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**BEST PRACTICES AND ORGANIZATIONAL MODELS
FOR ADVANCED MANAGEMENT OF OLDER PEOPLE
IN HOSPITAL AND PRIMARY CARE SETTINGS:
A TRANSLATIONAL APPROACH TO FALL PREVENTION**

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Dedicated to my mother

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PREFACE

"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."

(United Nations, *Universal Declaration of Human Rights*, Article 25- 1)

Every individual, belonging to any country in the world, should have the opportunity to live a long and healthy life. Good health and longevity, however, depend on the safety of the environment in which people live and the lifestyles they adopt, as well as the possibility of accessing health care, food and education.

The world's population is aging at an unprecedented rate. The number of people aged 60 years and older will increase to 1.4 billion by 2030 and 2.1 billion by 2050.

These changes are of historic significance for the world community, which will need to be able, in the years ahead, to change society in all spheres of life. The health sector, in particular, is already being called upon to transform its services at all levels of care and increasingly integrate social aspects into its services.

Transforming the global community into a more age-friendly society is a necessary and urgent response to current sociodemographic changes.

The path that will be outlined in this text, is a humble contribution to this development.

D. C.

EXECUTIVE SUMMARY

Introduction
Worldwide, aging populations are driving the adoption of new organizational and health-care models. Particularly needed are hospital and primary care organizational models that positively influence health outcomes and clarification on the best practices for preventing falls and the loss of physical function among older people living at home.

Purpose of the Thesis
The purpose of this doctoral thesis is to explore new organizational models for the advanced management of older people in hospital and in primary care settings and to implement best practices for reducing falls. The study was funded by the Italian Ministry of Education, University, and Research (MIUR) program Departments of Excellence 2018-2022, AGING Project, carried out in the Department of Translational Medicine at Università del Piemonte Orientale.

Chapters
This doctoral dissertation presents research carried out over three years. The text is divided into 12 chapters. The first chapter presents general considerations and provides a summary of the rationale behind the study design. The second chapter contains an explanation of the project's concept in more detail and an in-depth discussion of the thesis topics. The third chapter introduces an innovative hospital model for intensive care in the geriatric setting, and the fourth chapter presents an application of that model.

The fifth chapter presents the results of the application of the model at the primary care level in which the setting has been shifted from the hospital to the patients' homes. The sixth chapter introduces two examples of how the evidence discussed here can be applied in practice. Preliminary results are contained in the meta-analysis in chapter seven.

The eighth and ninth chapters present best practices for fall prevention in the elderly, and chapter ten addresses the challenge of fall prevention in the home setting through the use of technology that records falls and monitors the patient over time. This tool, which has been validated across borders, is the topic of chapter eleven.

In chapter twelve, the general research pathway and additional considerations are discussed.

Conclusion
Although studies are still ongoing and, therefore, conclusive inferences are not possible, preliminary results on the use of the organizational health-care model and best practices presented here are promising.

Future Research
Further studies are needed to investigate the impact of the models and best practices studied in this thesis in terms of the quality of clinical and organizational care, as well as patient satisfaction and outcome.

CHAPTER 1

General Background

Campani D, Longobucco Y, Quali sono le priorità per i pazienti a rischio di decadimento cognitivo e funzionale? 66° Congresso Nazionale SIGG, Roma.

Globally, the prevalence of individuals aged ≥60 years increased from 9.2% to 11.7% between 1990 and 2013 and is expected to reach 21.1% (over 2 billion) by 2050 (1). Life extension is certainly a success but must be accompanied by a good quality of life to be considered beneficial. Preserving autonomy and independence in the aging process are key goals for both individuals and the community (1).

The main challenges faced in a society whose average life span lengthens are:
- the biological challenge: maintaining a high level of physical and mental performance in life's later stages
- the social challenge: optimizing and enhancing the retirement years
- the cultural challenge: offering older people the opportunity to live with dignity in later years

To meet these challenges, all stakeholders must cooperate by building bridges between the relevant research areas in this area. Understanding the biological and lifestyle factors that modulate the trajectories of aging must be expanded and shared across multiple disciplines to promote aging as healthy and active as possible (2). Psychophysical decay and loss of functional autonomy increasingly occur as age progresses. As a result, many older people remain active by redesigning their lives professionally and familially.

The three main trajectories of aging are:
- active aging/healthy active aging
- aging with frailty or vulnerability
- aging with disability

The World Health Organization has defined healthy active aging as "the process of developing and maintaining functional capacity, which enables well-being in old age" (3). Healthy active aging is mainly determined by two factors: intrinsic capacity and environment (4). Intrinsic capacity represents a new concept that refers to all the mental and physical capacities people have throughout their lives. This capacity tends to decline with aging, even in the absence of chronic disease (5).

Identifying parameters that reveal an impairment of intrinsic capacity is crucial. Prevention of age-related physical and cognitive limitations would thus no longer be confined only to old age but could begin as early as adulthood within the community, from a proactive perspective that focuses on all community members instead of individuals.

Frailty is a condition of accelerated aging. It is defined by a state of vulnerability to poor homeostasis resolution after a stressful event and is a consequence of the cumulative decline of many physiological systems over the course of life (6).

On a purely operational level, the best-characterized model is that of physical frailty, understood as a reduction in the subject's physical performance (7). This model's advantage is that it identifies frailty as a well-identified and measurable clinical syndrome, as distinct from disability, and has also proven extremely valuable in predicting adverse health outcomes, such as hospitalization, disability, and death.

However, frailty, being a multidimensional phenomenon, cannot be defined and interpreted solely based on physical–functional aspects. A complete definition of frailty requires consideration of the psychological, cognitive, and social domains as well (8). In particular, cognitive frailty has recently been defined as the simultaneous presence of physical frailty and cognitive impairment in the absence of dementia (9).

Nevertheless, the response to the frailty condition is often only "reactive," which by its very nature can only intervene in the late manifestations of frailty, often already headed toward a disabling condition (9).

For these reasons, early intervention is necessary by implementing models of frailty screening and treatment in the context of primary care and close to the elderly population's living places, drawing on community-level resources.

Indeed, physical disability and loss of independence can be prevented through multiple interventions, including exercise and a secure home environment. These interventions have many health benefits and can also affect fall prevention. As such, enhancing the provision of preventive interventions is required, including the use of technology, especially in patients with cognitive disorders.

These needs match the recent introduction of the Family and Community Nurse figure, defined by Bill No. 1346 of June 19, 2019, as "the reference figure for the development and strengthening of territorial home care services in order to safeguard the health status of citizens."

The family and community nursing model is applicable in the home setting to strengthen the citizen care network. At the hospital level, on the other hand, additional organizational and care models can be applied to complement care provision in an appropriate, effective, and significantly impactful manner on the clinical conditions of patients, health care workers, and health care organizations.

The dissertation presented in the next chapters defines a research path through the study of organizational and care models and the implementation of best practices at the primary care level for advanced management of the aged population.

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CHAPTER 2

Advanced Management of the Elderly individuals in hospital and primary care: the AME project

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> Conoscere non significa scomporre,
> e nemmeno spiegare. Significa accedere
> alla visione. Ma per vedere bisogna prima
> partecipare. E' un apprendistato difficile.
>
> Antoine de Saint-Exupéry, (*Flight to Arras- Pilota di guerra*)

General background and rationale

The general population of Western countries is aging (1). In Italy, we are observing a constant increase in the population over 65 years old with multiple chronic conditions (2). On the basis of these sociodemographic changes, there is a strong need for disease prevention and management actions.

This doctoral research program is part of a larger project called "Advanced Management of the Elderly individuals in Hospital and Primary Care" (AME project; PI Prof. Alberto Dal Molin, CO-PI Prof. Mario Pirisi), which is composed of five work packages (WPs).

The whole AME project is harmonized so that the results of the WPs are complementary to each other to ensure greater coverage of elderly individuals' health problems.

The key WPs of the project are summarized below:

- – WP1) Develop models for managing frailty in elderly individuals living at home: implement new nursing roles (e.g., family health nurses), conduct an impact assessment,

and develop a multifactorial intervention to improve people's safety (e.g., to reduce falls)

- WP2) Develop an acute care pattern for in-hospital older patients: design and implement an interdisciplinary team model (e.g., an ACE unit) (3) and innovative patterns of nursing care (e.g., primary nursing, intentional rounding, and the PICO project) to improve patient care
- WP3) Examine the impact of elective surgery on elderly individuals' frailty: explore the effect of surgery and hospitalization on long-term functional performance through observational study
- WP4) Assess the feasibility and acceptability of delivering Tertiary ALS Centre specialty care to homes using technology: develop a model for geriatric care and explore the use of technology and telehealth in ALS patients, obtaining a model to reproduce in geriatric population
- WP5) Engage in epidemiology and develop a new model for the management of acute kidney injury (AKI) in elderly patients admitted to Novara Hospital (the NOV-AKI study): conduct an epidemiologic analysis of acute kidney injury in Novara Hospital with development of a new integrated model between nephrologists and general practitioners in primary care and identify AKI patients progressing toward chronic kidney disease via evaluation of epigenetic alterations in urine.

The research path addressed in the doctoral studies course is related only to WP1 and WP2. A brief introduction to both is presented below.

Models for managing frailty in the elderly at home

Scientific background and rationale

The presence of multiple chronic diseases in the elderly population is gradually increasing the number of people who are hospitalized. Increasing age is one of the risk factors for falls, which is an emerging problem among elderly people. As the number of elderly people increases, the number of **falls** is expected to increase, with an economic impact on the health system generated by direct and indirect costs (4,5). Falls have many negative consequences, such as fractures, mobility reduction (6–8), and psychological repercussions, including the fear of falling (9). They also increase the risk of admission to a nursing home (10). Some multifactorial interventions have been demonstrated to be effective in preventing falls (7,11–13). Multifactorial interventions appear to be more effective than single interventions, such as physical exercise (13). Developing effective, sustainable, and transferable prevention interventions (IPEST) is necessary to reduce falls in community-dwelling people.

Most chronic conditions can be adequately treated in the community, and primary care is the entry point of the healthcare system (14). To improve access to care, increase quality of care, and reduce costs, many countries have introduced nurses with advanced roles in primary care (i.e., **family health nurses**) (15,16). The PICO project presented in this paper is a preliminary example of implementing the family and community nursing model through a design aspect. In fact, the interventions developed in the above-mentioned IPEST manuals can be implemented by family and community nurses in the homes of the people being cared for. Nurses can

contribute to preventing falls (17), and the IPEST manuals support this process. To date, the impact of the manuals could not be determined but will be a focus of future work.

Among fall-related psychological concerns, depression seems to be the most important (18). Broadly speaking, depression is the most frequent cause of emotional suffering in older adults. Late-life depression is highly prevalent worldwide. It is not only a debilitating illness but also a risk factor for excess morbidity and mortality. Older adults with depression are at risk for dementia, coronary heart disease, stroke, cancer, and suicide. Individuals with late-life depression often have significant medical comorbidity and poor treatment adherence (18). Furthermore, depression has consequences for levels of everyday functioning and activity, perceived interest and meaning in life, hopelessness, and quality of life (18).

Some recent studies have supported the importance of fall-related depression. One study found that the correlation between emotional regulation and fear of falling in community-dwelling older adults was no longer significant when controlling for depression (19). Similarly, apathy was found to impact physical performance and fall incidents (20), and significant bidirectional relationships between depression and multiple falls have been described (21).

This theoretical background points to the importance of incorporating depression assessment and treatment in prevention programs for older adults at high risk of increasing/multiple falls (21). Given that treatment-resistant depression is common in this age group (23), the approach to depressive illness in later life should be multimodal, including but not limited to antidepressants that are appropriate for use in geriatric patients (22). From this standpoint, it is of great importance that healthcare personnel are adequately trained and educated in recognizing symptoms and warning signs of depression, which can differ between late life and young adulthood.

In conclusion, this project aims to develop advanced management models for providing care to the elderly at home through a holistic view of the problems related to aging and the introduction of an innovative and strategic nursing role.

Experimental plan

General objectives of the WP:

      a. To improve the care of older people in the community

      b. To prevent and reduce falls in community-dwelling people

      c. To explore the association between depression and falls.

Actions planned (tasks) and methods:

Tasks	Methods
Support the local health authority in the implementation of a family health nurse (PICO project)	Meetings Training Project work
Develop evidence-based interventions for fall prevention among community-dwelling older people	Literature review and development of the IPEST
Conduct tool validation for fall prevention in community-dwelling people	Delphi
Develop a multifactor intervention (which must include the IPEST) to prevent falls in community-dwelling people	Expert consensus
Understand fall-related psychological concerns (with a focus on depression); evaluate longitudinal associations between older adults' fall status and depression; and clarify the bidirectional relationships suggested by the existing literature	Literature review

Expected outputs and deliverables

The implementation of family and community nurses will make it possible to respond more effectively to the population's health needs, especially those of the elderly, fragile, and chronically ill.

Local health authorities will be guided in choosing "best practices" for prevention and health promotion and in their implementation of family health nurses. The operative manual should be used by professionals to support prevention programs. This tool will offer professionals a practical guide for making evidence-based decisions regarding fall prevention and the promotion of healthy aging. The final handbook could also be useful for maximizing health and social benefits and minimizing costs. Interventions will be planned to take into account transferability elements in contexts other than those studied.

