial

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TITLE:

Effectiveness and cost-effectiveness of a Home-based Functional Exercise Program for Community Dwelling Frail Older Adults, ACTIVE-AGE@home,Provided by Professionals and Volunteers: Protocol of a Pragmatic Randomised Controlled Trial

Dimitri Vrancken [1][2], Elke De Smedt [7], Jade Tambeur [1], Emma De Keyser [3], Elise Vanbeuren [4], Lieven Annemans [6], David Beckwée [1][3], Wim Peersman [4][5], Dominique Van de Velde [4], Siddhartha Lieten [1][7], Patricia De Vriendt [1][2]

Strengths and limitations:

+ This is the first robust pragmatic RCT with economic evaluation that entails a guided, homebased multimodal exercise program (ACTIVE-AGE@home), consisting of personal goalsetting, motivational interviewing, exercises based on daily activities and cognitive challenges, to counteract adverse health outcomes in community dwelling frail older adults.
+ The innovative ACTIVE-AGE@home intervention was developed according to the British Medical Research Council guidelines [1] and had a strong patient and public involvement.
- The sample size of community dwelling frail older adults aged 70 or over (n=195) might cause a challenge for the researchers and recruitment partners.
- Participants will know if they participated in the intervention or the control group, potentially jeopardizing the single blinded assessment during post- and follow up measurements.

Abstract

Between 2020 and 2050, the world's population aged 80 years and over will triple, drastically increasing the prevalence of frailty and associated healthcare costs. Multimodal exercise programs have proven to be an ideal countermeasure for frailty but the current Flemish standard of care does not include them. The purpose of this study is to investigate the effect of the homebased exercise program for frail community dwelling older adults (>70 years), ACTIVE-AGE@home, on frailty associated outcomes, when delivered by professionals or volunteers, as well as its cost-effectiveness. A pragmatic randomised controlled trial will be conducted. Participants will be randomized into three parallel groups using permuted block randomization. There will be two intervention groups: in one group the intervention is delivered by professionals with a bachelor or masters' degree in physiotherapy, occupational therapy and/or physical education and in the other by trained volunteers. Both groups will be compared to a control group receiving usual care. Participants (n=195) are community-dwelling *physically* frail older adults (>70 years), as defined by Fried et al. (2001). The intervention is a 24-week program that consists of three one-hour visits per week and contains aerobic, strength, balance, flexibility, coordination and dual tasking exercises, accompanied by goalsetting and motivational interviewing. The Timed Chair Stand (TCS) test is the primary outcome. Functional ability, cognition, loneliness, self-management, health related Quality of Life, health care utilization and meaningful activities will be measured in all groups at 0, 24 and 48 weeks. Time and expenses invested by professionals or volunteers will be kept in diaries for trial and model-based cost-effectiveness analyses, expressed in incremental cost per QALY (quality-adjusted life year). The model will be designed to associate the frailty at the end of follow up with further expected healthcare expenses beyond the duration of the trial. Statistical analysis will be blinded to group allocation and outcome assessors will be blinded to the maximal extent possible.

Ethics and dissemination

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Ethics approval has been obtained from the Medical Ethics Committee (MEC) of UZ Brussel (O.G. 016), Peer reflection group Biomedical Ethics, Laarbeeklaan 101, 1090 Brussels. Results will be disseminated in publications and other relevant platforms.This study was registered at Clinicaltrials.gov the 6th of July 2023 and posted on the 14th of July 2023 after National Library of Medicine (NLM) quality control (QC) review. Registration details: NCT05946109

INTRODUCTION

The population is ageing rapidly. It is expected that worldwide between 2020 and 2050, people aged >60 years will increase with 50% whereas people aged >80 years will triple [1]. In Flanders 20,9% of the population is 65 years or older, approaching the European average of 21,1% [2]. Older adults aged 85 or older make up 3,2% of the Flemish population, scoring 0,2% above European average. In addition, Flemish women and men only experience 64.4 and 64.8 healthy life years respectively [3]. One of the predetermining factors for the discrepancy between healthy life years and total life expectancy is the high prevalence of frailty in Flanders (21,5%)[4]. The onset of frailty rises with increasing age, independently of the assessment instrument [2]. Amongst community-dwelling adults aged 80 or over, an even higher prevalence of frailty is observed in populations with specific diseases or chronic conditions [5]. Since frailty has a severe impact on Quality of life (QOL) and health-care utilization, effective interventions should be developed and implemented [6].

Frailty is a clinically recognizable state in older people, resulting from age-related declines in physiological reserve and function across multiple organ systems [7], [8]. Frailty is, however, not inevitable or irreversible. Research has shown that people can move in and out of frailty status over time due to timely health and care interventions [6], [9]. In a systematic review of Sobhani et al. (2021), 21 conceptual and 59 practical definitions of frailty were identified but no consensus about one definition was reached. The authors found that frailty is characterized by physical, cognitive, psychological, nutritional and social dimensions. They also suggested to use the operationalisation which is best aligned with the goal of the research and the characteristics of the target population. In research involving community dwelling older adults, frailty is mostly operationalised in two ways: the unidimensional physical Fried Frailty Phenotype [10] and the multidimensional Rockwood Frailty index [11]. The Fried Frailty Phenotype is defined as a clinical syndrome in which three or more of the following criteria are present: unintentional weight loss, self-reported exhaustion, weakness (grip strength), slow walking speed and low physical activity (11). In line with the primary outcome for the ACTIVE-AGE@home exercise program (e.g. chair stand test) and the target population of older adults with physical frailty, the researchers adopted the Fried Frailty Phenotype for this study.

Regardless of the definition used, frail older adults struggle to cope with (minor) stressors like new medication, infection, illness or surgery and experience adverse health outcomes such as diminished mobility, falls, increased disability in activities of daily living (ADL), low performance of meaningful activities, loneliness, cognitive disorders, hospitalization, admission to a residential care centre and premature death [12], [13], [14], [15], [16]. Also, several studies pointed out that the average additional costs associated with frailty when controlled for ageing and multimorbidity range from 1.500 to 5.000 euro per person per year [17], [18], [19]. Stabilizing or reversing frailty has proven to lower hospital and ambulatory care uses [20].

Physical activity (PA) is the most effective intervention to counter frailty [21], [22]. A network meta-analysis reviewed 21 RCT's with PA interventions and concluded a decrease in frailty compared to placebo or usual care (SMD -0.92, 95% CI -1.55, - 0.29) [23]. PA has favorable effects on all

dimensions of frailty and provides fundamental improvements in risk and fear of falling, mobility, balance, functional ability, muscle strength, body composition and frailty status [24]. Recent literature also provides strong evidence for counteracting depressive symptoms, cognitive impairment and chronic diseases [25]. There is also evidence of a dose response relationship between higher intensities of PA and lower levels of frailty [25], [26]. WHO stipulates in their PA guidelines (2020) that older adults with or without frailty, should participate in moderate and/or high intensity aerobic PA for at least 75 (when high) and 150 (when moderate) minutes per week, strength training on two occasions per week and functional exercises (strength, flexibility and balance) on three occasions per week [27]. For frail older adults multicomponent exercise programs are most appropriate as a preventive and curative measure, including resistance and power training (e.g. lifting weights), functional exercises (e.g. standing from a chair), balance and gait exercises (e.g. standing on one leg, line walking)[24], [25], [28].

