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STUDY PROTOCOL

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Recovery from disability after geriatric-home rehabilitation versus standard of care: protocol for a pilot study in older persons with disability at hospital discharge

Bastiaan Van Grootven[1,2*], Margreet van Dijk[3], Farah Islam[1,2], Birgit Coucke[1], Steffen Fieuws[4], Gijs Van Pottelbergh[5], Johan Flamaing[6,7], Nele Van Den Noortgate[8], Anja Velghe[8], Anne-Marie De Cock[9], Sophie Gillain[10], Joris Meeuwissen[11], Ivan Bautmans[12], David Beckwée[12], Marie de Saint-Hubert[13], Jannique van Uffelen[14], Didier Schoevaerdts[13], Jos Tournoy[6,7] and Theo van Achterberg[1]

Abstract

Background Currently, there is insufficient evidence supporting geriatric home rehabilitation after hospital discharge. Some studies demonstrate a positive effect, but meta-analytic evidence demonstrates uncertainty on the magnitude of the expected effect. Yet, evidence from other populations indicates that home rehabilitation could also be an effective strategy for older persons. Therefore, we aim to evaluate the effectiveness of geriatric home rehabilitation in older persons discharged from the hospital with disability. Given the potential challenges in recruiting participants delivering the intervention, and executing other study procedures in a multi-centre study, we will first carry out a pilot study.

Methods The pilot study will commence with an initial start-up phase at two centres: UZ Leuven and CHU UCL Namur, Belgium. Up to three participants per centre will be included to test the procedures and assessments, excluding randomisation and intervention delivery. The study then progresses to the full pilot phase to evaluate and confirm the feasibility of the proposed trial. This pilot study will take place at the same two centres. The pilot study aligns with the design of the envisioned full trial, i.e. a pragmatic, multicentre, individually randomised superiority trial. A 1 to 1 allocation ratio will be used for the pilot. A total of 24 participants from the two centres will be recruited to investigate the pilot study objectives. The pilot endpoints will be used to determine the feasibility of recruitment and study procedures including data collection, assessments and delivery of the intervention (a 6-week program consisting of exercise sessions 3 times per week, 45 min each). The results from the pilot study will be discussed within the pilot study steering group. Progression criteria will be reviewed to determine if the study progresses to a full trial, and which adaptations are needed.

Discussion In case of a successful pilot, the study will progress to a full trial. The ambition of the full trial is to recruit 333 participants across 8 centres in Belgium, and to investigate the effectiveness of home rehabilitation for older persons discharged from the hospital with disability.

*Correspondence:
Bastiaan Van Grootven
bastiaan.vangrootven@unibas.ch
Full list of author information is available at the end of the article

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Background

Older persons, in particular those 75 years and older, often experience disability, i.e. dependency in activities of daily living (ADL) because of hospitalisation. More specifically, 1 in every 3 older persons on average, experience hospitalisation-associated disability, and prevalence numbers range between 17 and 61% [1]. The proportion of older persons who recover from their disability varies between 45 and 59% in older medical patients at 1-month follow-up [2, 3], and is 37% in geriatric patients at 1-year follow-up [4].

In the context of older individuals, disability is characterised by functional decline, increased fatigue and a reduced quality of life, and is associated with hospital (re-)admission, nursing home placement, and death [5–7]. Cost data from the USA estimated a yearly per person cost of 14,000 USD for mild disability and 20,000 USD for major disability [8], because of care-costs after hospitalisation. These high costs can be mainly attributed to a failure to regain functional independence and having to live with the many consequences of disability, e.g. the need for long-term care.

A meta-analysis of 17 trials identified high-grade evidence for specialised geriatric rehabilitation units' effects on short-term recovery from hospitalisation associated disability, but there was uncertainty about the long-term impact and cost-effectiveness [9]. Moreover, in standard practice, a small proportion of older persons can be admitted to these units because of limited capacity of specialised 'geriatric rehabilitation beds'. Therefore, the majority of patients will need follow-up in the community setting. Home rehabilitation could have important benefits due to the familiar home environment, the possibility of tailoring training to personal life circumstances, and the possibility for longer-term therapy. This approach allows therapy to be tailored to the individual's home setting and personal participation levels. A 2022 systematic review included 10 trials and reported the effects of home-based physical exercise after hospital discharge in older persons [10]. Effect sizes ranged from small to large on the outcome ADL, wide confidence intervals indicated uncertainty about the effect size. Three trials indicated small positive effects on quality of life and mobility [10]. An economic evaluation of one study concluded that there is a high probability of cost effectiveness for the outcome quality-adjusted life years [11]. A more recent 2023 review on outpatient geriatric rehabilitation including a mixed sample of geriatric patients and patients with stroke and hip fracture, included 24 studies [12]. The meta-analysis performed, indicated uncertainty on the magnitude of the effect of outpatient geriatric rehabilitation on the outcome of physical health (including ADL and instrumental ADL), demonstrated by a wide confidence interval around the mean difference on the Short Form 36 physical health subscale. Key interventions to support home rehabilitation included co-operation with primary care, individual goal setting, care coordination and enablement of carers through training and education [12]. Evidence from populations, e.g. stroke, demonstrated that home rehabilitation is feasible and effective in improving a person's functional status, and that it is likely to reach outcomes similar to those of rehabilitation units [13].

Thus, currently, there is insufficient evidence to determine the impact of geriatric home rehabilitation after hospital discharge due to the relatively small sample sizes, single centre designs, and few studies that measure key outcomes such as quality of life. Therefore, we aimed to evaluate the effectiveness of geriatric home rehabilitation in older persons discharged from the hospital with disability in a multi-centre pragmatic trial. As there could be uncertainties regarding recruitment of participants, intervention delivery, and other study procedures, a pilot study will first be conducted. The pilot is embedded in the full trial, meaning that in the case of a successful pilot and minimal adjustments to the study procedures, the data of participants in the pilot study will be transferred to the full trial. The pilot study commences with a start-up phase to initially test procedures and then moves to the full pilot phase. This manuscript reports the protocol for the pilot study.

Objectives

Start-up objectives

The overall objective of the start-up phase is to try out the study procedures (except for randomisation and intervention delivery) and assessments and data collection on a very small scale as to receive initial feedback and identify obvious problems in the procedures before starting the pilot study. The information will be used to optimise the study procedures for the pilot study. Information collected from participants included in this start-up phase will not be included in the full trial.

Pilot study objectives

The overall objective of the pilot study is to investigate the feasibility of recruitment of study participants, all study procedures (see Table 1; including randomisation, assessments and data collection), and the study intervention, as to inform the potential need to adapt the study protocol prior to the start of the full trial. The detailed objectives are presented in Table 1. The design of the full trial is detailed in Table 2.