In addition, the identification of fall prevention tools and the study of psychological components related to falls will lead to a reduction in falls, better control of risk factors, and the identification of the most vulnerable members of the population.

Pitfalls, caveats, and alternative approaches to achieve the expected objectives

This project is not without challenges. In particular, the implementation of family health nurses and fall prevention interventions is a complex process with several interacting components that present many specific problems for evaluators (e.g. assessment), and it will be difficult to standardize the design and deliver interventions. In addition, this project requires the collaboration of a variety of human resources (e.g., family doctors, family health nurses, and the local health authority).

Development of an acute care pattern for in-hospital elderly patients

Scientific background and rationale

It is well known that older patients are at high risk for loss of independence and institutionalization when they are hospitalized for any reason; in fact, they can be affected by a functional decline in just a few days (25).

To preserve patient independence and increase the quality of care, an interdisciplinary approach is needed. The **Acute Care for Elders** (ACE) Unit is one of the best recognized examples of such an approach (26). The ACE model is characterized by the following key elements:
  i) patient-centered care (proactive geriatric assessments; daily assessment by nurses; actions to improve self-care, continence, nutrition, mobility, sleep, skincare, mood, and cognitive performance; and daily rounds by a multidisciplinary team in which a **primary nurse** is involved);
  ii) early discharge planning;
  iii) medical care review; and
  iv) a modified hospital environment (e.g., large clocks and calendars, carpeting, and handrails)(27).

The first ACE unit was developed in 1990, and the first study on its efficacy was published in 1995 (27). The impact of this model has been described in several reviews (26,28,29), and one recent study reported the benefits of such an approach in reducing the incidence of **falls** among hospitalized elderly patients (30). To the best of our knowledge, however, there is no Italian hospital in which the ACE model has been implemented.

Furthermore, the implementation of innovative nurse-staffing models in Italy is necessary due to the healthcare professionals shortage. **Primary nursing** and **intentional rounding** seem to have a good impact on patient outcomes (e.g., falls) and organizational outcomes (31,32). In the former model, a "primary nurse" is responsible for caring for select patients and assessing inpatients, coordinating nurse diagnoses, scheduling care, and developing a discharge plan (33). Intentional rounding is a care pattern in which nurses satisfy their patients' needs with proactive regular checks (34,35); this approach improves the delivery of fundamental care to patients (36).

The development of new organizational and care models and the implementation of an acute management unit for the elderly are features of strong care-related innovations in the Italian context. Much evidence (37) supports the pivotal role of emergency departments in the clinical management of elderly patients, such as in properly assessing their clinical conditions and ensuring frail patients receive continuity of care, limiting emergency hospital admission to cases for which it is strictly required. Moreover, the emergency department is the appropriate setting in which to select patients to be admitted to the ACE unit. Given the evolution of population health issues, this project has been strategically crafted to address the ongoing evolution of population health issues within the context of existing health services.

These data can be useful for understanding the effectiveness of the aforementioned patterns of nursing care, which can be implemented in the ACE unit. The impact of the ACE model on

patient health outcomes (e.g. falls prevention), organization and staff satisfaction will need to be studied with future work.

Experimental plan

General objectives of the WP:

    d. To implement an interdisciplinary team model of acute care for older in-hospital patients

    e. To explore the effect of patterns of care on patients and organizational outcomes.

Actions planned (tasks) and methods:

Tasks	Methods
Understand the characteristics and core components of an ACE unit	Literature review
In agreement with the Hospital board, develop an organizational project with the main objective of implementing an ACE unit	Project work
According to the nurse manager, develop an organizational project with the main objective of implementing adequate patterns of nursing care (primary nursing/intentional rounding)	Project work Research study
Implement an ACE unit and innovative patterns of nursing care Develop training courses for professionals (doctors, nurses, social workers, nutritionists, physical therapists, and nursing assistants)	Meetings Training

Feasibility

The introduction of an ACE unit will be carried out in collaboration with the hospital board; an inspection has already been carried out, and a plan for its implementation is ongoing.

Pitfalls, caveats, and alternative approaches to achieve the expected objectives

This project is not without challenges. In particular, the implementation of an ACE unit is a complex intervention with several interacting components; they present many specific problems for evaluators, including the difficulty of standardizing the design and delivering the intervention. It also requires the agreement of a hospital board keen to innovate and collaborate with a variety of human resources (particularly doctors, nurses, and nurse assistants).

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CHAPTER 3

Introduction to the ACE Project, a model for a Geriatric Intensive Care Unit implementation

Acute care hospitalization linked to disability

The observation that 30% of hospitalized older adults, regardless of the length of stay, experience autonomy loss makes hospitalization an important risk factor of disability among older people.

Hospital-related disability (HAD), also known as loss of independence in activities of daily living (ADL) at hospital discharge compared to pre-admission baseline, is a serious threat to independence and quality of life in the elderly, thus posing a burden on the healthcare system.

A recent study (1) has shown how hospitalization can cause disabilities in older adults. The general objective of the systematic review and meta-analysis was to determine the overall prevalence of hospitalization-related disability, in terms of decline in ADL, in the elderly.

The study was a meta-analysis of randomized controlled trials (RCTs) published in English language from major international databases—e.g., PubMed, Embase, CINHAL, Scopus, ProQuest, NICHSR ONESearch and ClinicalTrials.gov—aimed to identify the changes in ADLs among people aged ≥ 65 years in acute care units or medical-surgical units.

Eligible RCTs, prospective cohort studies and quasi-experimental studies were considered. For quasi-experimental studies, only patients in control groups were considered. All studies measured functional independence at two or more study time points—e.g., before admission and discharge or during hospitalization. Studies that included rehabilitation facilities, such as hospital rehabilitation units or acute care for elders units (ACE), were excluded.

The meta-analysis examined 15 studies conducted between 1983 and 2013, for a total of 7,375 participants. Eleven studies were conducted in the USA, two in Italy, one in France and one in Israel. Thirteen studies assessed hospitalized patients, while the remaining two involved patients living in the community.

Among the hospitals included in the study, the prevalence of disability ranged from 17% to 61%, with an average of 30% (CI 95%: 24%, 36%; $P < 0.001$). Importantly, this value did not change when two studies on patients from psychiatric, cardiology and neurology units were included in the analysis. Likewise, the prevalence remained unchanged when two studies on patients treated in community hospitals were added to the analysis.

This review was the first to investigate ADLs in the elderly in the context of acute care. Furthermore, given the many geographical regions considered, it has good generalizability. Overall, the findings of this review call for the implementation of new helthcare approaches to limit disability in hospitalized elderly. One such approach could be the Acute Care Elderly (ACE) model.

Developing a new model for a Geriatric Intensive Care Unit

The Acute Care for Elders (ACE) model is an innovative tool for older people care designed to prevent disabilities and independence loss in daily life activities associated with hospitalization following an acute event. Health outcomes are improved through the application of four multidimensional key elements: *i)* person-centered care provided by nurses in collaboration with an interdisciplinary team; *ii)* a physical environment designed to promote the health and physical function of the person being assisted; *iii)* revision of medical prescriptions to ensure best quality treatment plan and clinical governance; and *iv)* an early discharge plan, already defined at the beginning of the hospitalization, drawn up by an interdisciplinary team.

The initially developed model (2) was based on the concept of dysfunctional syndrome (**Figure 1**), which was later on better defined as hospitalization-associated disability (3). This model predicted the predisposition to functional decline among the elderly due to compromised homeostatic abilities and the coexistence of multiple chronic diseases. Indeed, older people almost inevitably suffer from a series of age-related health conditions, such as decrease in muscle mass (i.e., sarcopenia), strength and balance, and often present with cognitive disabilities, which may all contribute to worsen their health status once they are hospitalized. However, many harmful consequences of these poor health outcomes, such as falls and related fractures, delirium and urinary catheterization-related infections, could be prevented.

Figure 1- Dysfunctional syndrome
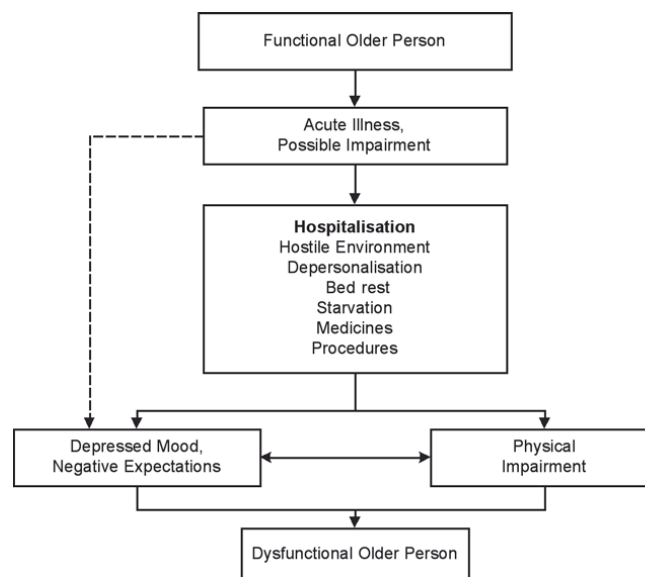
Hospitalization can increase the risk of functional decline of older patients, often leading to disability or dysfunctionality—either temporary or permanent—of the latter. Among others, determinants of functional decline include the presence of a perceived hostile environment, malnutrition, immobility and reduced physical functionality. In this scenario, the ACE model sets out general principles for the creation of an environment that allows patients to achieve greater mobility and autonomy in their daily life activities and self-care, while favoring socialization (4, 5). In this regard, a recent systematic review and meta-analysis by Fox *et al.*

(6) has shown how the introduction of an "ACE unit" in hospitals can reduce the frequency rates of patient falls and delirium, the length of stay, the functional decline at discharge and the number of discharges to a nursing home, thereby lowering healthcare costs.

With regard to the Italian healthcare system, the main obstacle to the implementation of the ACE model is represented by the endemic structural limitations affecting the majority of our hospital centers. Another critical aspect may be the initial economic investment required to create functional ACE units within the healthcare setting. Having learned the basics of the model, a case-by-case assessment is therefore recommended to determine the best solution to adopt for an effective implementation, within the limitations of the available resources. With regard to the model adopted, alongside the environmental changes, a cultural change should be also triggered by shifting from a multidisciplinary to an interdisciplinary care model. This transformation can be successfully achieved through a step-by-step process accompanied by effective training of healthcare workers.

The ACE project in Alessandria
The following project aimed to create and implement an ACE unit at the SS. Antonio and Biagio and Cesare Arrigo Hospital of Alessandria. This project, which involves all the main health stakeholders of Eastern Piedmont, will provide citizens with a center of excellence for the care of older people in need of hospitalization following an acute event. This model, and especially its interdisciplinary nature, could also be transferred to contexts other than geriatric and hospital settings.

This project was born within a collaboration of the University of Piemonte Orientale (UPO) and Azienda Ospedaliera of Alessandria (AO). It is part of the larger project of the UPO Advanced Management of Elderly in hospital and primary care which also includes five other work packages still focused on innovative models of elderly care.
The principal aim is to implement an ACE Unit within AO.
In order to implement the ACE, the following activities we carried out:
   a) in-depth organizational analysis of the existing Geriatrics of the AO (preliminary analysis);
   b) project planning (feasibility analysis and risk management, including the sustainability of results, cost analysis, expected results, deliverables and outputs, expected benefits, communication plan);
   c) responsibility matrix, staff training
   d) results dissemination, monitoring and evaluation (including cost management: relationship between estimated costs and expected results).

The following activities were carried out prior to the implementation of this project: 1) a mandate of the client with evaluation and choice of the structure in which to implement the ACE Unit. The criterion for choosing the structure was to redevelop an existing and currently disused structure that includes a space for hospitalization and adjacent structures (i.e. the Geriatrics of AO); 2) the creation of a multi-professional Working Group made up of both staff from the UPO and internal members of AO. To date, an in-depth organizational analysis of the

existing Geriatrics of the AO has been carried out, which led to the following sub-analyzes: general description of the AO; context analysis; internal context variables (individual, institutional, social and technical variables); basic structure (hierarchical division; division of functions, duties, tasks and operations; division of physical spaces; division of staff; economic and technological resources); operational mechanisms (decision and evaluation criteria); social processes.

The development of new organizational and care models and the implementation of an ACE Unit is a feature of strong innovation for care in the Italian context (7). Therefore, given the evolution of population health issues, this project appears to be of a strategic nature within the health services available to older patients (8).

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CHAPTER 4

Implementing a Geriatric Intensive Care Unit: the ACE Project

Preface

Ministerial Decree 70/2015 had redefined the standard of a maximum of 3.7 beds per thousand inhabitants (including 3.0 acute care beds and 0.7 post-acute rehabilitation and long-term care beds). This value, the lowest in Europe, has led the regions to adopt a measure of reorganization and reduction of accredited hospital beds, which has created a situation of distress in the system because the reduction of available beds has not been accompanied by policies to develop territorial medicine (a solution successfully adopted, for example, by Sweden and Great Britain). In the early 2020s, the shortage of hospital beds and inefficiencies in out-of-hospital care were exacerbated by the spread of COVID-19, a situation that further exacerbated the demand for beds. As highlighted in **Table 1**, the elderly population has been the most affected by the virus: to date there are 238901 cases including 29174 health care workers with a total of 33369 deaths (1).