Unfortunately, older adults often do not meet the requirements for health enhancing PA. According to the 2023 Health Interview Survey (HIS) in Flanders (Belgium), only 34,1% of the population between the ages of 65 and 74 engage in 150-minute moderate-intensity aerobic PA per week. For people aged over 74 this number drops drastically to 15,5%. In addition, more than 92% of the Flemish older adults do not perform exercises to improve muscular strength twice or more per week [4]. The barriers for older adults to engage in PA are related to their health situation, fear of falling, specific individual PA preferences and physical and social environment [29]. To motivate older adults, the emphasis should be brought to the health benefits of PA, the gains in functional capacity and long-lasting independence, lowering costs, eliminating the need for transport and offering personal guidance [29], [30].

To counter PA barriers for frail older adults the home based multimodal exercise program ACTIVE-AGE@home for frail community dwelling older adults was developed according to the subsequent steps of the British Medical Research Council (MRC) guidance for the development and evaluation of complex interventions [31] (the development of the intervention will be published in peer reviewed literature in the near future). The program offers basic functional exercises and connects to meaningful activities, goalsetting and motivational interviewing. The exercises from the ACTIVE-AGE@home program are based on daily activities like walking, cooking, playing with grandchildren and have been turned into structured exercises in line with evidence-based training principles [24], [25], [27], [28]. In this study, the program can be delivered by professionals experienced in PA or volunteers. Involving volunteers (e.g. friends, family, informal caregivers, neighbors, students, pensioners, …) holds a cost saving potential for the older adult and society. A systematic review in 2021 [32] showed that delivery of an exercise program by trained volunteers is feasible and effective in lowering frailty in community dwelling older adults.

The first aim of this study is to investigate the effect of the multimodal homebased exercise program ACTIVE-AGE@home on frailty associated outcomes for community dwelling frail older adults when provided by professionals (study arm 1) or trained volunteers (study arm 2) compared to usual care (study arm 3). The primary outcome is the Timed Chair Stand (TCS) and secondary outcomes are: physical functioning (e.g. Two Minute Step Test (TMST), Timed Up and Go (TUG), Fatigue resistance grip strength test), cognition (e.g. Montreal Cognitive Assessment (MOCA), Trail Making test (TMT), Rey Auditory Verbal Learning Test (RAVLT)), loneliness (e.g. De Jong Gierveld 11-item loneliness scale (DJGLS)), self-management (e.g. Self-Management Abilities Scale – Short Form2 (SMAS-S), National Health Interview Survey – (HIS)), health related Quality of Life(e.g. Medical Outcomes Study 36-Item Short Form Health Survey (MOS SF-36 / SF-36)), meaningful activities (e.g. Engagement in Meaningful

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Activities Survey (EMAS)) and health care utilization (e.g. iMTA Medical Consumption Questionnaire (iMTA-MCQ))

The second aim is to perform trial and model-based cost-effectiveness analyses, expressed in incremental cost per QALY (quality-adjusted life year), to associate frailty at the end of follow up with further expected healthcare expenses beyond the duration of the trial.The researchers hypothesize that the intervention will have a significant effect on primary outcome (i.e. 2 more rises from a seated position compared than the control group) and secondary outcomes of frail community dwelling older adults, but that the costs of the intervention will be lower when delivered by volunteers compared to professionals.

METHOD

Design

Therefore, a pragmatic randomised controlled assessor-blinded trial will be conducted. The RCT comprises two intervention groups: in one group the intervention is delivered by professionals with a bachelor or master's degree in physiotherapy, occupational therapy and/or physical education (e.g. personal trainers) and in the other by trained volunteers. Both groups will be compared to a control group receiving usual care. The duration of the intervention is 24 weeks and assessments will be done before and after the intervention (at 24 weeks) and at 48 weeks. In addition, trial and model-based cost-effectiveness analyses will be conducted, expressed in incremental cost per QALY (quality-adjusted life year). The trial is designed in line with The Geriatric ICF Core Set reflecting health-related problems in community-living older adults aged 75 years and older without dementia [33]. The template for intervention description and replication (TIDieR) will be used for detailed description of the intervention [34] and the SPIRIT statement will be followed for reporting on the RCT [35]. The start of the study was 04th of July 2023 and the planned end date will be at the 30th November 2026. These dates align with the start of the recruitment of patients and the end of T2 measurements.

Participants

Community dwelling frail older adults, aged 70 or more, should be frail according to the Fried frailty phenotype [10], defining frailty as the presence of three or more of the following five criteria: unintentional weight loss, weakness, exhaustion (low energy level), slowness (slow gait) and low PA level (see table 1). Because the exercise program has been developed and tested in a frail population without serious comorbidities e.g. dementia, Parkinson or Multiple Sclerose, these are listed as exclusion criteria. Moreover, the volunteer trainers are often inexperienced and laypeople in the field of older adults, exercise or medical background.

Table 1: Description of the Fried Frailty criteria and other exclusion criteria

Inclusion **Fried Frailty criteria** [10]		
Criteria	**Evaluation and Cutoff**	**Score**
Weight loss	*'In the last six months, have you lost more than 4,5kg unintentionally?'* • No • Yes	 No = 0 Yes = 1

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Weakness	Grip strength using the Martin Vigorimeter (with the dominant hand, average of 3 measures) Cutoff • Men : 71kPa • Women : 42kPa	Normal grip strength = 0 Lower Grip strength = 1
Exhaustion (low energy level)	Two statements from the CES-D Depression Scale *'I felt that everything I did was an effort'* *'I could not get going'* How often in the last week did you feel this way? • Rarely or none of the time = 0 • Some or little of the time = 1 • A moderate amount of time = 2 • Most of the time = 3	Score 0 or 1 on both statements = 0 Score 2 or 3 on either of the two statements = 1
Slowness (slow gait)	Gait speed over 4,5 meter Cutoff • Men ≤173 cm → ≥ 7 seconds >173 cm → ≥ 6 seconds • Women ≤159 cm → ≥ 7 seconds >159 cm → ≥ 6 seconds	Normal gait speed = 0 Low gait speed = 1
PA	*"How often do you engage in activities that require a low or moderate level of energy such as gardening, cleaning the car, or going for a walk?."* • More than once a week • Once a week • One to three times a month • Hardly ever or never	More than one a week or once a week = 0 One to three times a month or hardly ever or never = 1
Exclusion		
Life expectancy less than 12 months Receiving oncologic treatment Diagnosed with Parkinson or Multiple Sclerosis Having had a stroke in the preceding 6 months Participated in exercise therapy in the preceding 6 months Contra-indications for exercise as established by a physician Cognitive impairment is present (Mini Mental State Examination score <23/30) [36] Unable to understand instructions in Dutch		

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Recruitment

To recruit frail community dwelling older adults the TIBaR model of recruitment for 'hard-to-reach' older people for research will be adopted [37] (see table 2). This model consists of four basic principles: providing trustworthy companions (T), offering meaningful experiences or incentives (I), removing barriers (B) and being responsive to needs of the older adults (R). Flemish older adults will be recruited through local newspapers, pharmacies, general practitioners, (home) nurses, occupational therapists, informal caregivers and local government. Flyers and e-mails will be distributed but personal contact with local professionals and the target population is preferred.