Design

The pilot study consists of two phases, being (1) a start-up-phase; and (2) a pilot study. The start-up phase will take place in two medical centres: UZ Leuven and in CHU UCL Namur. UZ Leuven is a University Hospital in Flanders with 1995 beds. CHU UCL Namur is a University Hospital in Wallonia with 936 beds. Up to 3 participants per centre will be included to test the procedures (except for randomisation and intervention delivery) and assessments. The start-up includes the recruitment and the initial home visit for baseline assessment. Only information on the procedures and process of data collection is collected and no personal data will be collected. The results will be discussed between the Chief Investigator (TvA), Principle Investigators (DS, JT) and the project coordinator (BC) to optimise the procedures and adjust the protocol for the pilot study if needed. Data collected from participations during the start-up phase will not be used for the trial.

Table 1 Objectives for pilot study following the start-up phase

Objectives regarding recruitment

1. How many potential participants can and cannot be screened for their eligibility during the recruitment period? (i.e. a period of 6 months, or shorter when 24 participants are recruited earlier in time)
2. How many study participants are recruited and randomised per month (as an average per month for the recruitment period), and how many recruited participants are retained in the first 6 weeks after baseline?
3. What are potential participants' reasons for refusing to participate?
4. What are the profiles of study participants recruited with respect to their reason for hospital admission, unit where the participant was recruited, use of emergency or intensive care services during hospitalisation, and use of surgery during hospitalisation

Objectives regarding study procedures

5. What is the amount of time needed for each of the study procedures and assessments per study participant included in the pilot study?
6. How do participants included in the pilot study experience the burden associated with study procedures and assessment?
7. How does the recruiting healthcare staff (within internal geriatrics consultation teams or based at geriatric wards) experience screening older persons for potential inclusion in the study, and the pre-defined criteria for this?
8. How do physiotherapists experience the training to deliver the study intervention?
9. In how many study participants was blinding of the study nurse who assessed outcomes maintained?
10. How do the study nurses and PIs experience the feasibility of the randomisation procedure, the assessments and the data collection?

Objectives regarding the intervention and compliance

11. How do participants in the intervention group experience the home rehabilitation intervention?

11.a Is the intervention feasible for them?

11.b What would be their reasons to either fully engage in, or discontinue the intervention?

12. How do physiotherapists experience delivering the study intervention?

12.a Is the intervention feasible for them?

12.b What would be their reasons to either fully engage in, or discontinue the intervention?

Table 2 Design of the full trial

Pragmatic	- Screening for eligibility during routine care by healthcare staff
	- Using few exclusion criteria, allowing diversity in sample
	- Allowing for tailored delivery of the intervention and variation in usual care
Multicentre	- 8 hospitals will collaborate in the recruitment of 333 participants
Randomised	- Randomisation stratified on centre
Controlled	- The intervention will be compared with standard of care
Single blinded	- Study nurses will be blinded for group allocation
Superiority	- The trial is designed to show that the intervention is superior to standard of care
Intervention	- Delivered by physiotherapists working in community setting
	- 6 weeks, 3 sessions per week, 45 min per session
	- Focus on strength and power, balance, and speed, endurance and coordination
Main endpoints	- Disability
	- Quality of life
	- Physical performance
Economics	- Cost impact
	- Cost-consequences

In a next phase, the pilot study will be performed to investigate the feasibility of the envisioned trial, and this in the same centres as those included in step 1. The design of the pilot study aligns with the design of the envisioned full trial, i.e., a pragmatic, multicentre, individually randomised superiority trial with two intervention arms (see Table 2). For the pilot, a 1 to 1 allocation ratio will be used. For the full trial, a 1 to 1.3 allocation ration will be used. A total of 24 participants from the two centres will be recruited to investigate the pilot study objectives. The pilot endpoints will be used to determine the feasibility of recruitment and study procedures including data collection and assessments. The results from the pilot study will be discussed within the pilot study steering group. Progression criteria (detailed in Table 3) will be reviewed to determine if the study progresses to the full trial, and which adaptations are needed. If the trial is deemed

feasible, it will progress to the full trial. The data of participants included in the pilot study will be used for the full trial if no substantial changes to the study intervention and procedures are needed. The progression criteria are detailed in Table 3. The flowchart in Fig. 1 details the concept of the study design.

Study setting

Participants are recruited in UZ Leuven and CHU UCL Namur and within acute geriatric units as well as hospital wide through the internal geriatric consultation team; consultation teams provide a geriatric assessment and advice on a treatment plan for patients with geriatric syndromes on non-geriatric units. Screening for recruitment is performed by the healthcare team, using information they routinely collect. Data is collected by a study nurse during home visits. After hospital discharge, the study intervention will be delivered by physiotherapists in the primary care/home care setting for a period of 6 weeks. For the pilot study, 2 to 3 physiotherapists per centre are recruited for the delivery of the intervention. The dedicated physiotherapists will receive a training delivered by the study team. The training consists of a two-hour recorded presentation focusing on the theory behind geriatric rehabilitation, and a 1-day on-site training focusing on delivering the rehabilitation exercises and ways to tailor the exercises to the person and the person's specific domestic setting. Through hospital discharge notifications, general practitioners (GPs) and home care nurses (when involved) will be informed whenever one of their patients is discharged home. This is standard for both the older persons in the intervention and the control group. Standard of care is heterogenous and shows variation in the provision and follow-up of advice on geriatric needs and care (e.g. variations in the follow-up of appropriate medication use, follow-up on a rehabilitation trajectory and optimal nutritional intake). Follow-up of this advice is at the discretion of the GP, primary care nurses and allied health professionals, and will not be controlled through the study intervention.

Recruitment and eligibility criteria

Recruitment of physiotherapists who can deliver the intervention takes place prior to the recruitment of participants, and will be done in collaboration with Axxon Physiotherapy Belgium (the Professional Body for Physiotherapists in Belgium), the local groups of physiotherapists and the study centres. In the regions surrounding each of the two study centres we will recruit 2 to 3 physiotherapists (total of 4 to 6 for the two centres). For all physiotherapists, recruitment criteria are (1) being licensed for practicing in Belgium; (2) work experience as a physiotherapist during a minimum of 1 year, and (3) currently active as a physiotherapist.

Recruitment of participants starts prior to hospital discharge. The study nurse will communicate with the healthcare team to establish an anticipated day of hospital discharge. We include participants who (1) are 75 years of age or older, (2) have disability (i.e., dependent in one or more activities of daily living) at hospital discharge, (3) have rehabilitation potential, and (4) also give their consent. In each hospital the rehabilitation potential is assessed by the multidisciplinary team. On the acute geriatric units, the multidisciplinary team meets weekly to discuss all patients. In the internal geriatric consultation team, patients who are in their follow-up are discussed during a geriatrics team meeting. Discussions in both teams include, among others, discharge planning, disability and self-care, and rehabilitation progress in hospital. The potential for rehabilitation is discussed in the team, and the geriatrician is responsible for the final decision. Each study site conducts this assessment in line with their internal guidelines, as to reflect routine clinical practice. We exclude persons who (1) are discharged to a nursing home or rehabilitation centre, (2) receive palliative care, (3) are enrolled in a specialised rehabilitation programme, e.g. cardiac rehabilitation, stroke rehabilitation, respiratory rehabilitation for COPD, and oncology rehabilitation, (4) are in active follow-up with a physiotherapist for other indications, and for whom participation in the intervention would be too demanding or would interfere with the rehabilitation goals of the regular therapy. Research staff members and healthcare professionals involved in the screening, recruitment and data collection will also be recruited. For the purpose of the economic evaluation embedded in the full trial, an informal caregiver (if available) will be recruited per participant to estimate time invested by informal caregivers and the corresponding monetary value.