Table 1- Lethality rate for COVID-19 in the Italian elderly population

Age	Deaths (%)	Lethality rate (CFR)
60-69	3384 (10,1)	10,6%
70-79	8858 (26,5)	26%
80-89	13651 (40,9)	33%
≥90	5936 (17,8)	31,1%

From this it follows that the elderly, in the current epidemiological scenario, especially those with chronic, neurological diseases and disabilities, are to be considered as fragile subjects who require specific intervention strategies for the prevention and control of the epidemic. In view of this high and complex care need, the present project, which for the potential huge competitive advantages had been hypothesized long before the SARS-CoV-2 pandemic, is more consistent and necessary than ever for the advanced management of the geriatric patient with an acute event.

The goal for which this project was developed is the implementation of an Acute Care Unit for the Elderly at the A.O. SS. Antonio and Biagio and Cesare Arrigo in Alessandria (IT). Starting with an analysis of the existing reality, the proposal is subsequently described. Planning was done through the use of some of the typical project management tools such as: W.B.S. to list and break down the various activities, O.B.S. to assign responsibilities, R.A.M. to integrate the data previously described, Gantt chart and Milestones that allow a graphical and timing representation of the project phases. The development of the design was affected by the costs and resources available and the influence stakeholders had during planning. The planning of indicators (e.g., user-perceived quality), during program implementation, allows for an evaluation between what was planned and what will be implemented (2). In the concluding section, the proposed objectives are examined in relation to the results to be achieved. The project management techniques used refer to the text *"Project Management body of knowledge"* (3).

Background

Elderly patients are at high risk of loss of autonomy and institutionalization (4), a factor well known by the time they are acutely hospitalized for any cause; in fact, functional decline can affect them within a few days (5). To preserve the patient's independence and to increase the quality of care, an interdisciplinary approach is deeply needed. The Acute Care for Elders (ACE) Unit is one of the best recognized examples of such an approach (6).

The ACE model is characterized by the following key elements:

- Patient-centered care (proactive geriatric assessment);
- Daily nursing assessment;
- Actions aimed at improving self-care, continence, nutrition, movement, sleep, skin care, mood, cognitive abilities;
- Daily rounding by the multidisciplinary team in which a primary nurse is involved;
- Early discharge planning;
- Review of medical prescriptions;
- Modified hospital environment (large clocks and calendars; flooring, handrails, etc.)(7).

The first ACE Unit was developed in 1990, and the first study of its effectiveness was published in 1995 (7). The impact of this model has been described in a number of reviews (6,8,9) and a recent study reported The benefits of this approach in reducing the incidence of falls among hospitalized elderly patients (10). In Italy, to date, there is no Italian hospital in which the ACE model has been implemented.

The development of new organizational and care models and the implementation of an acute care unit for the elderly is a feature of strong innovation for care in the Italian context. Much evidence (11) support the pivotal role of the ER in the clinical management of elderly patients in order to correctly assess clinical conditions and direct frail patients toward continuity of care, limiting emergency admission to cases for which it is strictly necessary. In addition, the emergency room is an appropriate access point for selecting patients for admission to the ACE Unit. Given the evolution of population health problems, this project is strategic in nature within the provision of health services to the citizen.

Analysis of the policy, system and regulatory context

The Azienda Ospedaliera SS. Antonio and Biagio and Cesare Arrigo is a public administration within the meaning of Article 1, Paragraph 2 of Legislative Decree 165/01, as amended, however, Legislative Decree 502/92, as amended, reorganizing the Health Service has given health care companies entrepreneurial autonomy, recognizing their power of internal self-regulation through the adoption of the Company Act of private law. Coexist, within the Hospital Company, activities attributable to public/administrative law and activities attributable to private law, such as contractual activity and management of labor relations (12).

The Azienda Ospedaliera "SS. Antonio and Biagio and Cesare Arrigo" of Alessandria, formerly identified as a Hospital Presidium of national importance and high specialization by the D.P.C.M. April 23, 1993, is an Azienda with public legal personality and entrepreneurial autonomy, established by D.P.G.R. Dec. 28, 1994 No. 5534, pursuant to Regional Law Sept. 22, 1994 No. 39, by means of spin-off from the pre-existing USSL No. 70 of Alessandria. The Company has been active since January 1, 1995. As part of the reorganization of the Regional

Health Service initiated with the adoption of Regional Law No. 18 of August 6, 2007, the company was confirmed as a hospital corporation, maintaining the same name, by Presidential Decree No. 96 of December 17, 2007 (12).

The Azienda Ospedaliera SS. Antonio and Biagio and Cesare Arrigo is a Hospital Company of national importance; it is the point of reference for 2nd and 3rd level activities and plays a role as a basic presidium for citizens residing in the Province of Alessandria, in close correlation with territorial services. In particular, the Company has developed highly specialized skills in the following areas: cardiac neurosurgery, nephro-urology, pediatric, neuro rehabilitation, oncohematology, oncologic pulmonology, oncologic radiation therapy, vascular diseases, and oncologic surgery and gynecology. It is also home to pediatric presidium, referral center for functional recovery and rehabilitation Level III Presidio Borsalino, home to Level II Department of Emergency and Acceptance and Emergency Operations Center 118 , of the Province of Alessandria with Helicopter Base. It is home to the AO and ASL AL inter-agency degree program in nursing. The inter-agency degree program is part of the Department of Translational Medicine of the School of Medicine of Piemonte Orientale University. The AO AL and ASL AL hospital wards, as well as the district/territorial departments of the ASL AL, are home to the professionalizing internship course and complementary teaching for first-, second-, and third-year students, as well as students attending first-level master's programs organized by the School of Medicine (12). The hospital has also been identified as the site of internships for students in the medical degree program.

The Company's activities are guided by the criteria of effectiveness, efficiency and economy, quality and equity within the framework of the following general principles:

- Centrality of the citizen-user;
- departmental organization;
- Accountability for business results and process management;
- quality improvement.

The *Mission of* the A.O. has been outlined with the five-year strategic plan 2018-2023 called OPERA, an acronym that refers to 5 goals to be achieved in the next 5 years: Operation Excellence, Pursuing Efficiency, Being with the Territory, Research as a Mission, Hospitality and Wellness. The purpose of the plan is to create care pathways for citizens and offer better and more services; enhance the role of A.O. even beyond the regional border; collaborate with the territory; and enhance internal resources and excellence through organization, training, research and innovation.

Regarding Operation Excellence, the priority purposes are:

- strengthening high specialty: encouraging the activity and development of specialties that stand out for excellence, productivity and attractiveness;
- renewal of the technology park: improvement of the company's stock of biomedical equipment;
- monitoring and evaluation of results: providing citizens with the measurement of care capacity through health indicators to know the results of the work;
- reorganization of semintensive areas: a single area is planned for patients in need of semintensive care;
- new pediatric operating block: a new operating block is planned for the pediatric presidium;

- new dialysis: a renovated environment is planned in space and color.

To pursue efficiency by eliminating waste, the A.O. aims to:
- "*Lean* operational management": activation of projects aimed at eliminating waste and improving flows;
- Enhancement of surgical and endoscopic activities: reconversion of operating rooms in the old blocks and enhancement of surgical activity through separation of flows by complexity;
- new sterilization central unit: design and implementation of a single central unit for the sterilization of all materials needed for the surgical activities of the Corporate Garrisons;
- Enhancement of the activities of the Presidio Borsalino: increase level II rehabilitation offerings through the project of opening beds with a revision of the current organizational model toward a model by intensity of care;
- Enhancement of clinical/caregiver pathways: restoration of clinical/caregiver pathways already implemented at Geriatrics;
- Cardiac intensive care unit: new area to accommodate the patient unit;
- Quality System development and strengthening: reinforcement of the quality management system to facilities not yet certified;
- Energy efficiency: insulation initiatives and for insulation replacement of lighting fixtures with high-efficiency LEDs.

In terms of supporting and enhancing scientific production and research activities through integration with the university, the A.O. intends to:
- Supporting and enhancing the research and scientific production activities carried out by corporate practitioners through the corporate functional infrastructure: defining the research plan, consolidating the *Clinical Trial Center*;
- Develop and enhance training: support and enhance training interventions for practitioners;
- Increase scientific popularization: disseminate the achievements of professionals in collaboration with the university;
- Increase the activity of the robotic surgery teaching center.

The management and coordination of this project is entrusted to IRFI whose mission is to identify and promote synergies between scientific research and care activities, having as a priority objective the improvement of the citizen's health status, through the path of recognition towards the Institute of Hospitalization and Treatment with Scientific Character, synergy with the University of Eastern Piedmont and integration with the ASL AL. The transmural Department of Mesothelioma and Environmental Pathologies of ASL AL is attached to it. The Department of "Integrated Activities Research and Innovation" coordinates "unit diseases" for the development of care and research, i.e., multidisciplinary corporate working groups oriented toward research, training and innovation.

By D.G.R. No. 42-8606 of March 22, 2019, the Piedmont Regional Council supported the application to the Ministry of Health of the Azienda Ospedaliera di Alessandria and ASL AL as an IRCCS - Istituto di ricovero e cura a carattere scientifico (Institute for hospitalization and

care of a scientific nature), specialized in the treatment of environmental diseases and mesothelioma.

Regulatory framework
Legislative Decree No. 502/1992 "Reorganization of the discipline in health matters, pursuant to Article 1 of Law No. 421 of October 23, 1992," defined by the Piedmont Region in DGR (regional council resolution) No. 26-1653 of 06/29/2015 highlighted the need for a reorganization of the network of territorial services.

The Piedmont Region through DGR 1-600 of Nov. 19, 2014, conducted a reevaluation of regional care needs and a consequent redetermination of organizational structures and related beds, defining a new program of revision of the regional hospital network. With DGR Jan. 23, 2015 No. 1-924, supplementing the previous DGR, the company was recognized, within the hospital network afferent to the Southeast Piedmont area (lower Piedmont), as a referral Hub Hospital, site of Level II DEA.

Description and analysis of the problem

The S.C. of Geriatrics of the A.O. exercises the services of a medical-specialist nature proper to the homologous discipline. The facility is responsible for:

- Ordinary inpatient activities with emergency (from emergency room) and scheduled (for transfer from other departments, ward outpatient clinic, etc.) admissions;
- Consulting activities to the facilities of SS Antonio and Biagio Presidio and Borsalino Presidio;
- Intrahospital Outpatient activity (divisional outpatient clinic oriented to the diagnosis and treatment of the most frequent diseases of aging and outpatient CDCD Center for Cognitive Disorders and Dementia);
- Collaborates in the definition of diagnostic/therapeutic pathways aimed at improving the effectiveness and efficiency of emergency/emergency response;
- collaborates in the definition of diagnostic and therapeutic pathways in a network with territorial specialists in order to optimize the response to the need for care; actively collaborates in research projects, particularly with regard to telemedicine.

Is engaged in research and experimental activities (13).

Problem analysis is aimed at explaining and analyzing the underlying causes and related concauses to the problem of interest. The reasons that led to the initiation of the project were highlighted through the organizational analysis performed and discussed according to an organized analysis using the Ishikawa Diagram. At the end of the analysis, the advantages and disadvantages of implementing the project mandate were identified.

In a nutshell, the organizational analysis of the Geriatric Unit carried out showed that the facility has as its main critical issue the structural limitation: the ward in which care takes place is arranged longitudinally and dispersed, many rooms are not equipped with en-suite bathrooms, and in fact the environment does not offer patients much autonomy of movement. The common spaces that allow living outside the inpatient unit are not easily accessible for rooms located at

the end of the inpatient ward. Staffing includes a double shift of nurses useful to ensure high-intensity care. In the case of ACE Unit implementation it would be insufficient.

The organizational-care model still in use today should be revisited in accordance with the new organization of both structural and care aimed at an implementation of skills related to patient-centered care by the staff dedicated to the ACE Unit. A further critical issue is the fact that geriatric patients admitted following an acute event often receive care in specialized wards for the management and resolution of the acute event and not to the comprehensive geriatric assessment with attached care and rehabilitation plan. The result is a rapid loss of physical and cognitive function, affecting clinical outcomes and patient satisfaction with the care received.

Loss of physical function in elderly patients is therefore the problem that is intended to be countered with the implementation of the ACE project.

From the foregoing, it can be inferred that there may be many causes contributing to the problem under analysis, and those "distant" from the problem itself should also be sought (14), as evidenced by Ishikawa's Cause-Effect Diagram and have been divided into four macrocategories of business design according to H. Mintzberg (3):

- contextual factors;
- Human and social variables;
- technical variables;
- Internal and external environmental variables.

In the following table (**Table 2**), the causes of the problem have been given in tabular form.