Table 2: TIBaR model of recruitment for hard-to-reach older adults [37]

TIBaR model of recruitment in ACTIVE-AGE@home			
Build up trust	Offer incentives	Identify individual barriers	Be responsive
Trusted environment (e.g. Local service centers, general practitioners office, …) Warm referral: tailored information. Collaboration with existing projects. Primary care providers.	Making participation meaningful Offer tangible materials (e.g. flyer, exercise book, …). Enable social interaction	Interviews/ conversations with (possible) participants Interviews/Focus groups with healthcare providers Interviews/ conversations with family, friends, local residents…	Plan intake conversations and practice sessions together. Offer a confidant. ACTIVE-AGE@home telephone always available.

Screening and enrolment

After registration the blinded assessor contacts the older adult to make an appointment for the eligibility screening and, if eligible, baseline assessment at the home of the participant. Before the screening the informed consent form (ICF) is explained. If older adults agree and written consent is given, eligibility screening can start. Older adults who are eligible will be randomized within one week of baseline assessment and intervention starts within two weeks. Enrolment in the study and randomisation in three groups is visualised in Figure 1.

See attachment 3

Figure 1: Enrolment in the study and randomisation in three groups.

Randomisation and blinding

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A computer algorithm will be used to generate the random allocation sequence. Participants will be randomized in a 1:1:1 ratio, using permuted block randomization with blocks of variable sizes (3-6-9) into one of the three parallel groups. Randomization will be done centrally by an interactive web response system (IWRS). Once the participants are found eligible for the trial, they can be randomized via the IWRS by the Principal Investigator (PI) or qualified person to whom this study task has been delegated. This will generate a unique study randomization number and the treatment arm label (A professionals, B volunteers, C control) to which the participant is randomized. An accountability log with the corresponding label will be kept by the PI or delegated person to ensure that allocation was successfully performed. Participants will be scheduled to receive their randomisation within one week of eligibility assessment.

The statistician will be blinded to group allocation. Outcome assessors will be blinded to the maximal extent possible. Participants will of course be aware of the intervention received. Regarding this, participants will be asked not to communicate with the assessors about the intervention received. The professional or volunteer supervisors will not be involved in the assessments, and vice versa.

Interventions

In this pragmatic randomised controlled trial two intervention groups will be compared to a control group receiving usual care. In one intervention group the intervention is delivered by professionals and in the other by trained volunteers. In supplemental table 3 the ACTIVE-AGE@home program is elicited through the Template for Intervention Description and Replication (TIDier) [34]

Table 3: TIDieR - Template for Intervention Description and Replication ACTIVE-AGE@home [34]

See attachment 2

ACTIVE-AGE@home is a multimodal, homebased exercise program for frail community dwelling older adults, delivered by professionals or volunteers. The program is based on five innovative aspects. First, the program entails personal goalsetting (linked to meaningful individual and social activities) and motivational interviewing during the entire program [38]. Second, functional exercises were built out of daily activities (e.g. walking, standing from a chair, carrying objects, …) and aligned with evidence-based training principles to effectively improve muscle strength, aerobic endurance, balance, flexibility, motor ability, coordination and cognition [25]. Third, cognitive challenges (e.g. dual tasking) are added to improve executive functions and memory. Seven types of cognition (mental tracking, working memory, long term memory, recognition memory, verbal fluency, executive functioning, reaction time) are stimulated by counting, calculating, remembering, naming, recognizing, speaking and/or responding quick and correctly while performing the exercises [39]. Fourth, the program is delivered at the homes of the older adults and uses only those materials at hand such as grocery bags, chairs and towels [29]. Fifth, personal guidance is offered by a professional or a volunteer throughout the entire program to enhance motivation and safety [32]. A personal referral is made to relevant individual or group PA possibilities at the end of the program.

The frail participants are visited three times per week during 24 weeks, resulting in 72 sessions in total. Each session is 1 hour in duration. A session consists of 10 minutes warming-up, 45 minutes exercises and 5 minutes of cooling-down. There are 8 to 9 exercises in each training session. The workload will increase weekly with approximately 10%. There are three main periods of eight weeks where workload and complexity of exercises will be gradually increased within the period. After eight

and sixteen weeks new exercises will be introduced but at a lower workload and with less complexity in the first week of that period for supercompensation effects. Three goalsetting conversations, based on the CLEVER-protocol [40] will be held in the first and second week of intervention and 6 motivational interviews will be spread out over the remaining 22 weeks. Goalsetting or motivational interviewing takes about 10-20 minutes per session and replaces 2 or 3 exercises.

Study arm 1: professional led program

The exercise program is supervised by professionals with a bachelor- or master's degree and specific knowledge and experience regarding PA interventions and (frail) older adults e.g. physiotherapists, occupational therapists, personal trainers or physical education teachers. The professionals will receive an 8h training course and 4 hours (3x 1h20m) on the job training to gain more knowledge and practice regarding ageing, frailty, training and safety principles and goalsetting and motivational interviewing in the ACTIVE-AGE@home program. The professionals need to show sufficient knowledge and application of the evidence-based safety and training principles after the training course (pass / fail).

Study arm 2: volunteer led program

The exercise program is supervised by volunteers e.g. informal caregivers, students, (parttime) working people or pensioners. A relevant background is not mandatory. The volunteers will receive an 8h training course and 4 hours (3x 1h20m) on the job training to gain more knowledge and practice regarding ageing, frailty, training and safety principles and goalsetting and motivational interviewing in the ACTIVE-AGE@home program. The volunteers need to show sufficient knowledge and application of the evidence-based safety and training principles after the training course (pass / fail). During the remaining 23 weeks a coordinator will accompany the volunteer on seven training sessions in the home of the older adult, to provide coaching and support.