Interventions

Standard of care group

The control group will receive the standard of care. For most patients, this will include a prescription for physiotherapy after hospital discharge, and a discharge letter to the general practitioner and home care nurse with a summary of medical and care needs, and a suggestion for follow-up action points. Based on experience of the consortium, we assume that the majority of patients do follow-up with physiotherapy, and that care practices between therapists differ substantially.

Intervention group

The intervention group will receive the GAPP@HOME intervention a derivate of the Geriatric Activation Program Pellenberg [14]. GAPP@HOME is a 6-week

Table 3 Progression criteria

Criteria	Go–proceed with RCT	Proceed with changes	Stop–do not proceed
1. Feasibility of site start-up Can 2 participants be recruited per site within 2 months of the start of the pilot study? [a]	If 2 participants are recruited per site in ≤ 2 months	If 1 participant is recruited per site in ≤ 2 months	Not all sites have recruited at least 1 participant in ≤ 2 months
2. Feasibility of recruitment and training of therapists Can 2 physiotherapists be recruited and trained within two months of the start of the start-up phase, per site? [a]	If 2 therapists per site are trained in 2 months	If 1 therapist per site is trained in 2 months	If no therapists are recruited in 2 months
3.a Feasibility of participant recruitment Can 24 participants be recruited in 6 months?	If 24 participants are recruited in ≤ 6 months	If 12–23 participants are recruited in ≤ 6 months	Less than 12 participants are recruited in 6 months
3.b Feasibility of participant recruitment Can participants be recruited at both (a) geriatric hospital wards and (b) other hospital wards (via an internal geriatric consultation team)?	Of the 24 participants (see 3.a), at least 8 are recruited for each of the recruitment paths (i.e. via geriatric ward and via consultation team)	Of the 12 to 23 participants (see 3.a), at least 4 are recruited for each of the recruitment paths (i.e. via geriatric ward and via consultation team)	Not applicable
4. Feasibility of participant retention Can at least 75% (95% CI, 55% to 88%) of recruited participants be retained in the study until 6 weeks follow-up? [b]	If 18 participants are retained	If 14 participants are retained	< 14 participants retained
5. Feasibility of intervention[c] Is the intervention considered feasible by participants?	Qualitative data show that participants perceive the intervention as feasible[c]	Challenges with feasibility are reported in interviews[c] but clear improvements are identified	Qualitative data indicate that the intervention is not feasible for participants [c]
6. Feasibility of data collection Is it feasible to collect data on the primary outcome and both key-secondary outcomes, at the participants' home, as indicated through the completeness/missingness of data? [d]	< 5% missing data on the primary endpoint and on the two key secondary endpoints in participants who complete 6 weeks follow-up	6 to 15% missing data on the primary endpoint and on the two key secondary endpoints in participants who complete 6 weeks follow-up	> 15% missing data on the primary endpoint and on the two key secondary endpoints in participants who complete 6 weeks follow-up
7. Feasibility of intervention implementation[c] Is intervention delivery by physiotherapists feasible?	Data from qualitative interviews with physiotherapists indicate that intervention delivery is feasible	Data from qualitative interviews with physiotherapists indicate that intervention delivery is challenging that, but clear improvements are identified	Data from interviews indicate that intervention delivery is not feasible; measures to increase feasibility would compromise core intervention mechanisms

[a] Site initiation date of start-up phase and pilot study as defined in the protocol approved by the EC

[b] Retained in the study refers to the completion of the home visit at 6 weeks follow-up

[c] The results of the qualitative investigations are presented to the Trial Steering Committee. A group consensus decision is made by the Trial Steering Committee. If no consensus can be made, a majority vote will decide

[d] Completeness of data is assessed in participants who are in follow-up in the study and refers to the primary endpoint of disability and the two key secondary outcomes physical performance and quality of life. Participants who are lost to follow-up will not be considered in the calculation of criterion 6