Table 2- Tabular Ishikawa diagram

Context factors	Human and social variables
✓ Health care cuts to acute care beds ✓ Limited availability of economic resources ✓ Long hospital stay times ✓ Organizational model in use ✓ Difficulties in bed management ✓ Difficulties in patient placement	✓ Inappropriate management of admissions by staff ✓ Poor information/training in patient pathway management ✓ Poor social case management autonomy ✓ Possible resistance to change by some staff members. ✓ Reduced staffing levels
Technical variables	**External and internal environmental variables**
✓ Absence of direct protocols for admission of the elderly person ✓ Absence of information system to support patient division	✓ Wide catchment area ✓ Poor integration with the territorial network ✓ Poorly located services ✓ Multipathological and elderly population

The table above summarizes the main causes contributing to the manifestation of the problem. See **Table A** (in Appendices Chapter 4) for the frequency with which the possible causes affect the analysis question.

Thus, the three main causes identified with the overall analysis are:

1. Presence of multi-pathological elderly population;
2. Structural causes;
3. Organizational model.

In the face of these problems related to context, technical, human, social and environmental variables, the organizational solution that could best solve the problems related to the management of the elderly patient in acute care is the implementation of an Elderly Acute Care Unit. The proposed solution, after careful analysis, was found to be the best among a range of other organizational proposals related to the context and in relation to international realities where this Unit has already been implemented.

The other organizational assumptions considered concern the deployment of materials, personnel and resources, which have been shown in the literature to improve clinical outcomes of elderly patients with acute events.

✓ Proposed structural improvement: the creation of communal spaces within the existing facility, rehabilitation and recreational spaces as well as general modernization of the existing Geriatrics; structural change can allow patients greater autonomy of movement within the unit, ensuring rapid functional recovery and significantly reducing discharge times. Providing out-of-bed care requires the assumption of a more person-centered organizational-care model and adequate staffing levels to ensure safety. This solution is only successful if the hospital has high budgets and flexible hiring policies.

✓ Proposed improvement of protocols: revision of current protocols related to the management of the geriatric patient could improve hospital flows. The current discharge process, however, cannot be positively affected in any way by improved protocols if they are not coupled with advanced interdisciplinary care. The implementation of an acute and subacute pathway may improve the appropriateness of inpatient admissions from the PS and reduce inpatient waiting times, but the effects on clinical outcomes would remain essentially unchanged. This solution could be successful in the case of a hospital with a large budget that is willing to significantly increase staffing and invest in advanced geriatric training for many providers.

For this set of reasons, taking into account the multiplicity of factors that influence the needs of the target elderly population, the organizational proposal that is best for the context is the implementation of an ACE Unit.

Advantages and disadvantages

Among the advantages reported in the literature (15) are worth mentioning:

- Reducing health care costs;
- Reduction of complications and readmissions;
- Efficient and highly specialized care;
- Improved functional recovery and outcome;
- Opportunities for quality improvement.

Disadvantages include the initial costs of implementing the unit (which will later be amortized by productivity) and the criterion that not all elderly people accessing the hospital facility are automatically eligible for admission to the ACE Unit (15).

Description of beneficiaries and parties involved

Stakeholders refer to individual individuals and organizations with an interest in the activities of the A.O. They are those individuals who are actively involved in the project, which is why they are referred to as stakeholders. The identification of stakeholders to A.O. is a necessary step for several reasons. Indeed, stakeholder mapping identifies those with the greatest power of influence, as well as those who hold numerous expectations from the public body. This allows the strategic management of the Company to be better able to direct the activity aimed, by definition, at satisfying public needs.

Second, the identification of stakeholders represents the fundamental architecture for the drafting of a health company's social report. Stakeholders may be positive, that is, they may benefit from the changes proposed by the project, or they may be negative, that is, they may hinder the initiation itself or the changes that the project may make; they may be internal or external to the project.

POSITIVE STAKEHOLDERS:
- business *management*→ the A.O. intends to target and make the best use of internal and external resources, improving resource allocation and reducing waste through the adoption of "*lean operational management*"; the introduction of this new unit appears to be in line with the company's mission and vision and will result in the A.O. becoming more attractive to users;
- geriatry→ geriatrics plans to promote a new line of management of the acute geriatric patient;
- limitary hospital companies→ have the advantage of the most appropriate patient referral;
- limitary public/private facilities→ facilities that share users with the referring A.O. may benefit from the fact that discharged patients will have a better quality of life and thus result in less care effort;
- Asl and territory→ patient management is improved with reference to the number and type of care interventions as there is a reduced need for territorial care;
- staff→ geriatrics staff themselves can foster and support the project with a view to better patient management; for medical and nursing staff, adoption of the new model will result in better management of the geriatric patient;
- patients and citizens→ are the direct beneficiaries of the project as the adoption of a new acute care model will ensure maintenance and functional recovery. they also benefit from appropriateness and proper targeting of hospitalizations, ensuring that they have access to high-quality health services based on compliance with precise standards;
- project management group→ is the main promoter and stakeholder in project implementation.

NEGATIVE STAKEHOLDERS:
- personnel➔ changing internal dynamics and organizing a new facility could be difficult for health workers.

An analysis was conducted about the current and desired level of stakeholder involvement. Current stakeholder involvement was assessed using the Involvement Assessment Matrix, and the result of the assessment was reported in **Table B** (see Appendices Chapter 4).

Stakeholder influence capacity was identified through the Matrix shown in **Figure 1** (see Appendices Chapter 4). A-level stakeholders are those who have the greatest degree of influence on the project and simultaneously play a strategic role in its effective success. The involvement of these stakeholders (**Table C**- see Appendices Chapter 4) is therefore imperative to support project implementation.

Project Description

This project was created within the Department of Translational Medicine of Eastern Piedmont University in collaboration with A.O. SS. Antonio and Biagio and Cesare Arrigo of Alessandria. The project aims to implement an ACE Unit at A.O. SS. Antonio and Biagio and Cesare Arrigo for the purpose of:
- Subdividing geriatric patients with an acute event by directing them to admission to an acute care facility;
- Ensure the appropriateness of admissions of geriatric patients within the A.O;
- Limiting inappropriate admissions coming in from the PS;
- Reduce improper occupancy of beds;
- Reduce waiting time in the PS through rapid intake;
- Alleviate the territorial management of discharges as well as reduce the number of transfers/re-admissions to other intermediate care facilities;
- Improve clinical outcomes in highly functional patients before the acute event;
- Ensure the maintenance and recovery of functional abilities of geriatric patients.

This project proposes the opening of an ACE Unit or Acute Care Unit for the Elderly to provide advanced and highly specialized geriatric care aimed at facilitating functional recovery in those patients who, if admitted to other facilities, would have longer hospital stays with a worse outcome on physical function outcomes.

Project identity

The project is called the "ACE Project" or "ACE Project" and is part of the AME Project of Excellence (Advanced Management of Elderly).

General and specific objectives

The aim of the project is to implement an ACE Unit within the A.O. SS. Antonio and Biagio and Cesare Arrigo of Alessandria.
Secondary objectives:
1. to develop a hospital implementation project of a new Acute Care Unit for the elderly (project management);
2. train staff in the ACE model;

3. establish a plan for communication and dissemination of results.

Feasibility analysis and benchmarking

- **Feasibility analysis**

The definition of the minimum requirements necessary to implement an ACE Unit was obtained by dividing the requirements into 6 macro-areas: structural requirements, plant requirements, technological requirements, furniture, staffing, and organizational requirements.

The project, from a structural point of view, can include three types of solutions shown below. To simplify the interpretation of the project, the floor plan of the structure is shown below (**Figure 1**- see also **Figure 2a** in Appendices).

Figure 1- Hypothetical floor plan of the new facility (Scale 1:200)

First solution: Low Care Zone

Reopening and possible renovation of currently closed inpatient rooms (one/two beds each) (yellow area in **Figure 2a** in Appendices) to obtain 12 beds and adequate space for out-of-bed care. On the same floor, there are plans to create a living space to allow for the presence of *caregivers*, as well as renovation of staff space and restrooms.

The area dedicated to Low Care is all air-conditioned and includes:
- No. 3 two-bed rooms with bathrooms;
- No. 3 two-bed rooms without bathroom;
- No. 2 rooms dedicated to storage (dirty/clean material)
- communal bathing area;
- services for health personnel;
- No.1 room dedicated to infirmary/medication room;
- kitchen;
- Common spaces to be devoted to living and caregiver areas.
- Advantages: proximity to gymnasium and existing living area.

Disadvantages: high cost of renovation and difficulties already stated by technical department for subdividing rooms and creating bathrooms.

Second solution: Diabetology Zone

The area is adjacent to the Geriatrics ward (orange area in **Figure 1**), is air-conditioned and includes 10 beds distributed as follows:
- No. 4 Two-bed rooms with bathrooms;
- No. 2 one-bed rooms with bathrooms;
- No. 2 rooms dedicated to storage;
- communal bathing area;
- services for health personnel;
- No. 1 room dedicated to infirmary/medication;
- local kitchen;
- Common spaces to be devoted to living and caregiver areas.

Advantages: rooms already renovated and with few changes to be made; possibility to dedicate space to living area and dedicated spaces for caregivers.

Disadvantages: moving the diabetology rooms to another corporate area; area away from the existing gymnasium.

Third solution: mixed solution

Reopening rooms previously used for LOW-CARE and dedicating them to low-complexity care patients on their way to discharge but with logistical or family problems.

Dedicate the part that now includes diabetology and some rooms of geriatrics to ACE UNIT so as to make the SOC geriatrics a complex facility capable of admitting all types of patients over 65 and offering them the necessary care without having to think about transfers to other departments.

Advantages: fewer patient endorsements at other departments; less chance of missed care and medication errors as the patient is followed by the staff (physicians nurses obs) referring to the

facility; time optimization (no more out-of-department staffing); direct patient intake by professionals.

Disadvantages: hiring staff to supplement.

See Appendices (**Paragraph 1**) for the analysis of proposed solutions.

Planning

The ACE Unit is an acute care unit for the elderly with finish and architectural features congenial to the permanence of the persons being cared for; it involves a change in the organizational-functional structure of hospital units and presupposes that staff have received specific training. The activities and processes implemented with the ACE model will lead to:

- Increased patient mobility and independence;
- Reduction in length of hospital stay;
- Reducing readmissions;
- Optimal functioning of mind and body:
- Patient comfort and dignity;
- Prevention or reduction of falls, skin injuries, functional decline, immobility, and delirium;
- Safe and quick discharge.

Preliminary to the implementation of the project, the following activities were conducted:

- Mandate of the Principal with evaluation and selection of the Facility in which to implement the acute care unit for the elderly.

The facility selection criterion adopted was to redevelop an existing and currently disused facility that includes an inpatient space and adjacent facilities.

- establishment of a working group (Working Group)

The Working Group is multiprofessional and made up of both personnel pertaining to Eastern Piedmont University and internal components of A.O. SS. Antonio and Biagio and Cesare Arrigo of Alessandria.

WBS

The task of writing the WBS (*Work* Breakdown Structure) is to provide a complete description of the project, so that the process of analysis and decomposition is a valuable tool for planning and controlling project activity. Activities and sub-activities are broken down to an increasing level of detail. The purpose of the WBS is to identify and place work packages at the last hierarchical level that are clearly manageable and attributable to a single manager so that they can be scheduled, controlled and evaluated.

Authorization and deliberative aspects

- o Resolution to open ACE Unit, assets and personnel
  - Resolution to open ACE Unit and amend the corporate charter
  - Resolution to the Bursar's Office to call for tenders to purchase goods and materials
  - Resolution of the Personnel Office for the recruitment of personnel

- o Resolution for local restructuring, information system, technology and communication
    - Resolution of the technical department for renovation of the premises
    - Resolution of the Office of Communication and Information Systems
    - Clinical Engineering resolution for the acquisition of technology
- o Internal mobility notices and competitions
    - Establish internal mobility competition for nursing and support staff recruitment
    - Establish internal mobility competition for the appointment of the Nursing Coordinator
- o Place profile creation
    - Create ACE Unit nurse position profile
    - Create place profile for geriatric physician

Costs center

- o Economic and financial management
    - Request to the management control office of the cost center justifying the reason;
    - Cost center number code entry

Resource allocation

- o Bursar's office materials procurement/acquisition of goods and services
    - Prepare tenders
    - Prepare logistics
- o Restructuring
    - Locate the premises
    - Define the project
    - Approve the work
    - Perform the work
    - Setting up the premises
- o Warehouse
    - Prepare supplements
    - Prepare/update information system
- o Information system
    - 3Implement the information system

Clinical engineering

- o Drafting technical specifications
- o Drafting of special contract specifications
    - Define the subject, requirements, duration of the contract
    - Define participation requirements
- o Drafting tender specifications for new equipment procurement
- o Purchase of new equipment
    - Proposed purchase of new equipment
    - Draw up the investment plan
    - Evaluate and approve the annual investment plan
    - Activate the purchasing procedure

- o Delivery and testing
  - ▪ Testing
  - ▪ Maintenance plan

Human resources
- o Recruiting
  - ▪ Define staffing levels
  - ▪ Cost analysis
  - ▪ Set the budget for staff recruitment
  - ▪ Select personnel
  - ▪ Hiring staff
- o Allocation of personnel
  - ▪ Place staff at the Unit

Training
- o Create training courses
  - ▪ plan training events regarding required entry skills, No. of meetings, duration, venue, managers, budget, content, objectives, course evaluation criteria; involve any out-service faculty
- o Define teachers
- o Delivering training
  - ▪ Course Accreditation

Information system and communication
- o Information system
- o Intake and inpatient process
- o Creation of the computerized medical record
  - ▪ Identification and implementation of early discharge system
  - ▪ apply scales to stratify patients, fill out forms as appropriate

Quality system
- o Facility Accreditation
- o ISO Certification
- o Quality standards and checklist creation
  - ▪ Activity monitoring
  - ▪ Planning preventive and corrective activities
  - ▪ plan quarterly briefings
- o Indicator system

OBS

The term OBS (Organization *Breakdown* Structure or analytical organization structure) refers to a design tool (tree diagram) that accompanies the WBS by defining responsibilities within a project. Making an OBS requires precise knowledge of the actual human and material resources available for the project under consideration.