Study arm 3: care as usual

In the third group, frail older adults receive care as usual in Flanders. PA and lifestyle interventions are not part of the standard frailty management in Flanders for community dwelling frail older adults [4], [41]. Only when they are admitted to a geriatric department or a residential care facility a structural screening, evaluation and possibly physiotherapy is provided. In some cases, the general practitioner will detect onset of frailty due to underlying comorbidities and prescribe physiotherapy [42]. Local government, health- and care services or health insurance companies promote general health enhancing activities for older adults e.g. healthy foods, exercise and sometimes also fall prevention. Utilization of these services by frail older adults are limited and provide challenges such as accessibility (e.g. location) and affordability (e.g. costs), [43].

Regardless randomization in the intervention or control groups, all participants in the three arms will receive the same monthly newsletter with tips and tricks to obtain good health in older age.

Outcome measures and data collection

Outcome measures

Outcomes were chosen in line with WHO's vision on Healthy Ageing (functional ability and intrinsic capacity) [44], [45] and the Geriatric ICF Core Set reflecting health-related problems in community-living older adults aged 75 years and older without dementia (Spoorenberg et al., 2015). Older adults will receive assessment of primary, secondary and explanatory measures at baseline (T0), after the

intervention of 24weeks (T1) and at 48weeks (T2). A blinded assessor will administer 4 physical performance tests and 9 questionnaires at T0, T1 and T2 (see table 4).

Table 4: Measurements of participants at base line (T0), after intervention of 24weeks (T1) and follow-up of 48weeks (T2).

OUTCOME	ELIGIBILITY	T0 (BASELINE)	T1 (24WEEKS)	T2 (48WEEKS)
EXCLUSION CRITERIA				
Exclusion questions	X			
Mini Mental State Examination	X			
FRAILTY PHENOTYPE OF FRIED				
Unintentional weight loss	X		X	X
Handgrip strenght (weakness)	X		X	X
Center for Epidemiologic studies - Depression Scale (exhaustion)	X		X	X
Gait Speed (slowness)	X		X	X
Physical Activity	X		X	X
DESCRIPTIVE OUTCOMES				
Age	X			
Gender		X		
Height		X		
Weight		X	X	X
BMI		X	X	X
Race/ethnicity		X		
Marital status		X		
Educational level		X		
Household composition		X		
Income		X		
Medication use		X		
Fall risk		X		
Charlson Comorbidity Index		X		
Medical history (National Health Interview Survey)		X		
PRIMARY OUTCOME MEASURE				
The Timed Chair Stand		X	X	X
SECONDARY OUTCOME MEASURES				
Two Minute Step Test		X	X	X
Montreal Cognitive Assessment		X	X	X
Trail Making Test		X	X	X
Rey Auditory Verbal Learning Test		X	X	X
Fatigue resistance grip strength test		X	X	X
Timed Up and Go		X	X	X
iMTA Medical Consumption Questionnaire		X	X	X
Medical Outcomes Study 36-Item Short Form Health Survey		X	X	X
EXPLANATORY OUTCOMES				
De Jong Gierveld 11-item loneliness scale		X	X	X

Engagement in Meaningful Activities Survey		X	X	X
Self-Management Abilities Scale – Short Form2		X	X	X
Activities of Daily Life (National Health Interview Survey)		X	X	X

Primary outcome

Timed Chair Stand (TCS)

In the TCS test, participants are asked to stand upright from a seated position in a chair (height 43 cm) with their arms folded across their chest and return to a seated position as many times as possible within 30 seconds [46]. The TCS measures lower body strength and relates to important Activities of Daily Living (ADL) like walking up stairs and getting out of a chair or bed [46], [47]. The test is frequently used in older adults with fall-risk or frailty and is a reliable and valid instrument (Reliability: ICC 0.84 – 0.92, r = 0.93;) [48], [49].

Secondary outcomes - Physical outcomes

Two Minute Step Test (TMST)

In the TMST participants need to march in place as many times as possible within two minutes, lifting the knees to a benchmark on the wall placed at the height of the exact middle between the patella and the iliac crest. The score is the number of times the right knee passes the benchmark in two minutes [46]. The test measures aerobic capacity and relates to ADL e.g. walking in and around the house, climbing stairs and shopping. The test is a valid and sensitive alternative to the 6 minute walk test with a test-retest reliability coefficient of 0.90 [46], [50].

Timed Up and Go (TUG)

The TUG test is measured by the number of seconds the participant needs to get up from a seated position, walk 8 feet (2.44 m), turn, and return to the seated position. The purpose of the TUG test is to assess functional mobility, more specific agility and dynamic balance. These are important in tasks that require quick displacement such as getting on and off public transport or getting up to answer the phone [46], [51]. The TUG has been proven to be a reliable The TUG has been proven to be a reliable (ICC ≥ 0.83) [52] and valid instrument to test functional mobility and balance in frail older adults [51], [53], [54].

Fatigue resistance grip strength test

In the Fatigue resistance grip strength, the Martin Vigorimeter is used to measure muscle fatigability [55]. The subject is seated with both feet on the ground, the shoulder in neutral position and the elbow flexed in 90°. The participant holds the large bulb of the Martin Vigorimeter in the dominant hand by enclosing it on one side with the thumb and on the other side with four fingers. The participant is instructed to push the large pear as hard as possible and to maintain this force as long as possible [56]. A good to excellent inter- and intra-observer reliability is observed (ICC values ranging from 0.77 to 0.94). Hand grip strength is seen as an indicator of overall body strength for frail older adults and other populations [55], [56], [57]. Lower body strength leads to adverse health outcomes e.g. falls, disability and a higher risk of frailty [58].

Secondary outcomes - Cognitive outcomes

Montreal Cognitive Assessment (MOCA)

The MOCA is a global cognitive test developed to screen for mild cognitive impairment [59]. It can also be used as a repeatable measure to evaluate treatment response. In our study the MOCA will be used to evaluate the effect of the intervention on the cognitive function. The total score for the MOCA ranges from 0 to 30 points assessing following domains: visuo-constructional/executive function skills, verbal memory, attention/working memory, language/executive function, conceptual thinking and orientation [60]. The MOCA is a reliable and valid instrument demonstrating adequate to excellent internal consistency and construct validity; an adequate to excellent test-retest reliability, and adequate to excellent inter-rater and intra-rater reliability in community dwelling older adults [60]. Feeney et al. observed a standard error of measurement of 1.5 points, with estimates of minimum detectable change of 4 points at 95% level [61]. This is supported by Kopecek et al, indicating that changes of at least 4 points are necessary to assume a reliable change [62].

Trail Making Test (TMT)

The Trail Making Test is a widely used neuropsychological test, originally part of the Army Individual Test battery [63] and then included in the Halstead-Reitan Neuropsychological Battery [64]. The TMT consists of two parts, namely TMT-A and TMT-B. In TMT-A, the subject is asked to connect the encircled numbers (1 to 25) in consecutive order as quickly as possible. In TMT-B, encircled numbers and letters must be connected in a numerical and alphabetical order, but alternating between numbers and letters (1,A,2,B,3,C etc). The score represents the time to complete each part [65]. TMT-A score is associated with measures of visual scanning, graphomotor speed, and visuomotor processing speed, while TMT-B performance reflects more executive functions such as working memory and inhibition control [66], [67]. The TMT has an adequate test-retest reliability (r = 0.70) [68] and has also demonstrated an adequate construct validity [64], [67].