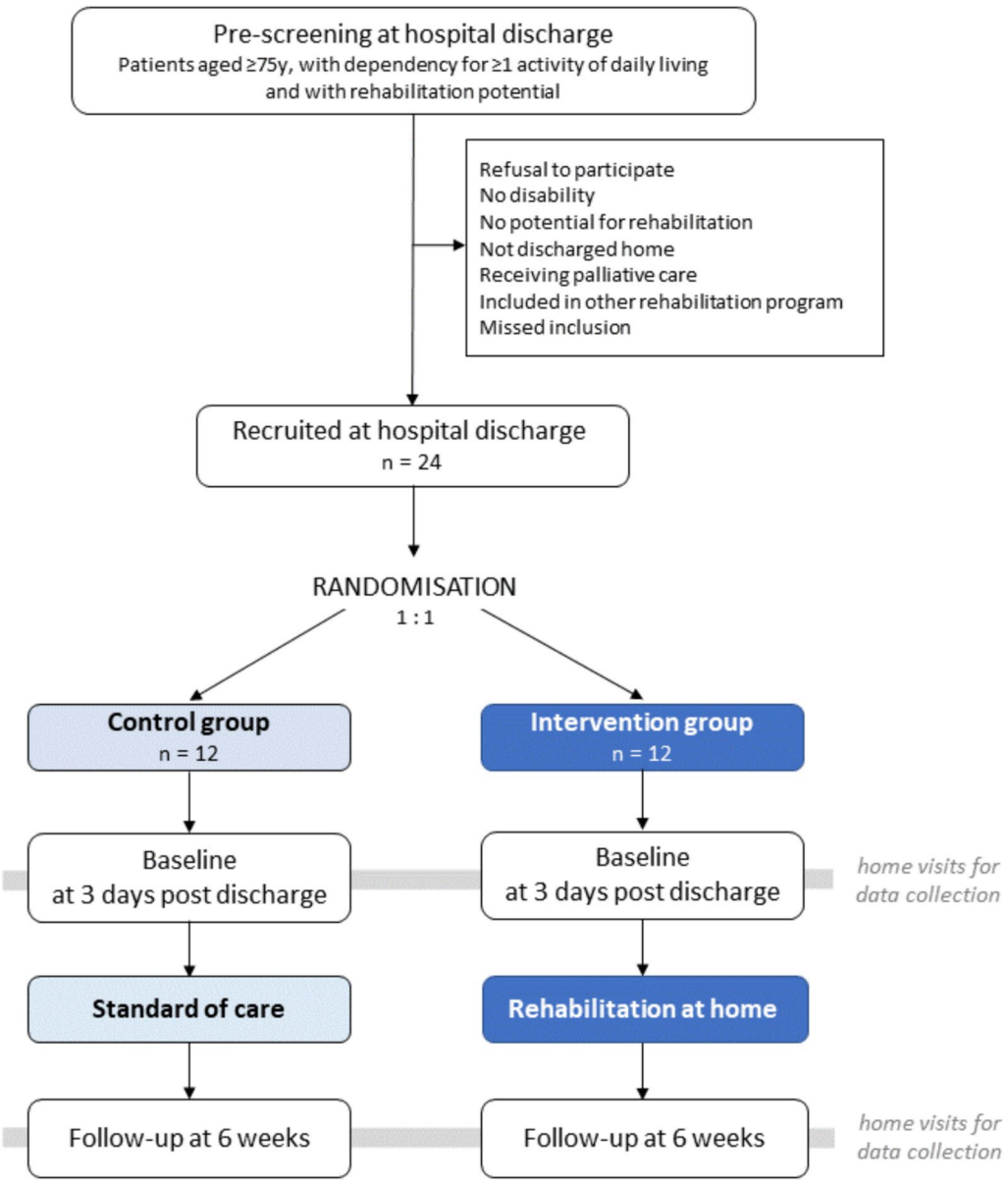

Fig. 1 Study flowchart

program and consists of exercise sessions 3 times per week of 45 min each; day 1 strength and power, day 2 balance, and day 3 speed, endurance and coordination. Each exercise day starts with 10 min of gait training. A set of written-out exercises is available for each of the 3 exercise days. The GAPP@HOME trained physiotherapist will select several exercises based on the person's abilities and needs. Therapists can adjust the protocol to older persons' (improved) capacities on a daily basis. Hands-on guidance is permitted and encouraged to achieve proper execution of the exercises. The intervention protocol starts with goal setting. The main goal of GAPP@HOME is to enhance the daily functioning of older individuals in their own homes. This program considers each person's specific situation and adjusts the approach to optimise the program to the environment of each person. Together, the older person and the therapist set personal goals for the older person's progress. These goals are established based on the person's wishes and preferences, such as activities like climbing stairs, engaging in outdoor activities, or handling household tasks independently, like hanging up laundry. Exercises aimed at improving strength and balance are chosen to align with the set objectives. During the initial session, these goals

are written down, and progress is evaluated after the second, fourth, and sixth week to track advancements. The physiotherapists received a seven-hour training session for the delivery of the intervention protocol. An intervention protocol is detailed in Appendix 1. All exercises within the program are described in the Geriatric Activation Program Pellenberg at Home (GAPP@Home), version 2024, and can be accessed in Dutch through reference [14].

Endpoints start-up phase

The first experiences of the study nurses and principle investigators with the study procedures will be assessed using structured interviews. The interviews are conducted by the Sponsor team (KU Leuven). The interview questions focus on their experience with adherence to the study protocols, barriers for executing the study protocols, opportunities for improving these and for improving efficiency. A Rapid Research Evaluation 'RAP' sheet per centre will be drafted following the guidance of the Rapid Research Evaluation and Appraisal lab (a 'RAP' sheet is a structured document where interview data can be summarised. It is ideally suited to collect practical data to inform actionable results, when theorising is not the aim) [15]. The interviews will be performed after the 3 study participants per centre have been recruited and their baseline assessment performed. Interviews can also be scheduled sooner if sites report major problems. The endpoints will be expressed as suggestions to improve the procedures and assessments.

Endpoints pilot study

The pilot study will capture the following endpoints related to recruitment, study procedures (including assessments and data collection), and the study intervention.

Recruitment

The number of potential participants screened or not screened for inclusion

The study nurse will register all admissions of eligible participants on the 'acute care for elders units' and all consultations from the 'inpatient geriatric consultation team' relating to persons aged 75 years or older who were discharged home with disability, and will monitor how many of these older persons were (1) screened for rehabilitation potential and (2) were contacted by the study team for inclusion. These data are registered in a logbook and no identification information is documented. Aggregated data (i.e. not at the level of individual participants; only listing the number of refusals and frequencies for alternative reasons) are transferred to the sponsor. This endpoint addresses the first objective of the pilot study.

The number of (potential) participants recruited/not recruited, randomised and retained (for whom 6-week outcome data is collected) The aim is to include 24 study participants across two study centres. For the pilot study, the aim is to successfully randomise and retain at least 18 (95% CI, 13 to 21) of the 24 participants up to the follow-up of 6 weeks. The endpoint will be expressed as the number and proportion of participants who were randomised and who completed the follow-up at 6 weeks.

Potential participants' reasons for refusing to participate The study nurse will register all recruitment activities using a screening log. Study nurses are instructed to record a brief reason for non-participation in the study and to keep an anonymous log of this. Nurses will register how many patients refuse to participate and for which reasons. The nurse will always explore whether refusal relates to a lack of interest in rehabilitation because they feel the study intervention is not for them, because they would have to choose from a limited number of therapists, because they anticipate a large study burden, or for any other reason. If a person declines to give a reason, then the reason will not further be explored. This endpoint will also be expressed as frequencies per reason for declining to participate in the study. This endpoint addresses objective 3 of the pilot study.

The profiles of study participants Baseline characteristics of participants are assessed by the study nurse and entered in the eCRF (REDCap). This endpoint will be articulated in terms of the reasons for hospital admission, the specific hospital unit from which patients were recruited, and the utilisation of emergency or intensive care, as well as surgical interventions during hospitalisation. It will be presented as frequencies and proportions in the sample. This endpoint addresses the fourth objective of the pilot study.

Study procedures

Time spent on study procedures and assessments

The study staff participating in the study will log the time they spend on the study in an electronic logbook. Time logging will be done for participants 5 to 12 at each site, as the first participants might take relatively more time because nurses and doctors need to get used to the procedures. Time will be recorded in minutes per day, and will be stratified for screening, informed consent, randomisation, baseline visit, visit at 6 weeks follow-up, administration, and other. Data will be gathered up to 6 weeks when the intervention protocol is completed and

follow-up data at 6 weeks are gathered. The endpoint will be expressed as the median time to complete the study procedures per participant. This endpoint addresses the fifth objective of the pilot study.

The study burden for participants (older persons)

The study burden for individual study participants will be assessed in two ways. First, semi-structured interviews are performed by the sponsor team (KU Leuven) with informed consent of the person. Audio recorded interviews using open-ended questions will focus on understanding how persons experience study participation and which aspects of the study might be perceived as hindrances or barriers in relation to their daily lives. The audio recordings will be used to process the interview in a RAP sheet per participant. The audio recording will be deleted after the RAP sheet has been validated by a second researcher. Second, a modified version of the Perceived Research Burden Assessment instrument is used to quantify the study burden for individual participants [16]. The instrument assesses several aspects of psychological, physical and logistical study burden using 5-point Likert scales. We will modify the scale by deleting items that do not apply to our study (e.g. travelling to a study centre), and by adding items that adequately capture burden in relation to our specific study intervention. As the scale will be adapted by the team, we will only report descriptive data at item level (and not scale level). The assessment of study burden is completed at the 6-week follow-up point. This endpoint addresses the sixth objective of the pilot study.