At the apex of the OBS diagram (see **Figure 3** in Appendices Chapter 4) is the project manager; he or she has no functional or hierarchical authority, but assumes a project management coordination function to be enhanced by assuming full responsibility for planning and control tasks.

RAM

At this point in the design, it is possible to cross-reference the two tree structures of the WBS and OBS in order to represent the responsibility assignment matrix, called RAM (*Responsibility* Assignment *Matrix*), where: the columns constitute the structure of the product and the rows indicate the entity called upon to implement it. Thus there is a precise assignment of elementary tasks to elementary resources, with the ability to identify the precise responsibilities and the correct balancing of loads to resources (**Table F** in Appendices Chapter 4).

Gantt chart

The scheduling work, that is, the representation and visualization of the duration and time placement of activities, is supported and facilitated by the Gantt chart (**Figure 2**). The total calculation for project implementation is 12-18 months.

Each activity corresponds to a segment of length proportional to its duration, the extremes of which correspond to the instants at which the start and end events are scheduled to fall, evaluated with functional links in mind.

With such a diagram, both activities that concur in the same time period and activities that must necessarily be performed before the next activity begins are easily visualized.

Figure 2- Gantt chart
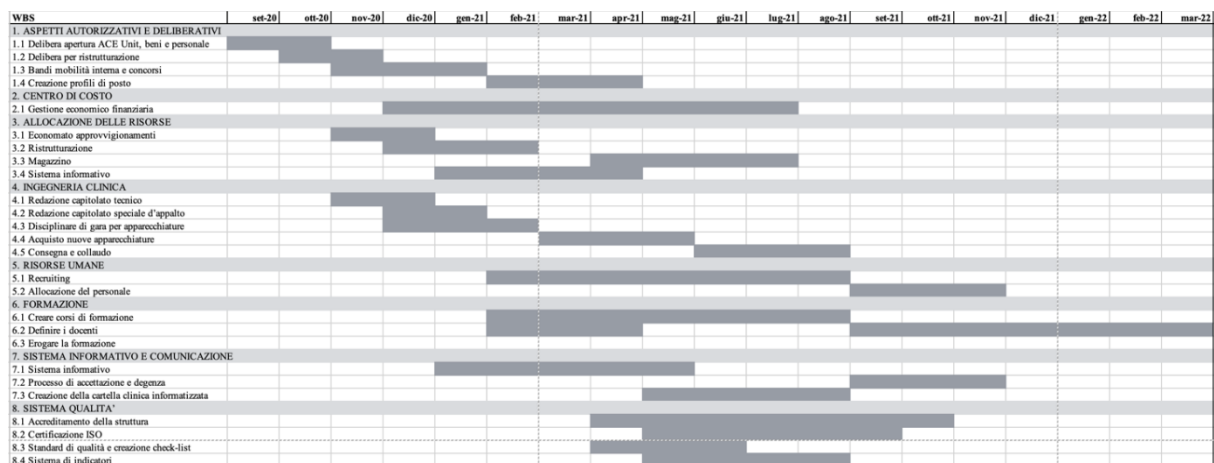
Milestones

The following table (**Table 3**) shows the project milestones, i.e., those intermediate and final project control events necessary to assess the overall progress and to submit reports to senior management. Milestones are the key points of project work.

Table 3- representation of project milestones

WBS	MILESTONE	TYPOLOGY
1.1	Resolution establishing ACE Unit	Milestone project
3.2	Renovation	Milestone payment
5.1	Recruiting	Milestone project
6.3	Delivering training	Milestone project

Quantification of resources

The valuation of resources in order to achieve the project objectives, is a very delicate phase, leading to the identification and quantification of all the specific resources that need to be implemented in order to produce the *deliverables* envisaged by the WBS described above. The project cost estimation process involves the quantification of the resources needed and then the valorization of the identified resources.

The technique used for this type of evaluation is heuristic and inaccurate because the project has a high degree of innovativeness. The preparation of an expenditure forecast given by design, broadly includes the following items of expenditure:

- Start-up costs: project planning, expert advice on space redesign, sizing of person-time commitment from analysis of individual planned activities;
- Systems management costs: overhaul of facilities, renovation of space, sizing of person-time commitment from planned activities based on the quali-quantitative characteristics of the systems to be managed and the required service levels plus other resources used in service delivery (technologies, premises, consumables, etc.), security audits;
- Personnel costs;
- Training costs and organizational processes: staff training, protocol review/creation;
- Procurement costs: calls for tenders, purchasing, logistics;
- Contingencies.

See **Paragraph 2** in Appendices Chapter 4 for the economic evaluation.

Expected outcomes

In order to achieve the set goals, the project is structured into activities that result in specific outcomes. For convenience and different timing of implementation, they have been divided into short-, medium- and long-term results.

In the short term (1 year after the implementation of the ACE Unit) you want to achieve:

- Full functionality of the ACE Unit;
- Initiation of staff training;
- Adoption of the Primary Nursing model by nurses;
- Initiating creation of new clinical pathways;
- At least 60% patient intake according to the interdisciplinary team model;
- Initiation of research studies with respect to the model and outcomes.

In the medium term (3 years) you want to achieve:

- End of field training for staff;
- At least 80% adoption of the interdisciplinary team model;
- At least 80% patients taken in under the Primary Nursing model;

- Improved clinical outcomes;
- Improved job satisfaction of staff;
- Decrease of 30% in discharges to other facilities;
- Optimization and integration of resources in Geriatrics;
- Publication of the results of research studies.

In the long term (5 years) you want to achieve:
- 100% adoption of the interdisciplinary team model;
- 100% of patients taken in by Primary Nursing model;
- Minimum 50% decrease in discharges to other facilities;
- Reduction in adverse events (e.g., falls);
- Increased patient satisfaction;
- Dissemination of the ACE model on the territory of Piedmont and Italy.

Further development of the project: following the implementation of the ACE model, it is possible that A.O. will become a national reference point for the dissemination of this model. Strategic recognition of this model and subsequent implementation in other national settings is expected. At the corporate level, and in line with what is also desired at the national level, it is considered necessary to enhance the value of staff who have acquired highly advanced skills in the management of the acute geriatric patient. In the international context, such a figure is framed as an *Acute Care Nurse Practitioner* and follows a specialization training course.

Strengths and weaknesses of the project: a SWOT analysis
Since data from an Italian benchmark are not available, it is not possible to weigh the project against an existing reality. The project is carried out on the basis of similar characteristics with other facilities of a different nature or type; this aspect, which can be considered a limitation of the project, was mitigated by the identification of an international benchmark and review of available literature. The project was then weighed through a SWOT analysis (**Table 4**). This kind of analysis allows the identification of strengths, weaknesses, opportunities and threats for each project type in order to arrive at an objective and shared assessment by team members on the strategy to be adopted.

Table 4- SWOT analysis

Strengths	Opportunities
Renovation of existing spaces Larger spaces that can be used independently by patients and caregivers Reduced waiting time in the PS by elderly patients Comprehensive geriatric assessment New intrahospital operating protocols Patient-centered care Early resignation Reduction in discharges to other facilities Increased volume of activity Innovation Improved interactivity with other services	Appropriateness of admissions and care pathway Improved clinical outcomes Professional development of geriatric caregivers and recognition of skills Research opportunities in advanced geriatric care. "*Lean*" operational management Diagnostic-therapeutic decision support Dissemination of the ACE model in other realities Creation of an acute care protocol Improved patient satisfaction
Weaknesses	**Threats**
Basic structure not very functional Absence of an Italian benchmark Difficulties in fitting the model Implementation timeframe Resistance to change	Initial costs Regional directives Ingovernability of stakeholders

The SWOT analysis illustrates a concise and non-exhaustive list of the main strengths and weaknesses of the project. Weaknesses need to be anticipated and governed with specific actions, while threats can be managed through careful analysis and planning of activities to be undertaken.

It is also evident that the strengths and opportunities of the project positively influence change, generating not only short- and medium-term benefits, but also long-term opportunities that could even be extended to other healthcare realities making this model an Italian benchmark.

Deliverables and output

Project deliverables include:
- Project plan development
- Project budget planning;
- Project progress and evaluation report;
- Formation of a working group;
- Working group meetings;
- Formation of a Coordination Group;
- Coordination group meetings;
- Development of a contextualized ACE model;
- Identification of the target population;
- Establish a system for data collection and analysis;

- Definition of skills, processes and services required for implementation;
- Staff enlistment;
- Staff training;
- Defining the communication plan;
- Budget setting.

Among the outputs:
- Participation in seminars and conferences;
- Social media communication.

Expected benefits (outcomes)

The intervention logic has 4 levels.
Contextually, the existing relationships between the project components are shown graphically:
- objectives;
- results;
- activities;
- indicators;
- the sources of verification;
- assumptions.

Sustainability and risk management

- **Sustainability of financial, institutional, political and social outcomes**

The sustainable development of the company is linked to the process of continuous improvement of economic, environmental and social performance. The sustainability of this project is linked to the result of managing this process. The implementation of an ACE Unit is a solution in line with the Piedmont Region's 2015 Territorial Reorganization Plan: "*One of the most relevant objectives of regional planning is the development of a network of territorial health and social-health services, necessary to ensure well-being and quality of life for citizens, as well as to introduce virtuous paths in the use of services in the acute and post-acute area, thus reducing the inappropriate protracted stay in hospital wards or long-term care facilities of people in the post-acute phase who present situations of complex disability and/or severely disabling chronic degenerative diseases, through the use of* appropriate *care settings.*" (16).

- **Risk Analysis**

During the course of implementation, situations could occur that slow down or hinder the actual development of the project. In order to anticipate possible critical issues, an analysis of the risks and timelines against which they might occur was carried out. The timing analysis of the main risks identified is shown in **Table 5**.
The possible risks identified are:
- Long project implementation time;
- unanticipated costs;
- Resistance from staff;
- Resistance from management;

- Delays due to bureaucratic aspects;
- structural limitations;
- Delays due to staff recruitment.

Table 5- Representation of the *Timing of Risk versus Project*

Risk analyzed	Timing of risk versus project	
Long project implementation time	RI	RT
Unanticipated costs		RT
Resistance from staff		RT
Resistance from management	RI	
Delays due to bureaucratic aspects	RI	
Structural limitations	RI	RT
Delays due to staff recruitment	RI	

Legend: RI- immediate risks; RT- late-onset risks.

Monitoring, evaluation and cost management

- **Monitoring Indicators**

Indicators are all those objective and measurable elements that support the final evaluation analysis of the project and provide information on the efficiency and adequacy of the activities carried out in relation to the expected results. Monitoring involves the preparation of the collection of codified, updated and recorded information. In the present case of the project they include three dimensions which are represented by the indicators of structure, outcome and process.

Table legend: short-term results*, medium-term results**, long-term results***.

- **Structure indicators**

The facility includes resources and means necessary for the delivery of care for beneficiaries envisioned by the implementation process according to the plan.

Verification criteria	Outcome indicators
Verification of structure integration*	Recognition within the department of the effective implementation of the new unit through an activity report
Verification of the functionality of the discharge pathway**	Effective activation of early discharge plan, verification of average length of stay and turnover

- **Outcome indicators**

Includes capabilities acquired by direct and indirect beneficiaries (e.g., health status and activity volumes); effectiveness of the model in transferring innovation to other contexts.

Verification criteria	Outcome indicators
Verification of appropriateness criteria***	Verification of the percentage of hospitalizations with medical DRGs
Define the patient pathway*	Data collection and analysis through the use of reports
Verification of patient satisfaction**	Patient completion of a satisfaction questionnaire on services provided

- **Process Indicators**

Degree of application of results (treatment activities, care, and organizational processes) with beneficiaries in the hospital setting and from other sectors.

Verification criteria	Outcome indicators
Checking the effectiveness of the model after 3 and 5 years by assessing the number of admissions made to other facilities**	Decrease in admissions to other facilities
Verification of the effectiveness of the model with respect to the maintenance and recovery of physical function*	Decrease/absence of re-access to hospital

Implementation of the ACE Unit

For the elements described so far, specific training of service-related personnel is planned to be delivered in a mixed residential and field form. Staff training, in addition to being a project goal and milestone, is a cornerstone of the ACE model. The adoption of an interdisciplinary model requires overcoming any current form of organization, constituting one of the main innovation factors brought by the project.