Rey Auditory Verbal Learning Test (RAVLT)

The Rey Auditory Verbal Learning Test (RAVLT) is a neuropsychological assessment designed by Rey (1958) to evaluate verbal episodic memory [69], [70]. A list of 15 words (LIST A) is presented orally, after which the participant is asked to recall as many words as possible. This procedure is repeated over 5 trials. Then the participant listens to an interference list of 15 different words (LIST B) and is asked to recall as many words as possible from list B. Immediately after the interference list, the participant should recall the words from LIST A again. After a 20-minute delay, the participant is once again asked to retrieve the words from list A [71]. Outcomes measures used are the total number of words retrieved in 5 trials (=Sum trail 1-5), and the number of words recalled immediately and following the 20 min-delay. Different studies have demonstrated the construct, criterion, convergent and divergent validity [72], [73], [74], and reported a good internal consistency (Cronbach's alpha = 0.80) [73]. When alternate forms are used the RAVLT is a reliable instrument for repeated neuropsychological assessment [75]. The total score (= the sum of scores across the five acquisition trials) and the delayed recall score are the most reliable measures [71], [75], [76].

Secondary outcomes - Quality of Life evaluation

Medical Outcomes Study 36-Item Short Form Health Survey (MOS SF-36 / SF-36)

Health related Quality of Life will be measured by the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) [77]. The SF-36 questionnaire is widely used to monitor general population health status, evaluate the efficacy of interventions, monitor health status in patients with chronic disease and determine the relative burden of various diseases [78]. Also, a strong inverse association between (pre)frailty and quality of life in community-dwelling older people was detected by the SF-36 [79]. The SF-36 includes a multi-item scale that assesses eight health concepts: limitations in physical activities due to health problems (1 item), limitations in social activities because of physical

or emotional problems (2 items), limitations in usual role activities because of physical health problems (4 items), bodily pain (2 items), general mental health due to psychological distress or low well-being (5 items), limitations in usual role activities because of emotional problems (3 items), vitality due to low energy and fatigue (4 items) and lastly general health perceptions (5 items). In addition to the scale scores, a Physical Component Score and a Mental Component Score can also be calculated. The SF-36 is suitable, reliable and valid for use in frail older adults [80], [81], [82]. The SF-36 also allows to calculate utilities (with 1 = perfect health and 0 = dead) allowing the calculation of Quality Adjusted Life Years (QALYs). People with mental or physical problems and/or aged over 75 may need assistance of an interviewer [83].

Secondary outcomes – Psychosocial outcomes

De Jong Gierveld 11-item loneliness scale (DJGLS)

The De Jong Gierveld loneliness scale is an appropriate scale for the assessment of loneliness among older adults [84]. This scale consists of 11 items, 6 items are formulated negatively and 5 items are formulated positively. Participants can respond with 5 possible answers ("yes!", "yes", "more or less", "no", "no!"). Cut points can be used to classify people into not lonely, moderately lonely, or strongly lonely [85]. The scale's developers note that this scale can be used as a unidimensional measure for overall loneliness or can provide information about two subscales: the emotional and social loneliness [85]. Most studies confirm this two-factor structure [80], [86] nevertheless some studies conclude that the scale is unidimensional [87], [88]. The 11-item De Jong Gierveld loneliness scale proved to be a valid and reliable instrument for overall, emotional and social loneliness with Cronbach's alpha >0.8 [80], [85], [89]

Secondary outcomes – Activities of Daily Living outcomes

Engagement in Meaningful Activities Survey (EMAS)

The Engagement In meaningful activities survey (EMAS) is a 12-item questionnaire with statements about the meaningfulness of activities in one's life [90]. Each item can be scored with rarely (=1), sometimes (=2), usually (=3) and always (=4). The sum of the 12 items ranges from 12 to 48. People perceive their activities as low, moderate or high when they score respectively less than 29, between 29 – 41 or more than 41. Standard deviations for the EMAS in community-dwelling older adults are 36.4 (6.2). EMAS is a valid instrument, available in Dutch, with moderate reliability [91], [92], [93].

Self-Management Abilities Scale – Short Form2 (SMAS-S)

The Self-management abilities scale short form (SMAS-S) is a questionnaire designed to measure six self-management abilities in older adults based on five dimensions of well-being specified in the social productions function (SPF) theory [94], [95]. These consist of the ability to ensure multifunctionality, maintain variety in resources, keep a positive frame of mind, invest in resources for longer term benefits, self-efficacy and taking initiative [96]. SMAS-S is a shorter version from the originally developed SMAS-30 and consists of 18 items [95], [97] [96]. Having a shorter instrument makes it more feasible to assess self-management abilities in a broader number of people, especially among frail older adults [97]. SMAS-S has a good internal consistency, all subscales are .63 or higher (Cronbach's alpha) and total reliability of the SMAS-S is .90 [96].

National Health Interview Survey – (HIS)

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Every five years a national Health Interview Survey (HIS) is held in Belgium. This cross-sectional population survey includes questions on health status, lifestyle, use of health services and socio-demographic characteristics and is administered in a representative sample of the Belgian population [4]. In the ACTIVE-AGE@home study, questions regarding Activities of Daily Living (ADL) are adopted from the HIS.
The respondent is asked to indicate if they have difficulties performing daily activities and/or household tasks. The 7 daily activities and 7 household tasks are read out loud, answers are given by selecting a predefined 4-point scale ranging from 'no, no difficulties', 'yes, a few difficulties', 'yes, a lot of difficulties' of 'not possible to perform'. When a question is not applicable 'does not apply' can be noted as well.
Activities of Daily Living are getting in and out of bed, sitting down or standing up from a chair, getting (un)dressed, taking a bath or shower, washing your face or hands, eating with knife and fork or using the toilet. Household tasks are preparing meals, using the telephone, doing groceries, taking medication, doing light chores, doing heavy chores and handling money.

Secondary outcomes – Health economic outcomes

Trial and Model-based cost-effectiveness analyses will be conducted, expressed in incremental cost per QALY (quality-adjusted life year). Therefore, the MOS SF-36 (to enable calculation of the QALYs) and the iMTA-MCQ (to measure resource use) will be used. Frailty status (11) is measured at T0, T1 and T2 and will be used to associate frailty at the end of follow up with further expected healthcare expenses beyond the duration of the trial. Volunteers and professionals also register time and expenses made for every training session in a field log.

iMTA Medical Consumption Questionnaire (iMTA-MCQ)

To measure medical costs experienced by frail older adults the Dutch version of institute for Medical Technology Assessment - Medical Consumption Questionnaire (iMTA-MCQ) will be used. The iMTA-MCQ is not related to a specific disease and measures medical consumption through 36 questions covering the past 3-month period. Formal (physician, dietician, …) and informal (family, …) care services are registered as well as out-of-pocket expenses [98]. For the purpose of this study one question was excluded from the iMTA-MCQ regarding the consultations with an occupational physician. Despite the widespread use of the iMTA-MCQ in older adults [99], [100], [101], [102], [103] and other populations [104], [105], [106], [107] the validity and reliability of the iMTA-MCQ still needs to be established [98], [105].