The study burden for healthcare professionals

The study burden for healthcare professionals will be assessed in a structured interview (one with the acute geriatrics team and one with the internal geriatric consultation team per centre). The interviews are conducted by the Sponsor team. Healthcare professionals involved in the screening of older persons will be invited for the interview. This includes professionals on the acute geriatric units and those with a role in the internal geriatric consultation teams. If possible, group interviews will be organised, but individual interviews can also be considered to accommodate interview participants. In the group interview, the aim is to collect individual responses from multiple participants at once, gathering each person's input on a specific set of questions. Participants can build on each other responses, but it is not meant to go into discussion. Interviews will focus on understanding how healthcare professionals experienced screening for eligibility and how this could be disruptive for their daily practice. Additionally, healthcare professionals involved in the treatment and care of the patients, such as general practitioners, home care nurses, occupational therapists and family care are included to understand if the intervention influenced their practice. Each interview is audio recorded and the recording will be used to process the interview in a RAP sheet per participant. The audio recordings will be deleted after the RAP sheet has been validated by a second researcher. The assessment is completed at the end of the recruitment period of the pilot study. This endpoint addresses the seventh objective from the pilot study.

Physiotherapists' experiences with the training protocol

Physiotherapists delivering the intervention to the patients in the experimental arm will be interviewed about their experiences with the training needed to deliver the rehabilitation protocol. The structured interviews are conducted by the sponsor team. Interview questions will focus on the format, the delivery, the content, and the duration of the training, and potential improvements will be explored. The interview is performed online after completion of the training, and is audio recorded. Depending on the planning and preference of the therapist, it can also be combined at the end of the intervention delivery (where a second interview is planned about experiences with the intervention). The recording is used to process the interview in a RAP sheet per physiotherapist. The audio recording will be deleted after the RAP sheet has been validated by a second researcher. This endpoint addresses the eighth objective from the pilot study.

Blinding of outcome assessors

The efficacy of blinding of the study nurses who assess outcomes in recruited study participants will be assessed using a structured interview. The interviews are conducted by the sponsor team (KU Leuven). The questions will address for which participants the study nurses feel they know, suspect or do not know to which group a person was randomised, and—if relevant—how they found out. Nurses' ideas of group allocation will be checked against the actual group allocation. This information will be used to construct a Blinding Index [17, 18]. The brief interview will be completed at the end of the pilot once assessments have been completed, as to not interfere with the study nurses' routine. This endpoint will be expressed as the frequency and proportion of participants where blinding was not achieved. This endpoint addresses objective nine of the pilot study. In the case that a study site notifies the sponsor team that blinding has been breached in several participants, the sponsor team will also conduct unstructured interviews with the site team to discuss reasons for unblinding and evaluate

if blinding procedures are to be maintained or should be dropped.

Feasibility of the study procedures, assessments and data collection

The feasibility of all study procedures, including the randomisation, assessments and data collection, will be assessed using a structured interview. The interviews are conducted by the Sponsor team (KU Leuven). The questions will focus on the timeliness and practicality of the randomisation, the assessment and the data collection in the participants' home, processing and managing the data and study administration. The principal investigators and study nurses will be interviewed at the end of the pilot study. The interview will be audio recorded, and the recording will be used to process the interview in a RAP sheet per study nurse and PI. The audio recording will be deleted after the RAP sheet has been validated by a second researcher. This endpoint addresses objective ten of the pilot study.

Intervention

Study participants' experience with the intervention

Experience of study participants with the intervention will be assessed using semi-structured interviews. The interviews are conducted by the Sponsor team. The interview is organised when the participant completes the follow-up at 6 weeks, or stops participation (but still agrees to the interview). The open questions will address how the intervention did or did not meet their needs, intervention elements they did or did not appreciate, their perceived adherence to the therapy sessions, the level of difficulty of intervention elements in relation to their level of disability, the support from their therapist, the perceived benefit or lack thereof, their reasons for engaging or discontinuing the intervention, and reasons for (not) recommending the intervention to others in the same position. To better understand the feasibility of the intervention, additional questions will focus on understanding challenges or barriers in participating in the intervention. The interview is performed at the participant's home, or online if preferred by the participant, and will be audio recorded. The recording will be used to process the interview in a RAP sheet per person. The audio recording will be deleted after the RAP sheet has been validated by a second researcher. The data resulting from the interviews will allow us to meet objective eleven of the pilot study.

Physiotherapists' experiences with the study intervention

Interviews with physiotherapists who deliver the intervention to the patients in the experimental arm are held to capture their views on the feasibility of the study intervention. The interviews are conducted by the Sponsor team. Open questions will be used to explore experience with the different elements of the intervention protocol in the population of older persons with disability. Questions will address feasibility with a view to adaptations of the intervention, the target group, the setting and their professional capabilities and limitations. The interview is performed online and is audio recorded. This endpoint addresses the tenth objective of the pilot study. The interview on the feasibility of the intervention (see previous point) will be extended to also capture physiotherapists' personal experience with the intervention and any reasons why they might want to continue or end intervention delivery. Questions will also explore their experience with the adherence of the participants, and their perceptions regarding factors that influenced this. This part of the interview will probe for their personal and subjective experience and views, as well as reflections on how the intervention matches the professional roles of physiotherapists in general. The recording of the interview will be processed in a RAP sheet per therapist. The audio recording will be deleted after the RAP sheet has been validated by a second researcher. The data resulting from the interviews will allow us to meet objective 12 of the pilot study.

Study timeline

The overview of study steps is presented in Table 4. The timeline only includes those steps relevant for the pilot study. The full trial will include an additional home visit at 6 months, and administrative data regarding survival and institutionalisation will be collected up to 1-year follow-up. Table 5 presents the complete overview of data collection in the full trial.

Sample size

The sample size for the start-up phase ($n = 6$) was determined with the assumption that including up to three participants at each of the two study sites would be adequate to identify and rectify any prominent issues or misunderstandings in the study procedures prior to the initiation of the actual pilot study. The sample size for the pilot study is not based on a formal sample size calculation as the aim is to test the feasibility rather than provide an estimated effect size. Within the consortium, it was agreed upon that including 24 participants at two study sites ($n = 12$ at each site) would allow for (1) a representation of participants in the two main Belgian language areas, (2) variation in recruitment routes, some variation in older person's characteristics (demographics and medical profiles), (3) sufficient qualitative data to evaluate participants' experiences with the intervention as well as the study procedures, (4) multiple experience with

intervention delivery for physiotherapists (experience with delivery in 3 older persons) as to inform their views on the study training, the study intervention, and their roles in data collection (intervention protocol adherence, adverse events), (4) multiple experience with all study procedures for study teams at both sites, as to allow for qualitative evaluations of their experience with performing the study, multiple contacts with hospital based and primary care based health professionals, as to allow for qualitative evaluations of their experience with study procedures. This sample size corresponds to the rule of thumb of 12 participants per group to study the feasibility in a pilot study [19]. While Julious (2005) originally proposed this recommendation in the context of estimating the standard deviation for continuous outcomes under the assumption of normality, the justification is broader and includes considerations of feasibility and precision around estimates. Therefore, the selected sample size supports the practical needs of assessing recruitment strategies, variation in participant characteristics, and study procedures across sites and stakeholders. With 24 participants recruited, an assumed retention of 75% can be estimated with a 95% CI of (55%, 88%).