From the perspective of the nursing organizational-care model in the narrow sense, the adoption of Primary Nursing is suggested because recent work reports this model as improving clinical outcomes for patients and caregivers (17).

Conclusions

The hypothesis of implementing an ACE Unit within A.O. SS. Antonio and Biagio and Cesare Arrigo is an effective response to the emerging acute health problems of the elderly population. The Working Group spoke favorably of the domestic adaptation of a model that originated in an Anglo-Saxon context and whose cornerstones are the maintenance and recovery of patients' physical function. A thorough organizational as well as contextual analysis was carried out in order to frame and describe the basic structure and operational mechanisms, subsequently identifying priority objectives. In the feasibility study and design chapter, special attention was paid to the set of planned activities, highlighting the possibility of structural adaptation of existing premises, implementation of technology and revision of operational processes. This elaboration was conducted through the analysis of the minimum structural requirements of the existing Geriatrics unit and those required for the implementation of the ACE model, including through international benchmarking. From the comparison with the international world, given

the current Italian performance standards, information was gathered to guide the project and management strategy, as well as suggestions regarding possible barriers and facilitators to implementation.

Ultimately, the suggested organizational proposal focuses on the elements of change in the health care organization that are redefining care objectives and priorities in the current context and in the coming years. In a logic of strong innovation in the geriatric sector, the ACE model represents a factor of competitive advantage for the Company, which is an essential point of reference for the citizens of the Alessandria area.
Currently, this project is at a standstill at the design stage due to the pandemic.

Abbreviations within the chapter

Acronym	Description
ACE	Acute Care Elderly
DIMET	Department of Translational Medicine
UPO	Eastern Piedmont University
WBS	Work Breakdown Structure
OBS	Organization Breakdown Structure
RAM	Responsibility Assignment Matrix
AO	Hospital Company
IRFI	Infrastructure research training innovation
DIPSa	Health professions department

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CHAPTER 5

Project proposal for the reorganization of primay care through the implementation of the family and community nurse: the PICO project

Fabbrini E, <u>Campani D</u>, Carbone C, Cremonesi D, Mangiacavalli B, Capitolo 13: Modelli di assistenza territoriale: un'analisi strategica. Chapter incuded in: Previtali P (a cura di), Nuovi modelli in sanità. Organizzazione, innovazione tecnologica e processi decisionali. Pavia University Press, 2022.

> I think about my condition as an elderly person
> And I realize the pleasure I get from being in my own home.
> And to be helped at home, in the place where I have always been,
> Where I could shoot with my eyes closed.
> My home is the place of my life. Woe if they uproot me.
>
> (Norberto Bobbio, *Dialogue Around the Republic*)

Introduction

The evolution of health care needs toward greater chronicity has long brought to the attention of health care systems the issues of territorial social-health care and the territorial facilities that deliver it in order to ensure continuity of care and less reliance on hospital facilities. Territorial social-health care involves a response to community needs through the provision of social-health services by a network of coordinated actors (outpatient specialists, family physicians and pediatricians, hospital and non-hospital residential facilities, community nurses, etc.) with the aim of guaranteeing citizens effective health care in the territory with a consequent containment of waiting lists and to the benefit of the appropriateness of interventions. By proximity health care we mean a system of services spread throughout the territory, integrated and easily accessible to citizens, capable of delivering preventive, diagnostic and medical and nursing care in a short time, avoiding inappropriate access to PS and hospital wards. Different types of territorial facilities can be established to ensure proximity health care: each regional system has variously interpreted and named these facilities (outpatient clinics, health homes, territorial care garrisons, etc.) and to date there is a varying degree of their diffusion on the territories of the SSRs.

In this direction goes the path of evolution of the Lombard SSR started in 2015 with Regional Law 23 due to the intensification of complexity in the management of patients, given by the lengthening of life expectancy and the consequent increase in chronicity (average life expectancy at birth in Lombardy of about 84, 30% incidence of chronic patients on the total Lombardy population)(1). In the perspective of the Lombardy reform, the central entity has become the ASST, which houses all health and social-health services within it, with a view to greater integration between different types of services, ensuring continuity of care and

overcoming the traditional distinction between hospital and territory. The initiation of this integration process has been useful in the management of the health emergency due to Covid-19, which has imposed territorial management and taking care of infected patients in the territory, and has highlighted even more the relevance and necessity of this type of social-welfare services and their coordination in the territorial and home network.

In light of these premises, with the outbreak of the Covid-19 epidemic, many health care providers, in compliance with regional regulations, had to structurally review the processes of access and supply of their services especially in the territorial area. More specifically, in the social-health area, new and relevant pathways have been activated in terms of the number of services provided (e.g., swabs, vaccines, activation of home care, etc.) and that have involved the interaction of different professional figures, in some cases recently introduced in the system (such as, for example, the community nurse).

Strategic goals

The resulting change in the health and care needs of the population, in which an increasing percentage suffers from chronic disorders, requires a re-design of the service network, especially in order to enable a rationalization and integration of territorial services. Therefore, the Proximity, Innovation, Person-Centeredness, Organization (PICO Project) of the ASST Nord Milano has the strategic aim, acting by horizontal processes, to ensure the effective taking care of the citizen along the entire diagnostic, therapeutic and care and social-health pathway, ensuring continuity of care in a unified and integrated logic, even disregarding rigid territorial constraints, overcoming the classic organization based on disciplines and activities. Key word of the project becomes "Community Engagement", which finds its added value in the participatory process, becoming, through interconnections with volunteers and the community as a whole, collective welfare.

In recent years, the most recent models of care are oriented toward greater enhancement and involvement of the person being cared for within the clinical care processes (patient engagement). Patient Engagement is defined as "Processual and multidimensional experience resulting from the joint cognitive (thinking), emotional (feeling) and conative (acting) enactment of individuals towards their health management. In this process, patients go through four experiential positions (disengagement, arousal, adherence and eudaimonic project) (2, 3). The unreached synergy between the different subjective dimensions (thinking, feeling, acting) at each stage of the process can inhibit patients' ability to engage in their care" (2, 3).

The transition from passive care models to an active behavior model is based on a complex process of interaction between emotional and psychodynamic factors. The psychosocial model Patient Health Engagement (PHE) could support the study of the level of engagement of caregivers through a new Family and Community Nursing service.

With the introduction of the figure of the Family and Community Nurse (IFeC) at the territorial level, it is intended to offer citizens better care and personalization of care by fostering the processes of patient engagement and self-care.

The purpose of the project is:
- Make user paths more fluid and integrated;

- Reduce improper access and waiting time in the PS;
- Improve the appropriateness of services and reduce waiting times;
- Reducing early admissions of the elderly to RSA by promoting home care;
- Enhance the role of the Family and Community Nurse in primary care.

Materials and methods

The project has been carried out on the case of the Azienda Socio-Sanitaria Territoriale Nord-Milano for its role in the hospital and territorial network in the area north of Milan within the ATS of the Metropolitan City of Milan (4). The method used in the present study can be traced back to the Action Research strand (5) that, through the inclusion of key figures (such as, change agents) in the company, organizational change is promoted.

Although involved in different ways and with different purposes, all types of business actors collaborate in defining the problems under investigation, collecting data and information, and designing innovative clinical-care and organizational-management solutions that are contextualized to the reality under study.

The methodological model that has been developed in the following paragraphs consists of the following steps:
- The analysis of the literature on the topic of networks in health care by recalling the relevant theoretical framework;
- Planning the process of accompanying change in terms of defining the time frame, project phases and organizational feasibility;
- the forecasting of expected results based on a selection of previously defined monitoring indicators, including with reference to existing national and regional regulatory frameworks.

An analysis of the territorial context, epidemiological, sociodemographic and health data of the target population was preliminarily conducted. Next, the organizational structure of the currently present health and social-health services was analyzed, and indi conducted a mapping of related business processes and information flows. Several research methods were combined in the project design including literature review, focus groups, and in-depth interviews with key stakeholders. For project analysis and planning, operational methods and tools specific to project management were used.

Reference framework

The so-called "network organization," conceives of the network as a set of nodes linked together by continuous connections and implies a reconfiguration of supply in terms of redefining the type of services and volumes, as well as technical and scientific coordination among the nodes that are part of it.

With respect to "network" organization, the key organizational models for hospital network redesign are the so-called "hub and spoke" and "pole and antennae" organizational models (6). Rereading these models from the perspective of hospital-territory integration, it is possible to envisage:
  - a "hub and spoke" model, which is based on the differentiation of the delivery sites with respect to the complexity of the case histories treated: the hub (both hospital

and territorial) are the pivots of the system, in which all the major technologies and specialized teams are concentrated to carry out the high-medium complexity case histories of all medical specialties (hospital hub and territorial hub); in the spokes, on the other hand, low complexity treatments are carried out (territorial spokes);

o The "poles and antennas" model is built on the basis of the search for complementarity between specialist vocations: the poles are the centers that specialize in certain disciplines (e.g., cardiology pole) or specific areas of a specialist branch (e.g., neurological dementia.) and act as the pivot of the system precisely for that area of interest; the antennas have the function of first access, diagnosis and low-complexity treatment for the disciplines treated in the poles, referring the patient who needs a more complex response to the specialist pole of reference. In this case, these are horizontal, peer networks with several pivots, each specializing in a branch/area.

Critical aspects related to the implementation of these network models include (a) the distance, physical-orographic conditions of the territory and the possibility of easily reaching the network nodes through road systems, which constitute an element of equity in access for citizens as well as sustainability; (b) the rotation of staff among social-health facilities, in order to allow everyone adequate professional development through the acquisition and strengthening of advanced skills.

The *Hub and Spoke* model is the model of choice for this project.

Context analysis

The catchment area of ASST Nord Milano can be traced back to the territory north of Milan, which refers to 6 municipalities (Cinisello Balsamo, Cologno Monzese, Cormano, Bresso, Cusano Milanino, Sesto San Giovanni) and has nearly 270,000 inhabitants. In this territory the incidence of the over-65s is 25.2 percent placing itself at a higher level than the regional average (23 %).

The old-age index is higher than the regional average (188 elderly residents per 100 children in the ASST Nord Milano territory compared to 169 at the regional level) and the incidence of chronic patients stands at 36 percent of which 50 percent have two or more chronic diseases (prevalence of cardiovascular diseases). In socio-economic terms, the ASST North Milan area also ranks above the regional average (corporate structural index =61 vs. regional structural index =56).

ASST Nord Milano (DGR of Dec. 10, 2015 no. X/4478 from Jan. 1, 2017 in implementation of Regional Law no. 23/2015), consisting of two hospital garrisons (Presidio Ospedaliero Edoardo Bassini in Cinisello Balsamo) with 477 beds (to which are also added technical places between cribs, BIC beds, MAC beds, dialysis beds, sub-acute, Hospice), has on the territory 4 psychiatric sites, 9 family counseling centers and 2 vaccination centers; in addition to the 17 Territorial Outpatient Clinics located throughout the metropolitan area and 2 in North Milan.

Internally, there are distinctive cultural elements that could contribute positively to the implementation of network policies in the territory, such as the synergistic relationship with local authorities and alliances with the third sector (voluntary associations), which have

traditionally played an important role in the local social-health scenario. In addition, the push given by the Covid emergency on the organization of territorial care (such as, for example, the introduction of the figure of the community nurse) has also had a positive effect in the social-health processes of the last year. However, there is no shortage of areas that still need to be invested in: first and foremost, the phenomena of integration between professional figures and multidisciplinary collaboration in taking care of frail and complex patients.

Project description

The objective for which this project was developed is the reorganization of territorial care at ASST Nord Milano. Starting with an analysis of the existing reality, the proposal is subsequently described. Planning was done through the use of some of the typical tools of project management (7). In the concluding part, the proposed objectives are examined in relation to the results to be achieved. The project management techniques used refer to the text *"Project Management body of knowledge"* (8).

Target audience

The project's target audience can be traced back to the main stakeholders:
1. the community in the area covered by ASST Nord Milano;
2. all key regional institutional stakeholders and local institutions (municipalities, voluntary associations, third sector, families, etc.);
3. people with chronic diseases and frail users who can benefit from accessibility to social-health facilities through the organization of dedicated pathways;
4. the multiple health workers involved in the social and health network because everyone can enrich their skills and grow professionally from integration and collaboration with the various professionals.

Hospitals of the Lombardy Region's social-health network located near the area north of Milan could also benefit indirectly and directly from the activation in the territory of transitional care facilities on which to organize post-discharge pathways of eventual caretaking. An analysis was carried out about the participation of stakeholders.