During the intervention volunteers, professionals and participants are also required to fill in a log after each training session to signal adverse events and measure adherence, motivation and fidelity to the intervention protocol.

Adverse events reporting

An adverse event is an unexpected medical problem that occurs between pre-testing (0w) and follow-up testing (48w) of the intervention [108]. These events can be mild, moderate or severe, and may be linked to the intervention or not. Professional and volunteer trainers will be assigned to complete a log after every training session stating cardiovascular or musculoskeletal problems, falls and health care utilization (e.g. doctor visit, hospitalization, …) on the three-point scale [109]. Besides adverse events, this log will register intensity, feasibility, pleasantness and training progress as well. After the intervention (24 weeks), participants will be asked to note possible adverse events related to the intervention themselves.

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Data management and analysis

Sample size

Physical capacity, measured by the timed chair stand (TCS) is the primary outcome of this study Based on the major clinically important improvement (i.e. 2) [110] (intervention group improves by 2 more rises from a seated position to a standing position than the control group), and a population standard deviation of 3.2, coming from our pilot study with process evaluation, a sample size of 54 participants per study-arm provides 90% power at the 0.05 level of significance. To allow for dropouts it is planned to recruit 65 participants per study arm, resulting in 195 frail community-dwelling older adults to be recruited.

Data management

The assessor will register data from baseline, T1 and T2 measurements in a secure web application for databases called REDCap. A detailed and pseudonymised Case Report Form (CRF) will be created per participant so blinded extraction and analysis can be carried out. The assessor will be adequately trained to collect and register sociodemographic data and administer the four physical performance tests and nine questionnaires.
Participants and the deliverers of the intervention (professional trainers, volunteers and volunteer coordinator) also register proceedings of every training session in their own pseudonymized log on REDCap. The CRF of the assessor and the logs of the participants and deliverers are strictly separated by disabled user rights. Participants and volunteers first register their findings in a paper log which is collected at 12 and 24 weeks. A designated and blinded researcher will then enter the data in REDCap.
All digital data will be securely stored in a secure cloud-based repository at Vrije Universiteit Brussel, which is encrypted and password-protected and can only be accessed by the Principal Investigator (PI) and/or its representatives. Offline copies of data and the informed consent forms will be separately archived in a locked cabinet in a room only accessible by the PI (access with key card).
The collected data from the target population applies to physical and mental health and, following the European law, it will be kept in secure storage for 25 years after final contact with the research participant. All other data will be kept for at least 5 years.

Quality assurance

An independent research partner with no link to the collection of the data will be responsible for fidelity and quality assurance. The intervention groups will be monitored at different times throughout the study in both intervention arms (arm1: intervention provided by professionals and arm2: intervention provided by trained volunteers) by means of video-recordings and live observations. The recordings and the observations will be evaluated by two researchers independently from each other by completing a checklist with predefined quality indicators. The quality assurance plan is compiled out of three major steps: (a) developing a set of critical indicators of the intervention in a focus group [111] with the original developers, (b) collect data to measure the indicators by video recordings and life observations and (c) evaluate the indicators on a five-point Likert scale. When a score lower than 4 on the Likert-scale is marked, feedback will be given to the trainer.
The researchers adhere to the data management guidelines of the funding partner [112], a formal data monitoring committee (DMC) is not requested but the blinded statistician and independent quality assurance partner will execute data monitoring tasks.
Data regarding the quality assurance will be securely stored in a secure cloud-based repository at University of Ghent, which is encrypted and password-protected and can only be accessed by the

responsible of the quality assurance. Offline copies of data will be archived in a locked cabinet in a room only accessible by the responsible researcher at University of Ghent (access with personal key).

Statistical analysis

Before statistical analysis of primary outcome, secondary outcomes and explorative outcomes, data will be coded to permit blinding to group allocation, afterwords data will be cleaned.
The effect of the intervention over time on outcome measures will be primarily investigated with intention-to treat analyses. For the primary outcome variable, analysis of covariance (ANCOVA) will be used with the measurement at 24-weeks and at 48 weeks as outcome and baseline values as covariates to provide an unbiased estimate of the mean group difference. Comorbidity will be considered into the analysis as a covariate. Mean differences will be reported with 95% Confidence Intervals. P values less than .05 will be considered statistically significant, and all the tests will be 2-sided. A similar approach will be applied for the other study outcomes that will be treated as continuous variables. Additional sensitivity analysis will be carried out with different imputation approaches to handle missing data.

Health economic evaluations
The health economic evaluations concern incremental analyses in terms of incremental costs over incremental effects between the alternatives. Therefore cost-utility analyses will be conducted. The thresholds suggested by the Belgian Health Care Knowledge Centre will be applied, expressed in Gross Domestic Product (GDP) per capita ≈40,000€/Quality Adjusted Life Year (QALY). This threshold represents a willingness-to-pay, as society, for one adjusted QALY gained. There is, however, no "hard" cut-off in determining interventions to be cost-effective or not. The investigators will conduct threshold analyses which look for a tipping point for one or more specific input parameters that lead to an incremental cost-effectiveness ratio above or below the threshold. Additionally, probabilistic sensitivity analyses will be conducted and presented in cost-effectiveness acceptability curves indicating at each possible threshold the likelihood whether one of the intervention arms is cost-effective compared to the alternative. Both trial and model based economic evaluations will be made. First a within trial health economic evaluation will be conducted, with a time horizon aligned with the follow-up time (48 weeks). Next, a model based approach will link the results at 48 weeks on the Fried Frailty criteria with reported healthcare costs (healthcare perspective) and quality of life in order to predict over a lifetime horizon the impact of the intervention.

Trial-based evaluation
In the trial-based economic evaluation, the effects are expressed in utilities, derived from the national values of the MOS-SF-36. QALYs will be calculated using the area under the curve method. The cost-effectiveness of the intervention will be expressed in incremental cost per QALY. The incremental cost per QALY will be calculated as a ratio of (Expected Cost ACTIVE-AGE@home - Expected Cost standard care) / (Expected Outcome ACTIVE-AGE@home - Expected Outcome standard care). The robustness of the results will be analyzed by probabilistic sensitivity analyses on the cost as well as on the outcome. Bootstrapping with replacement will be employed utilizing @Risk and MS Excel®, using a minimum of 1000 iterations to obtain 2.5% and 97.5% percentiles of the incremental cost-effectiveness ratio (ICER) distribution. All bootstrapped ICERs will be presented on a cost-effectiveness plane to determine the robustness of the ICER, and to determine the probability that ACTIVE-AGE@home is cost-effective at various willingness-to-pay thresholds. A cost-effectiveness acceptability curve will be used to depict the probabilities of acceptable ICERs.