Allocation

Participants will be randomised after the baseline home visit using a 1:1 ratio for randomisation to the control group and intervention group respectively, stratified on centre. A randomisation list will be constructed by a researcher not affiliated with the study team from the Leuven Biostatistics and Statistical Bioinformatics Centre. The randomisation list will be uploaded to REDCap. The principle investigator or study nurse (or other person to whom this is delegated) enrols the participant in REDCap to randomise the person. Participants allocated to the intervention group receive a prescription for physiotherapy, and are supported in contacting a physical therapist in their region who has been trained to deliver the intervention.

Blinding and unblinding

The study nurse will be blinded, and REDCap will be used to support blinding of the study nurse. It may be considered during the pilot study to stop blinding the study nurse if the site teams indicate that the quality of the study procedures are hindered by blinding (e.g. insufficient personnel available for randomisation, administrative follow-up, coordinate with physical therapists). This decision will be made by the Sponsor team together with the two PIs of the participating centres.

Data management

(e)CRFs are provided by the Sponsor for each participant. The Trial data will be transcribed from the source records (i.e. participant's medical file or trial-specific source data worksheets) into an (e)CRF by trial staff. Transcription to the (e)CRF will be done as soon as possible after a participant visit and in a pseudonymised manner using a unique identifier assigned by the Sponsor. Data are collected by study nurses from both study centres, and registered in

Table 4 Participant timeline

Pilot preparations	→ ***Actions***	***in chronological order***	→
Start-up phase in UZ Leuven and CHU UCL Namur	Start-up phase: testing recruitment and first home visit (up to 3 participants per site)	Feedback on study procedures, including data collection and assessments	Optimising study protocols
Pilot study			
Recruitment (in hospital or at home)	Pre-screening of older persons by staff of the internal geriatric consultation team and acute geriatric unit	Eligibility screening and recruitment of both older persons and informal caregivers (if possible) by nurse and geriatrician	Informing treating physician about recruitment in study
Baseline (at home)	Collecting baseline data during home visit; instruction on use of diaries	Recruiting informal caregiver (if not feasible in hospital)[a]	
Randomisation (at home)	Geriatrician prescribe the rehab program for intervention group participants	Informing GP on study participation/follow-up suggestions in all participants	Informing primary care professionals about inclusion in study
Intervention delivery	Delivering the 6-week rehabilitation program by physiotherapist	Logging of sessions and exercises delivered and any deviations	Monitoring and logging of AEs and SAEs by physical therapist (intv. group)
Follow-up at 6 weeks	Collecting follow-up data during home visit of study nurse	Assessing caregiver time and burden	Monitoring and logging AEs and SAEs by study nurse (both groups)
Qualitative interviews	Interviews with participant	Interviews with health care team and therapists	Interviews with study team members

[a] Participants can participate if no informal caregiver is present

Table 5 Overview of data collection in full trial

Activity or assessment	Data and instruments	Assessment type	Responsibility	Timing						
				Prior to hospital discharge Screening in hospital	**3 days post-discharge ± 1 day (baseline) T0 *home***	**3 days post-discharge ± 1 day Allocation**	**During 6 weeks Intervention**	**At 6 weeks ± 4 days T1 home**	**At 6 months ± 10 days T2 home**	**At 1 year T3 admin**
Activities for older persons as participants										
Inclusion criteria	Age, hospital unit, disability, hospital discharge plan, rehabilitation potential, eligibility for rehabilitation	Use of routine data	Healthcare team, Study nurse (site)	x		x				
Informed consent	Screening log	N.A	Study nurse, PI (site)	x						
Demographic data	Age, gender, ethnicity, educational level, monthly household net income, living situation	Interview	Study nurse (site)		x					
Clinical data	Reason for hospital admission, use of emergency services, use of intensive care, use of surgery, unit of hospitalisation	Electronic record	Study nurse (site)		x					
Comorbidity	Age-adjusted Charlson comorbidity index	Electronic record	PI, investigator or study nurse (site)		x					
Depressive symptoms	Geriatric depression scale	Interview	Study nurse (site)		x					
Cognition	Mini-cog	Interview	Study nurse (site)		x					
Frailty	Tilburg frailty indicator	Interview	Study nurse (site)		x					
Disability	Groningen activity restriction scale	Interview	Study nurse (site)		x			x	x	
Physical performance	Short physical performance battery	Test	Study nurse (site)		x			x	x	
Quality of life	EQ-5D-5L	Interview	Study nurse (site)		x			x	x	
Fall anxiety	Falls efficacy scale-international	Interview	Study nurse (site)		x			x	x	
Fatigue	Multidimensional fatigue inventory	Interview	Study nurse (site)		x			x	x	
Strength	Handgrip strength	Test	Study nurse (site)		x			x	x	

Table 5 (continued)

Activity or assessment	Data and instruments	Assessment type	Responsibility	Timing						
				Prior to hospital discharge Screening in hospital	**3 days post-discharge ± 1 day (baseline) T0 *home***	**3 days post-discharge ± 1 day Allocation**	**During 6 weeks Intervention**	**At 6 weeks ± 4 days T1 home**	**At 6 months ± 10 days T2 home**	**At 1 year T3 admin**
Hospital (re)admissions	Hospital (re)admissions, all cause	Diary Administrative data	Study nurse (site) Sponsor team		x			x	x	x
Emergency visits	Emergency visits, all cause	Diary Administrative data	Study nurse (site) Sponsor team		x			x	x	x
Institutionalisation	Institutionalisation	Interview Administrative data	Study nurse (site) Sponsor team		x			x	x	x
Survival	Survival, all cause	Interview Administrative data	Study nurse (site) Sponsor team		x			x	x	x
Randomisation	Randomisation log: REDCap	N.A	PI (site)			x				
Intervention participation	N.A	N.A	Participant				x			
Safety	Fall incidents	Witnessed	Study nurse (site) Physiotherapist		x		x	x	x	
	(Serious) Adverse events	Self-reported, medical record	Participant–study nurse (site) General practitioner Sponsor team		x		x	x	x	
Process evaluation	Adherence to intervention	Observed	Physiotherapist				x			
	Goal attainment	Interview	Participant – Physiotherapist				x	x		
	Use of healthcare services	Diary	Participant – study nurse (site)				x	x	x	
Economic outcomes	Healthcare consumption	Administrative data	Sponsor team				x	x	x	x
Endpoints for Pilot	Experiences with the interventions	Interview	Sponsor team					x		
	Study burden Perceived research burden assessment	Interview Interview	Sponsor team					x		
Activities for informal caregivers as participants										
Informed consent	Screening log	N.A	Study nurse, PI (site)	x	x					
Economic outcomes	Valuation of informal care questionnaire	Interview, eCRF	Study nurse (site)					x	x	