Description of the project idea: the PICO Project

The project idea is summarized in the acronym PICO (Proximity, Innovation, Person-Centeredness, and Organization) and is based on the creation of a social welfare network that envisions a pivotal role of the Family and Community Nurse (IFeC) as a central element of continuity between the hospital and the territory and intra-territorial integration. Three levels are envisaged:
- *Hospital level*: definition of hospital-based specialist outpatient clinics that refer patients eligible for territorial care to the hospital IFeC/Case Manager according to frailty criteria, through assessment tools (e.g., SUNFRAIL scale);
- *Transition level*: the hospital IFeC/Case Manager interfaces with the territorial IFeC for early territorial intake (**Figure 1**), who addresses the case through a multidimensional assessment in synergy with General Practitioners (GPs) and Pediatricians of Free Choice (PFCs);

- *Territorial level*: definition of outpatient clinics in charge of IFeCs with guaranteed h 24 presence (indicatively hours 8-20 with activation of night units for the management of home emergencies that can be managed by the IFeC, which can refer the most serious cases to the local PS);
  - o GPs and PLSs: play a Clinical Manager role in the system in synergy with the relevant territorial IFeC;
  - o Specialist outpatient clinics where services are provided that do not require close proximity to a hospital facility;
  - o Integrated Home Care, which can also be activated by the IFeC, for home delivery of services of varying complexity;
  - o Mobile Continuing Care Unit;
  - o Nursing care planning with standardized/coded language and integrated computerized chart;
  - o Activation of service network and synergy with municipalities for social aspects;
  - o Implementation of a tele-health service.

Figure 1 – Project design
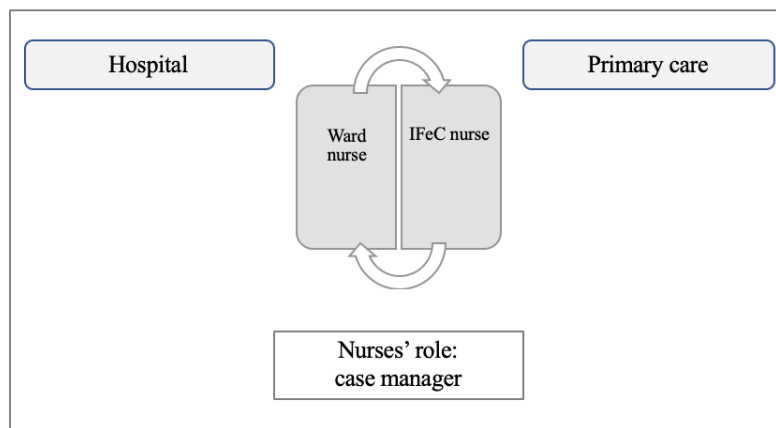
Based on this model, the PICO project envisions 6 Community Homes in the territorial network of ASST Nord Milano, coinciding with the 6 municipalities (Cusano Milanino, Bresso, Cinisello Balsamo, Sesto San Giovanni, Cologno Monzese, Cormano) in order to ensure a homogeneous offer in the territory, with respect to the locations of inpatient facilities with referrals for certain specialties/performances. See **Figure A** in Appendices for the distance between different territorial locations.

Timing and stages of implementation

The project must include:
- The operational structure of the project, i.e., a breakdown of project activities into intermediate milestones and activity packages (Work packages)
- The organizational structure of the project, i.e., identification of the Operational Units involved

- The temporal dimension of the project, that is, the temporal evolution of the project (Gantt Diagrams).

Project activities can be aggregated into 5 phases as listed below and described in **Table 1** and **Table 2** (see Appendices- Chapter 5):
- Reorganization of care activities at hospital wards from the perspective of intensity of care through the use of care level assessment scales in order to identify patients eligible for community care;
- Introduction of new organizational roles (hospital IFec, territorial IFeC, Bed Manager) to facilitate the functioning of hospital-territory interconnection pathways;
- Establishment of procedures to formalize the integration pathway between the acute hospital phase and the inpatient intake phase;
- Activation of the network with different actors in the area: GPs/PLS, municipalities, third sector, etc.
- definition of the service model for each node in the network in terms of the services/services offered, target patients and service delivery mode (hours, days, etc.). The project involves project management that coordinates the different activities assigned to individual contact persons. The timeline calls for the implementation of all activities within 5 months.

The introduction of organizational figures with coordinating and bonding roles (such as, for example, project management, IFeCs and the Bed manager) together with the establishment of procedures are the main ingredients for grounding the project. The choice of human resources to be included in the working group is the responsibility of the project manager, who is then also responsible for managing the identified group.

In this project, a project manager has been identified to coordinate hospital and territorial figures, as well as liaise with stakeholders outside the company.

Feasibility analysis

The following is a proposed SWOT analysis of the external context of ASST Nord Milano with a list of the main strengths and weaknesses of the project, arising from the internal business context, so that opportunities with positive influence on change can be finalized, producing short- and medium-term benefits, with the aim of generating value for other healthcare realities in the Italian healthcare landscape.

Opportunities
- Aging population
- Introduction IFeC on the ground
- Adoption of community-based care network model with social and health integration
- Corporate visibility in terms of engagement and proximity
- Adjacency to numerous hospital facilities
- Emergency Covid 19

Threats
- Shortage of health personnel
- Resistance to change
- Poor recognition of the nursing role

Strengths
- Innovative and proactive model
- Family and Community Care with One Health approach
- Integration between services (institutional, management and professional)
- Centralized coordination (Territorial Operations Center)
- Protected discharge management
- Enhancing the IFeC role
- Collaboration with municipalities and the third sector

Weaknesses and perfectible aspects
- Internal communication and passage of information
- Organizational aspects (e.g., lack of information/informational tools).

The design and development of the primary care system, in the organizational rethinking of hospital facilities, is in line with the provisions of the National Recovery and Resilience Plan (NRP).

Territorial facilities, whether identified as Community Hospitals, Territorial Operations Centers, Community Homes, are predominantly nurse-led entities. The Family and Community Nurse present on the territory ensures continuity of care by interfacing directly with the hospital level (Case Manager) or with the protected discharge service. In the territory, the creation of a network of proximity and integration of services is a key element for the effective response to users' needs. Also in light of what emerged with the pandemic emergency, the new care units will be equipped with technological, instrumental and digital devices that can further promote the timeliness of intervention, as in the case of specialist teleconsultation. In parallel with measures to redefine territorial health care, it is possible to envisage innovative organizational-assistance reorganization at the hospital level as well.

In fact, the peculiarity of the population afferent to ASST Nord Milano implies the need to strengthen the offer aimed at the elderly population with possible activation of an Acute Care of Elderly Unit or ACE Unit in order to prevent and counteract the functional disability that may arise following an acute event (9, 10, 11, 12). Such a unit is characterized by the presence of an interprofessional staff to take care of the user, with high-intensity care assurance, multidisciplinary geriatric assessment, review of medical prescriptions, and an early discharge plan from admission to the unit (9, 10, 11).

Results

Three community facilities were opened during 2022. Within each facility, basic functions including reception and orientation service, nursing and primary care services, vaccination and blood drawing service, specialized outpatient clinics, night continuity of care service, administrative services, social and psychosocial services were provided.

Expected results

In terms of expected outcomes, the project predicts a number of effects related to a reduction in hospitalization and an increase in the effectiveness of caregiving. Specifically, the expected outcomes are:

- Hospital Outcomes:
    o Reduction of improper admissions to the PS (as per DM No. 70 of 2/4/2015)
    o Reduced waiting time in the PS
    o Appropriateness of hospital admissions
    o Reduction in access/re-hospitalizations over 65 years of age
    o Reducing repeat hospitalizations
- Territorial Outcomes:
    o Reducing admissions to RSA
    o Reducing early admissions to RSA.
    o Improvement of health outcomes
    o Improving Patient Engagement.

In order to measure the improvement of outcomes and, thus, monitor the project implementation process, a set of indicators is planned as listed below:
   - % accesses with minor code in PS/total accesses in PS
   - % ARI
   - hospitalization over65 years
   - % repeat hospitalizations out of total hospitalizations
   - % change in RSA admissions from previous period

An improvement in the above indicators reflects the interdependencies that exist between territorial and hospital facilities: an improvement in the management of the processes of taking care of patients in the territory has a non-negligible effect on the organization of the SPs and the activities of inpatient units.

In order to achieve the set goals, the project is structured into activities that result in specific outcomes. For convenience and different timing of implementation, they have been divided into short-, medium- and long-term results.

In the short term (1 year after implementation) you want to achieve:
   - Full functionality of land management;
   - Initiation of staff training;
   - Initiating creation of new intake pathways.

In the medium term (3 years) you want to achieve:
   - Completion of training for staff (100% of staff trained);
   - Improved clinical outcomes;
   - Improved job satisfaction of staff;
   - Decrease of 10% in improper admissions to the PS;
   - Optimization and integration of resources (e.g., integrated outpatient specialist agenda).

In the long term (5 years) you want to achieve:
   - Reduction in adverse events (e.g., falls);
   - Increased patient satisfaction;

- User retention.

The sustainable development of the company is linked to the process of continuous improvement of economic, environmental and social performance. The sustainability of this project is linked to the result of managing this process. See Appendices (**Paragraph 1**) for the risk evaluation.

Discussion

The PICO design model, which conceptually traces the *hub and spoke* system set-up, is transferable to other contexts in which there is a need to streamline the design process with a view to organizational change in an attempt to integrate the different supply nodes of the social-health network through multi-service facilities. In terms of system sustainability, community engagement is imperative as the community itself becomes an active part of the care setting.

The present project work, in the light of the extensive literature in health care with regard to hospital networks, sought to reread the dynamics of interconnections also in the territorial social-health field by appreciating their effects also from the perspective of hospital-territory integration. The choice of the project was to plan a network model of social-health facilities in ASST Nord Milano trying to offer in a widespread but also rational way throughout the territory Level I social-health services and patient care, made possible also thanks to the introduction of new organizational roles (such as, for example, the IFeC). The *hub and spoke* model proposed in the territorial social-health field intends to enhance each node of the network by emphasizing a particular characteristic but, at the same time, to create an interconnection between the various nodes (hospital and territorial) in order to homogenize paths of services offered.

However, as the history of the past two decades testifies, health network construction processes-although now shared in their underlying motivations and supported by design schemes-have struggled to fully develop in the Italian context due to a lack of information elements to support design and specific attention to implementation processes.

The network model elaborated in this Project Work goes in the direction of proposing a new track to improve the effectiveness of design processes--seeking a sustainable balance between local, professional and system interests--and implementation--which require the consensus and strong involvement of professionals and adequate tools for controlling and directing behavior. In fact, for effective redesign of health networks, at least two interrelated and complementary conditions must be taken into consideration:

- on the one hand, a sound analysis of the external and internal environment to identify barriers and facilitators to change and the critical factors against which to define the organizational model;
- on the other hand, a phase of accompanying the change process by the corporate strategic management to share the development lines with various professionals and to affect the actual operation process.

A final thought concerns the variables that are critical to the implementation of a project:

- project planning with the definition of clear objectives, responsibilities and related deadlines is the project compass for both the project coordinator, but also for all stakeholders;

- the role of the project manager is relevant in project planning and management; this role, on pain of project success, is required to have problem solving skills, the ability to coordinate the actors involved even if they are not always linked by hierarchical organizational dependence, and the ability to manage unforeseen events by contributing effectively to the decision-making process;
- the measurement of outcomes in clinical terms on the population, with direct indicators, since the collection of process data alone would not be sufficient to determine the magnitude of project impact while providing an important benchmark for the final evaluation of the results obtained;
- the phase of capitalization and dissemination of results, as well as external project communication, which is many times neglected, is fundamental to enhance the project experience: validation of the project's impact on stakeholders, reporting on the improvements achieved and the innovative management tools used through the different communication channels represent forms of motivation for the operators involved in project implementation, as well as ways to participate externally in the projects achieved by the company. In social-health terms, the involvement in terms of engagement of the care community targeted by the project is essential for the sustainability of the system as the community becomes a privileged place of care.

Conclusions

Currently, the project is continuing, and two additional community-based facilities and a community hospital will be opened during 2023.

The challenge in the coming years is precisely to be able to achieve full integration between the different supply nodes of the social-health networks by shifting the perspective from hospital-centric (hospital as a "cathedral" isolated from the rest of the system) to a vision of multiservice social-health facilities integrated with each other to ensure, on the one hand, a concentration of activities in relation to skills and experience (13, 14, 15); on the other hand, higher levels of appropriateness and clinical effectiveness through connecting continuity of care solutions between hospital and territorial facilities.

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CHAPTER 6

Transferring evidence into practice to prevent falls in homebound older adults through exercise and home environment modifications: building effective, sustainable, and transferable intervention manuals

Healthy and active aging is important for sustainability of public health systems and falls preventions in elderly is a current challenge. In Italy, it is necessary to transfer scientific evidence into operational protocols to standardize prevention activities and reduce geographical imbalances.

The aim of the following systematic review and meta-analysis was to assess what type of exercise is associated with fall risk reduction among apparently healthy adults aged 50 and older (chapter 7).

The aim of the next chapters (chapter 8 and 9) were to identify effective, sustainable, and transferable interventions for fall risk prevention in elderly, which can be implemented by health professionals during home assistance.

Following a validated Italian model for "best practice" identification, we have reviewed in the main databases (as PubMed, guideline databases) the most effective and cost-effective evidences on fall risk prevention in elderly people. Three blinded reviewers have assessed evidences for quality, risk of bias and strength. Successively, we have presented results to a pool of experts (clinical, health service managers, nurses, and other stakeholders) and, by mean a focus group, we have identified the best way for implementation in order to assure effectiveness and sustainability (economic, social and along time) in Italian local contexts.