Model based evaluation
In addition to the trial-based evaluation a model based evaluation will be performed to account for the expected costs and health outcomes in both intervention and control groups beyond the follow-

up period of the trial. A probabilistic Markov model will be developed compliant to Belgian guidelines for health economic evaluations [113]. The rationale of the model is based on the association between frailty and healthcare resources and cost, and on the expected outcome of reduced frailty in the intervention arms compared to the control arms. The investigators assume a cycle of 1 year in the model and applying a lifetime horizon. Lifetime incremental costs and QALYs will be the input for the ICER calculation. Discount rates of 3% for costs and 1.5% for utilities will be applied, which is in line with the Belgian guidelines. Non-parametric bootstrapping will be applied for both costs and outcomes to test the robustness of the results. These iterations will be presented in cost-effectiveness planes. Probabilities to be cost effective for the different willingness-to-pay thresholds will be presented in cost-effectiveness acceptability curves.

ETHICS AND DISSEMINATION

The procedures of this study were reviewed and approved by the Medical Ethics Committee (MEC) of UZ Brussel (O.G. 016), Peer reflection group Biomedical Ethics, Laarbeeklaan 101, 1090 Brussels on 17th of May 2023 (B.U.N. 1432023000089). Modifications to the study or intervention protocol will require a formal amendment by the MEC. High priority is given to safety principles and ethics during this study. Professionals and volunteers need to adhere to an ethical code of conduct during the intervention. All participants and volunteers in this study are covered by a 'no fault liability' insurance.

The research team will submit a yearly progress report regarding the scientific progress, financial plan and study results to the sponsor, being the Research Foundation Flanders (FWO). The findings of this study will be published in peer-reviewed journals and presented at conferences. Meanwhile, the results will be disseminated to the advisory board.

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Author contributions

All authors (DV, EDS, JT, EDK, EV, LA, DB, WP, DVdV, SL and PDV) contributed to the development of the study and reviewed, commented and edited the manuscript and have read and agreed upon the submitted manuscript. DV is study and volunteer coordinator and conceived the manuscript with support of EDS who is assessor. JT and EDK recruit participants, deliver the intervention and will be involved in analysis. LA, DB, WP, DVdV, SL and PDV were involved in the methodological design and planning of the study. WP is the study statistician who designed and wrote the analysis plan together with LA for health economics. DVdV and EV wrote the quality assurance plan. PDV and DVdV developed the goal-setting protocol and the motivational interviewing. DB supported the design of the intervention. SL supervises ethical and safety aspects in the study. PDV is the lead principal investigator (PI), guarantor and developed the conceptual idea of the program and has overall responsibility for the design and conduct of the study.

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Competing interests

None declared.

Patient and public involvement

The pre-trajectory of this study was based on the 'British Medical Research Council guidance' for the development and evaluation of complex interventions [31]. This resulted in a strong patient and public involvement in the development of the multidmodal exercise program: ACTIVE-AGE@home.

Community dwelling frail older adults (n=25) were involved in the design of the program through in-depth-interviews to identify motivators and barriers for PA. Feasibility of the program was later tested in a pilot

study with 71 frail older adults. Finally, long term reminiscence and effect were questioned in a qualitative follow-up study with 50 participants.

Public partners and healthcare professionals were continuously involved through an advisory board. They provided feedback on the design, feasibility and implementation possibilities of the program and concurring studies. Recently, members of the advisory board were questioned in an online questionnaire and two focus groups before the start of the ACTIVE-AGE@home study.

Public partners and healthcare professionals will be involved in the cocreation of educational materials and a guideline for implementation of ACTIVE-AGE@home in practice. Participants will be consulted on the text, photos and videos used in these materials.

Competing interests

None declared.

Provenance and peer review

Not commissioned; externally internationally peer reviewed

Patient consent for publication

n/a

Provenance and peer review

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Data availability statement

Each party of the research consortium has the right to use the joint project results of which it is a co-owner for further research (including conducting research in collaboration with third parties, whereby no license for commercial exploitation of these joint project results is transferred to the third party), for patient care and for educational purposes. Any other use of joint project results requires the prior written consent of the other party. This consent will not be unreasonably refused. When a party wishes to valorise joint project results, they will request the prior written consent of the other parties. The other parties have this permission to come under terms and conditions.

Supplemental material

n/a

Open access

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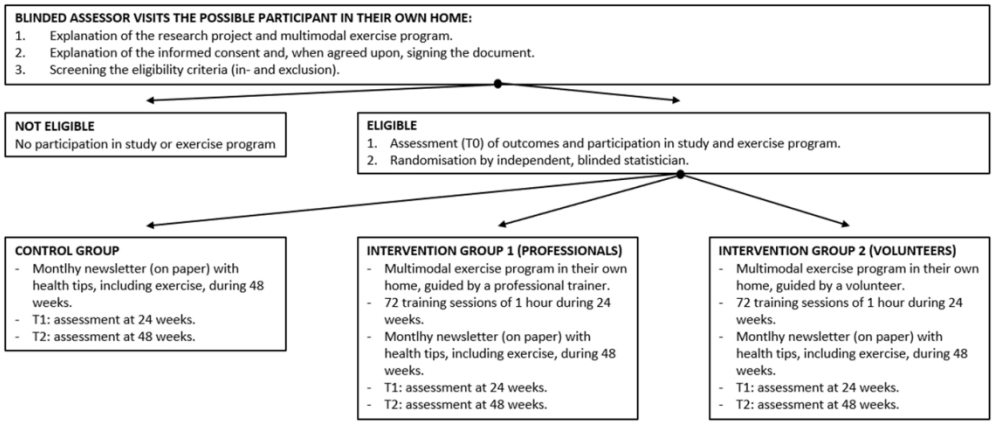
Attachments

Attachment 1: Informed Consent Forms

Attachment 2: Table 3: TIDIER: Template for Intervention Description and Replication

Attachment 3: Figure 1: Enrolment in the study and randomisation



Enrolment in the ACTIVE-AGE@home study

245x105mm (144 x 144 DPI)