Table 5 (continued)

Activity or assessment	Data and instruments	Assessment type	Responsibility	Timing						
				Prior to hospital discharge Screening in hospital	3 days post-discharge ± 1 day (baseline) T0 *home*	3 days post-discharge ± 1 day Allocation	During 6 weeks Intervention	At 6 weeks ± 4 days T1 home	At 6 months ± 10 days T2 home	At 1 year T3 admin
Activities for physiotherapists as participants										
Intervention delivery	Intervention training and study protocol	N.A	Physiotherapist				x			
Informed consent	Screening log	N.A	Study nurse, PI (site)					x		
Endpoints for pilot	Experiences with training program and delivering intervention	Interview	Sponsor team					x		
Activities for healthcare professionals as participants										
Informed consent	Screening log	N.A	Sponsor team	x						
Endpoints for pilot	Study burden of healthcare professionals	Interview	Sponsor team	x						
Activities for site teams as participants										
Endpoints for pilot	Potential participants screened	Screening log	Study nurse (site)	x						
	Participants randomised	REDCap log	Study nurse (site)			x				
	Participants who completed follow-up	REDCap log	Study nurse (site)					x		
	Time needed for study procedures	Time log	Study nurse, PI (site)	x	x	x		x		
	Profiles of study participants	Baseline assessment	Study nurse (site)		x					
Informed consent	Screening log	N.A	Study nurse, PI (site)							
Endpoint for pilot	Feasibility of study procedures	Interview	Sponsor team					x		
	Blinding of study nurse	Interview: CRF	Sponsor team					x		

REDCap. REDCap is also used by physiotherapists to log the adherence to the intervention protocol. Qualitative data will be audio recorded and transcribed. Recordings are made using a hand-held Dictaphone. The audio file is saved directly to a protected file on the KU Leuven central server, only accessible to the chief investigator project, coordinator, and researchers involved in the analysis. Transcriptions are saved using the same conditions. The audio files will be deleted as soon as the data is processed into a RAP sheet and validated by a second researcher. Both documents will only contain the pseudonymised study number. Diaries will be a paper-based study document, which will be discussed with participants at the home visit at 6 weeks. During this discussion of the diaries, nurses will extract relevant information from the diaries and add any additional information on use of healthcare a participant might offer, to directly insert this in the eCRF. The paper-based documents are archived in a secure locker at the site of recruitment.

Analysis

For quantitative endpoints of the pilot study as well as the progression criteria for proceeding to the full trial, simple descriptive statistics (frequencies, proportions, median or mean scores) will be used. Recruitment information will be used to produce a CONSORT flow diagram. Finally, descriptive statistics are used to explore participants' scores on all outcomes for the full trial. Based on descriptive data from the pilot study, assumptions used for calculating the sample size needed for the full trial will also be evaluated. The sample size will be recalculated in the full trial using a blinded interim analysis after 80% of the sample has been obtained.. These will include the standard deviation for disability as well as the correlation of endpoint and baseline values for disability, the dropout rate, and the ICC for study centre; note, the sample size calculation for the full trial will be reported in a separate protocol.

The RAP sheets contain structured information from the qualitative interviews in a summary format. To arrive at a descriptive content analysis, an inductive coding process will be performed to summarise key themes from the interviews. This will be performed in a group process where RAP sheets are discussed within the project management team and themes are defined through discussion. Such discussions are organised for each of the relevant endpoints for the pilot study. In a second step, a deductive approach will be used matching interview experiences to the checklist for identifying determinants of practice as developed by Flottorp et al., which provides a structured framework for identifying and categorising barriers and enablers in professional healthcare practice [20]. A summary will be drafted identifying factors related to the feasibility of intervention delivery as well as delivering the full trial, and opportunities on how to improve the feasibility.

Monitoring

A Trial Monitoring Plan was developed and approved by the UZ Leuven Clinical Trial Centre based on the trial risk assessment. A study monitor will be responsible for the trial monitoring. The trial coordinator from the Sponsor team will regularly communicate with the participating sites. Any problems that come up will be logged by the coordinator and discussed with the Chief Investigator. Where possible, small changes in the procedures will be discussed, or an amendment of the protocol will be submitted to the ethics commission in case of substantial changes.

Harms

Exercises for strength, balance and gait are low risk overall, implying that the occurrence of an adverse event as a result of the study intervention is unlikely. Therefore, safety reporting will be limited to the safety reporting necessary in routine care. We will report all (Serious) Adverse Events (AEs and SAEs) that occur during the rehabilitation sessions as delivered by the physiotherapists. In addition, the physiotherapist will be instructed to ask participating older persons about any adverse events in between sessions at the start of every new session. Participants are encouraged to contact their GP in case of any adverse event they might experience. The study nurse will review the occurrence of adverse events (in both the intervention and control arm) during the home visits in case these were not already reported by the participant or the physiotherapist. For each (serious) adverse event, the following information will be collected: full details in medical terms and case description, event duration (start and end date), severity (mild–moderate–severe), outcome, potential causality (i.e., relatedness to the rehabilitation intervention) in the opinion of the investigator. Given the vulnerability of the sample, the research team do not exclude that some participants will die or be hospitalised during the follow-up. Only deaths and (S)AEs which are seen as potentially related to the intervention and as significant by the PI are immediately reported to the Ethics Committee. Unrelated deaths and all other (S) AEs are included in the annual progress report.

Ethics

Approval for the pilot study was obtained from the Ethics Committee Research UZ/KU Leuven and from the Cliniques Universitaires U.C.L. de Mont-Godinne (ethics reference number of UZ Leuven as central ethics committee: S65872). If the progression criteria are met, this

pilot will proceed to a full trial. If possible, data obtained from the pilot will be integrated in the full trial. Access to study data will therefore be linked to the full trial, and not this pilot study.

Discussion

This project originated from the uncertainties on the level of evidence associated with geriatric home rehabilitation. The designed pragmatic trial, with patient-centred outcomes, randomised and multicentre character, and embedded economic evaluation is expected to move the evidence forward. Due to the pragmatic trial design, many study procedures, including the intervention delivery, are performed in the context of everyday routine practice. We therefore expect that this project will generate real-world evidence informing the implementation of geriatric home rehabilitation in Belgium. This protocol paper defines the methodology for a pilot study investigating uncertainties before commencing a full trial.

Initial insights from the start-up phase point towards some challenges. Recruitment of participants requires daily monitoring of hospital discharges. Participant identification and the informed consent process demand substantial on-site presence and coordination. This challenge might intensify in the full trial, where the scale of recruitment will be significantly larger, and involving multiple centres. A second challenge is the coverage of home rehabilitation in discharged patients. Due to the smaller scale of the pilot study, fewer physiotherapists were trained and the current group of physiotherapists are not able to cover all eligible participants. This issue underscores the need for an extensive network of trained physiotherapists, which could be achieved through partnerships with local physiotherapy organisations. For the full trial, there are more recruiting centres and the volume of patients will be larger. This will allow us to increase the network coverage of the trained therapists. The report of the pilot study is expected in May 2025.

Appendix 1. Intervention protocol

Geriatric Activation Program Pellenberg (GAPP) adapted to the home setting (GAPP@HOME), is the intervention used in in this study.

GAPP@HOME is a 6-week program and consist of 3 different exercise days per week, each of 45 min; day 1 strength and power, day 2 balance, and day 3 speed, endurance and coordination. Each exercise day starts with 10 min of gait training. A set of written-out exercises is available for each of the 3 exercise days. The GAPP@HOME trained physiotherapist will select several exercises based on the person's abilities and needs. There is no set progression, however, therapists can adjust the protocol to older persons' (improved) capacities on a daily basis. Hands-on guidance is permitted and encouraged to achieve proper execution of the exercises.

Start of the intervention protocol:

1. Goal setting: The main goal of GAPP@HOME is to enhance the daily functioning of older individuals in their own homes. This program considers each person's specific situation and adjusts the approach to optimise their performance in that environment. Together, the older person and the therapist set personal goals for the patient's progress. These goals are established based on the person's wishes and preferences, such as activities like climbing stairs, engaging in outdoor activities, and handling household tasks independently, like hanging up laundry.

   Exercises aimed at improving strength and balance are chosen to align with the set objectives. During the initial session, these goals are written down, and progress is evaluated after the second, fourth, and sixth weeks to track advancements.
2. Rehabilitation schedule: The rehabilitation follows a weekly schedule

Session A	Gait training (warm-up) Strength and power training
Session B	Gait training (warm-up) Balance training
Session C	Gait training (warm-up) Speed, endurance and coordination

The following tables give more information on the individual sessions:

Gait training

Start each session with 10 min gait training. Depending on the space available, this will vary. If possible, go outside

	Description	Instructions/Execution
> 10 m	1. Walk forwards Walk sideways (holding hands if needed) Walk back wards 2. Interval training: walk 2–5 m as fast as possible (with support) alternating with normal walking speed 3. Walk without walking aid	1. Around the table, in the hallway, outside, … 2. Use visual cues, mark with tape, agility dots, …
< 10 m	1. Walk forwards and backwards Walk sideways (holding hands if needed) 2. Interval training: in place as fast as possible (with support) alternating with normal walking speed 3. Walk without walking aid	1. Even if it is just 1 m 2. Start with 30–30 s, build up (in 6 weeks) till 3 min–3 min

Day 1 Strength and power training

Type of exercises: sit-stand, stand on tiptoe, lifting a weight or use of resistance band, elbow extension, etc

Each exercise lasts 2–4 min, some exercises are separate per limb. Aim for high intensity of % 1RM. Repetition until failure (strength) or fatigue (power) is necessary. Count number of repetitions and check intensity. Older persons perform only one set of each exercise. Depending on the chosen exercises you can perform 6–10 exercises in 1 session

Warm-up: Gait training (see above)

Step 1	Choose exercise	Strength	Power
Step 2	Perform exercise twice	Controlled movement (able to stop at any point)	Controlled movement (able to stop at any point)
Step 3	Check Intensity Ask Borg Scale	Aim: 80% of 1RM 14–16 Somewhat hard-hard	Aim: 30–60% 1RM 10–13 Light–somewhat hard
Step 4	Adjust when necessary	Resistance/posture	Resistance/posture
Step 5	Perform exercise once	Constant pace (able to stop at any point)	Fast (1 s) concentric, slow (3 s) eccentric
Step 6	Repeat without rest until	Failure	Fatigue
Step 7	Monitor percentage of 1 RM	80% = 8–12 repetitions Holten diagram	50–60% = 15–25 repetitions
Step 8	Choose exercise, and repeat steps 2 through 7		
Step 9	Plan adaptation of training load for next session		

Day 2 Balance training

Type of exercises: weight shifts, reaching, narrow base of support, turning, stepping, etc

Each exercise lasts 5–10 min. Aim for high intensity and high repetition without repetition (motor learning). Depending on the chosen exercises you can perform 2–5 exercises in 1 session

Warm-up: Gait training (see above)

Step 1	Choose exercise	
Step 2	Perform exercise a few times	
Step 3	Check Intensity Balance Intensity Scale	Build up your exercise gradually, adjust limits during exercise and try to exercise at a high level (6–9 balance intensity scale) for at least several minutes (2–3) per exercise Rest is allowed within one exercise. For instance, 1 exercise takes 10 min with 2 breaks in between of 1–2 min

Day 3 Speed, endurance and coordination

Each exercise lasts 1 min. Aim to perform the exercise as fast as possible and do not stop before 1 min is reached. Allow 30 s till 2 min rest between exercises. You can perform 10–15 exercises in 1 session

Warm-up: Gait training (see above)

Step 1	Choose exercise
Step 2	Perform exercise for 1 min. Encourage them, tell them when they are half way, 20 s left, last 10 s

Abbreviations

ADL	Activities of daily living
AE	Adverse event
SAE	Serious adverse event
GP	General practitioner
GAPP	Geriatric Activation Program Pellenberg

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Data availability
Because the pilot study is intended to be an internal pilot, materials will be made available upon publication of the full trial.

Declarations

Ethics approval and consent to participate
This study was approved by the Ethics Committee Research UZ/KU Leuven and from the Cliniques Universitaires U.C.L. de Mont-Godinne (ethics reference number: S65872). Informed consent will be obtained from all participants.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

Author details
[1]KU Leuven, Department of Public Health, Academic Centre for Nursing and Midwifery, Leuven, Belgium. [2]Public Health, Institute of Nursing Science, University of Basel, Basel, Switzerland. [3]Department of Physical Medicine, University Hospital Leuven, Leuven, Belgium. [4]Department of Public Health, Leuven Biostatistics and Statistical Bioinformatics Centre, KU Leuven, Leuven, Belgium. [5]KU Leuven, Department of Public Health, Academic Centre of General Practice, Leuven, Belgium. [6]Department of Geriatric Medicine, University Hospital Leuven, Leuven, Belgium. [7]KU Leuven, Department of Public Health and Primary Care, Gerontology and Geriatrics, Leuven, Belgium. [8]Department of Geriatric Medicine, Ghent University Hospital, Ghent, Belgium. [9]Department

of Geriatric Medicine, ZAS Hospital Network Antwerp, Antwerp, Belgium. [10]Department of Geriatric Medicine, University Hospital Liège, Liège, Belgium. [11]Department of Geriatric Medicine, East Limburg Hospital, Genk, Belgium. [12]Rehabilitation Research Group, Faculty of Physical Education & Physiotherapy, Vrije Universiteit Brussel, Brussels, Belgium. [13]Geriatric Department, University Hospital Center UCL Namur, Godinne Site and Institute of Health and Society, UCL, Namur, Belgium. [14]KU Leuven, Department of Movement Sciences, Faculty of Movement and Rehabilitation Sciences, Leuven, Belgium.

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