The TIDier: Template for Intervention Description and Replication		
Brief name	**ACTIVE-AGE@home: multimodal exercise program for community dwelling frail older adults**	
Why	Between 2020 and 2050, the world's population aged 80 years and over will triple, drastically increasing the prevalence of frailty and associated healthcare costs (Hoogendijk et al., 2019; WHO, 2020; Eurostat, 2023). Multimodal exercise programs have proven to be an ideal countermeasure for frailty but the current Flemish standard of care does not include this (de Labra et al., 2015; Izquierdo et al., 2021; Sadjapong et al., 2020) (Fret et al., 2019). The ACTIVE-AGE@home program is expected to have positive effects on physical functioning, cognition, loneliness, self-management, subjective health, QOL, meaningful activity and health care utilization of community dwelling frail older adults.	
What	The ACTIVE-AGE@home intervention was developed according to the British Medical Research Council guidelines (Craig et al., 2013) and contains **five innovative aspects:** 1) **Personal goalsetting** (linked to meaningful individual and social activities) and **motivational interviewing** 2) **Structured multimodal and functional exercises** based on daily activities (e.g. walking, cooking, playing with grandchildren) in line with evidence-based training principles (Bull et al., 2020; de Labra et al., 2015; Izquierdo et al., 2021; Sadjapong et al., 2020) 3) **Cognitively demanding activities** (e.g. counting, calculating, remembering, naming, recognizing, speaking and/or responding quick and correctly) are added while performing the exercises. 4) The program is **homebased** and uses only materials available in the homes of participants (e.g. grocery bags, chairs, towels). 5) **Personal guidance** is offered by a professional or a volunteer and a personal referral is made to relevant individual or group PA possibilities at the end of the program.	
Who provided	In condition one, the exercise program is supervised by **<u>professionals</u>** with a bachelor- or master's degree and specific knowledge and experience regarding PA interventions and (frail) older adults e.g. physiotherapists, occupational therapists, personal trainers or physical education teachers.	In condition two, the exercise program is supervised by **<u>volunteers</u>** e.g. informal caregivers, students, (parttime) working people or pensioners. The participants can suggest their own informal caregiver or they can be matched with a volunteer. A relevant background is not mandatory.
	The professionals and volunteers will receive a 8h training course and 4 hours (3x 1h20m) on the job training to gain more knowledge and practice regarding ageing, frailty, training and safety principles and goalsetting and motivational interviewing in the ACTIVE-	

<table>
<tr><td></td><td>AGE@home program. The volunteers are also coached by a professional and receive supervision/support during 7 of 72 training sessions in the home of the older adult. Professionals do not receive additional coaching.

The professionals and volunteers are equipped with educational tools to master their role as a trainer:
1. Booklet/binder containing charts with the different training sessions.
2. Three flowcharts to determine the right intensity of the exercises. (strength, aerobic endurance, balance)
3. An online training course.
4. Instructional videos.
5. A quicksheet with dos and don’ts during training.
6. Motivation cards for goalsetting and evaluation + a step-by-step interview guide to apply the CLEVER goalsetting method.
7. Log with evaluative and motivational questions for the participant regarding the intensity, feasibility and pleasantness.</td></tr>
<tr><td></td><td>The professionals and volunteers need to show sufficient knowledge and application of the evidence based safety and training principles after the training course (pass / fail).</td></tr>
<tr><td>How</td><td>The training sessions are given one to one.</td></tr>
<tr><td>Where</td><td>Training sessions are given one to one at the participant's home.</td></tr>
<tr><td>When, how much</td><td>The frail participants are visited three times per week during 24 weeks, resulting in 72 sessions in total. Each session is 1 hour in duration. A session consists of 10 minutes warming-up, 45 minutes of exercises and 5 minutes of cooling-down. There are 8 to 9 exercises in each training session. The workload will increase weekly with approximately 10%. There are three main periods of eight weeks where workload and complexity of exercises gradually increases within the period. After eight and sixteen weeks new exercises will be introduced but at a lower workload and with less complexity in the first week of that period for supercompensation effects. Three goalsetting conversations, based on the CLEVER-protocol (De Vriendt et al, 2019) will be held in the first and second week of intervention and 6 motivational interviews will be spread out over the remaining 22 weeks. Goalsetting or motivational interviewing takes about 10-20 minutes per session and replaces 2 or 3 exercises.

<table>
<tr><td></td><td>Volume/intensity</td><td>Progression</td></tr>
<tr><td>(1) Strength exercises:</td><td>8-12 repetitions of every exercise. Strength exercises are performed at 80% of the 1RM</td><td>Low complexity
- Going from 1-3 sets</td></tr>
</table>
</td></tr>
</table>

		(Borg scale between 15-18), power exercises at 40-75% of 1RM.	- Increase repetitions - Change position - Include more power exercises - Combine exercises High complexity: - Combining exercises to ADL activity - Dual tasking
	(2) **Aerobic exercises:**	Aerobic exercises are performed at a score of 12-14 on Borg scale.	Low complexity: - Increase duration: Going from 5-10 minutes to 15-30 min - Increase pace - Add ankle weights - Combine exercises High complexity: - Combining exercises to ADL activity - Dual tasking
	(3) **Balance exercises:**	1-2 sets of exercises emphasizing static and dynamic postures Balance intensity scale (BIS): score 5: maximal effort	Low complexity: - Going from 1-2 sets - Decrease base of support - Decrease sensory input - Perturbations - Combine exercises High complexity: - Combining exercises to ADL activity - Dual tasking
	(4) **Flexibility exercises**	Dynamic flexibility: 5-10 repetitions Static flexibility: 30s Feeling of stretch, not feeling pain	Low complexity: - Going from 1-2 sets - Combine exercises High complexity: - Combining exercises to ADL activity - Dual tasking

ACTIVE-AGE@home, TIDIER table, 02/07/2024

	(5) **Coordination exercises/ fine motor skills**		Low complexity - Going from 1-2 sets - Combine exercises High complexity - Combining exercises to ADL activity - Dual tasking
Tailoring	To cater to the **individual needs of the frail older adults** and the environment they live in, functional exercises and materials will be tailored and adjusted, when necessary, but with respect to the evidence-based training principles. Every 4 weeks the participants individual level of difficulty of the exercises will be determined. Progression to a next level of difficulty will be based on: – Participant's ability to complete 12 repetitions for a given strength exercise – Quality of the exercise performance – Level of effort: 12-14 (for aerobic exercise) and 15-18 (for resistance training) out of 20; a Borg Rating of Perceived Exertion pr a score 4 or 5 on the BIS-E. – The objective checklist of signals that the participant gives when he/she trains at correct intensity The training schedule is made **meaningful and goal oriented** through the following strategies: - At the end of each training session, the participant chooses the last exercise according to his/her goal. - Adapt exercise to meaningful activity: object, space, … - Remind the participant of their personal goal		
How well planned (adherence)	The **adherence or fidelity** of the participants will be monitored at different times throughout the study in both intervention arms (arm1: intervention provided by professionals and arm2: intervention provided by trained volunteers) by means of video-recordings and live observations. The recordings and the observations will be evaluated by two researchers independently from each other by completing a checklist with predefined quality indicators. Professionals and volunteers are **adequately trained** to implement the ACTIVE-AGE@home program and use the accompanying tools for adherence e.g. intensity flowcharts, goalsetting and motivational interviewing guide and personal physical activity referral scheme.		

ACTIVE-AGE@home, TIDIER table, 02/07/2024