From literature review we found multicomponent interventions including individual and environmental assessment, physical exercises and home interventions (carpets removal, etc.) for fall risk prevention. We discussed the literature results in a focus group with experts in order to find the best way to implement the selected intervention considering resources, barriers and similar experience. Furthermore, we have developed an instruction manual about activities, methods, infrastructural resources, human capital, stakeholders, frequency and duration of intervention, information and educational materials, implementation models. This tool will offer to professionals a practice guide in order to making evidence-based decision for fall prevention and healthy ageing promotion. The final handbooks could also be useful to maximise health and social benefits, trying to minimize costs.

CHAPTER 7

Physical exercise and fall prevention: a systematic review and meta-analysis of experimental studies included in Cochrane reviews

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Introduction

The progressive aging of the general population represents a challenge for the public health of every country (1,2), and the development of effective fall prevention and management strategies is a priority objective worldwide (3,4). As the number of older people increases, the number of falls is expected to increase, with an economic impact on the health system generated by direct and indirect costs (5,6). One-third of community-dwelling older people (> 65 years) falls at least once a year (7,8).

Falls, which are commonly defined as "inadvertently coming to rest on the ground, floor or other lower level, excluding intentional change in position to rest on furniture, walls or other objects" (9), have many negative consequences, such as fractures, mobility reduction and psychological repercussions, including the fear of falling (10–12). They also increase the likelihood of admission to nursing homes (13). Thus, falls are considered risk factors for physical functional impairment during the aging process (14).

Many studies have attempted to identify the multiple risk factors of falls (15,16) and classified them in different ways, such as modifiable vs. non-modifiable factors or extrinsic vs. intrinsic factors.

Research has long shown that physical inactivity is a modifiable risk factor that contributes to the development of non-communicable diseases related to lifestyles (17). Regular physical activity is associated with a huge range of health benefits (18) including the prevention, management and treatment of many chronic diseases such as type 2 diabetes, obesity and hypertension and associated cardiovascular risks (19–21).

Some multifactorial interventions have been demonstrated to be effective in preventing falls (22–24). Multifactorial interventions appear to be more effective than single interventions, such as physical exercises (25), but the most effective combination of interventions is still not clear (26). Thus, as falls are still a problem for maintaining autonomy in the routine lives of seniors, it is important to conduct this review of the most recent evidence in order to understand what type of physical exercises must be "prescribed" to be effective. It is particularly important to study the effect of preventive public health interventions on healthy people to understand whether the interventions are effective in preventing disease.

The aim of this study was to determine the type of physical exercises effective in reducing accidental falls in community-dwelling older people by analyzing randomized controlled trials (RCTs) reviewed by Cochrane systematic reviews (SRs). Our outcomes were (a) accidental

falls, (b) number of people fallen, (c) people having sustained a fall-related fracture and number of fractures, (d) fear of falling.

Methods

We conducted an SR and meta-analyses of RCTs reviewed by Cochrane SRs on the effects of exercises on accidental falls. The study protocol was planned according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis protocols guidelines (PRISMA-P)(27), and the resulting report was written according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA)(28,29). This SR is part of a wider review that focuses on the type of physical exercises effective for healthy aging in people over 50. The protocol was not registered.

Eligibility criteria

We included RCTs reviewed by Cochrane SRs that were published in English and before October 4, 2019. RCTs were included that aimed to investigate the association between physical exercises and falls among community-dwelling apparently healthy people with a mean age ≥ 50 years. We defined "apparent healthy people" as those who were not on medication, without clinical frailty, or with well-controlled diseases. We took into account what the study authors reported. As an intervention, we selected any type of physical exercise defined as planned, structured, and repetitive physical activity with the final or intermediate aim of improving or maintaining physical fitness or health (30) compared with any type of intervention or minimal or no intervention. We selected studies related to outcomes such as fallers, accidental falls, fear of falling, fractures from falls, people sustaining fractures from falls, and the occurrence of at least one fall.

We excluded RCTs in which more than 25% of participants in a sample were ill, in treatment, or frail. For this exclusion criterion, we considered all types of conditions, including: obesity, frailty, physical disability, medication/drug use, hypertension or hyperglycaemia when treated with drugs, and a high score on the ADL/IADL scale. If the original article of RCTs did not report sufficient data about the health status of people observed, we considered the participants to be apparently healthy and included the study in this SR. We excluded RCTs when the original articles did not report sufficient details to classify the types of exercises for intervention groups.

Search strategy

For the purpose of this SR, we searched Cochrane SRs consulting Medline (PubMed) and Cochrane Library. Databases were searched independently by three reviewers. Disagreement was discussed by a wider team.

We used different strings, including MeSH terms (i.e., adult, over 50, aged, exercise, motor activity, locomotion, sports, aging), combined with the several keywords related to health condition, physical exercises, and prevention.

PubMed and Cochrane Library were consulted on March 22, 2017. The search was updated on October 4, 2019. The search strategies are detailed in **Table A.1** in Appendix A.

Study selection and data extraction

The selection process was performed in two steps. First, we screened all Cochrane SRs resulting from the search (strings are shown in **Table A.1** in Appendix A) applying the following criteria: over 50 people (Population), exercise intervention (Intervention), any type of control (Control), and fall-related outcomes (Outcomes). Then, we considered the primary studies included in the selected SRs. Once the full list of primary studies identified from the selected Cochrane SRs was deduplicated, two authors independently reviewed the titles and abstracts to identify studies to be included in the review by following the previously reported eligibility criteria (see the Eligibility Criteria paragraph). Finally, the full texts of the RCTs reviewed by Cochrane SRs that passed the screening and eligibility steps were retrieved and read by the same reviewers. Disagreements were documented and resolved through discussion within the wider team.

Two reviewers independently extracted data from the included trials. The extracted data were controlled by two other reviewers. Data were collected about the characteristics of the RCTs (i.e., nation, arms), populations (i.e., number of participants, risk factors, mean age), interventions (i.e., type of exercises, intensity level, frequencies, duration, sessions), controls, outcomes, and follow-up times. For each outcome, data were collected about the type of parameters and the values of estimates with their margins of error (± SD or 95% CI). In addition, data were collected about the dichotomous outcome measures (i.e., relative risk, risk reduction, rate ratio, risk ratio) and continuous outcome measures (i.e., standardized mean differences). Measures of effect were collected directly from Cochrane SRs.

Exercises were categorized using the Pro.FA.NE taxonomy (31) into the following categories: three-dimensional training (3D) (constant movement through all three spatial planes, e.g., Tai Chi, Qi Gonghi, dance; gait, balance, coordination, and functional task exercises (GBCFT) (e.g., ball exercises, walking in a line, obstacle courses, reactive games, foot eye coordination, static balance exercises); strength/resistance exercises (e.g., pilates, exercises on machines, weight training); endurance (e.g., walking at moderate/brisk pace, cycle ergometer, treadmill walking); general exercises (e.g., walking outdoor or indoor, swimming, cycling); mixed exercises (more exercises belonging to the other categories); multicomponent interventions (MI) (exercises accompanied by other types of interventions as supply devices or domestic interventions); flexibility exercises (e.g., yoga, stretching). Mixed exercises included interventions with exercise types belonging to more than one category, whereas MI were interventions with one or more exercises in combination with other components (i.e., advice, education, devices).

Risk of bias in individual studies

We used judgments about the risk of bias reported in Cochrane SRs, from which we extracted the selected RCTs.

Outcomes

Primary outcomes were fallers, accidental falls, fall-related fractures, and persons sustaining fractures from a fall as a number or risk.

The secondary outcome was fear of falling, measured using validated scales.

Summary measures and synthesis of results

A meta-analysis was performed on measures presented as the results in at least two studies by type of exercises. According to the current search, these measures included falls, fallers, persons sustaining fractures from a fall, and the fear of falling.

Meta-analyses were conducted using a random effects model using DerSimonian and Laird's method (32). Dichotomous outcomes were meta-analyzed together directly using measures of effect. Continuous outcomes (fear of falling) were meta-analyzed using standardized mean differences (SMDs).

Statistical heterogeneity was explored and quantitatively analyzed by the I-squared (I^2) test, which was judged acceptable if $\leq$ 30%; in the case of higher I^2 results, heterogeneity was further investigated using meta-analysis by subgroups (follow-up lengths, weekly minutes)(33).

Further analysis was performed excluding by quantitative synthesis all RCTs that did not report sufficient data about participants' health status at baseline. Our aim was to identify possible differences when considering only healthy participants (>75% of a sample) or participants not at risk of falling due to their health status or drug therapies.

Finally, we tested the risk of bias across studies using Peters' test for dichotomous data and Egger's test for continuous data to investigate small-studies effect. Funnel plots were used to examine publication bias (34,35).

Results

We found 2,162 records from the Cochrane Library, while additional records were obtained from Medline (PubMed). Cumulatively, our search collected 3,516 records. After record de-duplication (1,364 residual records), 1,334 records were excluded by reading the title and abstract, because they were not pertinent to our eligibility criteria. Hence, we evaluated 30 Cochrane SRs for eligibility, and 25 were excluded because they did not aim to evaluate the effect of exercises in older adults or for lack of outcomes.

We included five Cochrane SRs, totalling 289 primary studies. Among these, 257 were excluded after reading the full text of the original articles, mainly for the presence of unhealthy people (n = 109), other types of interventions observed (education about exercises and active lifestyles; n = 72), no outcomes of interest (n = 41), or more than one reason (n = 30). We included 32 RCTs in this SR and meta-analysis, totaling 6,622 participants (females 69.4%, 2,828 analyzed in intervention groups and 2,672 in control groups) with ages ranging from 60 to 96 years old. The full selection process is represented in **Figure 1**, while in Appendix A, the list of Cochrane SRs from which we extracted RCTs herein included is shown in **Tables A2–A4**.

Figure 1- Flow diagram of the selection process. The figure presents the flow chart of the selection process involving both Cochrane SRs and the primary studies reviewed by them. Identification of records was performed on the Cochrane Library and Medline. Overall, 1,364 records were overall identified and screened for eligibility by title and abstract. From the screening phase, we obtained 30 Cochrane SRs that were read. From these 30 SRs, we included 5 and 32 RCTs analyzed in this SR and meta-analysis.
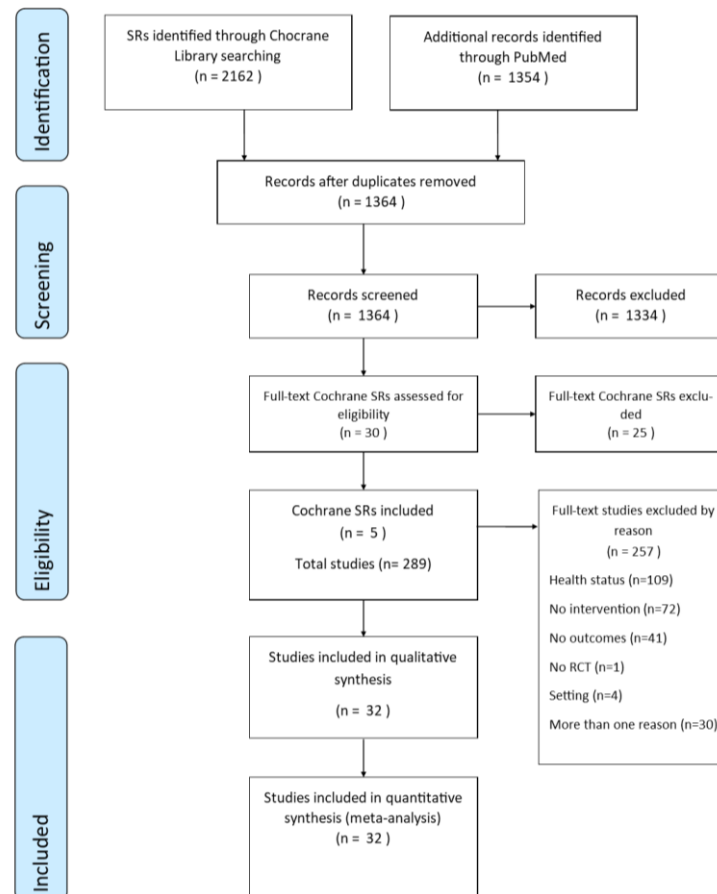
Study Characteristics

Of the 32 RCTs included, more than one third were conducted in North America (1 Canadian and 10 US RCTs) and about 30% in East Asia (3 in Japan, 2 in China, 2 in South Korea, 1 in Taiwan, and 1 in Vietnam). Meanwhile, a quarter was implemented in a European country (3 in Finland, 2 in the UK, and one each in Germany, The Netherlands, and Turkey), and the last three studies were conducted in Australia, New Zealand, and Chile (**Table 1**).

From these 32 trials, we included 46 comparisons between experimental groups involved in the exercise intervention and control groups: exercises observed were mainly mixed (37%) and 3D (24%), followed by GBCFT and strength/resistance exercises (both 13%). Mixed exercises were mainly GBCFT in combination with strength/resistance exercises. Some trials observed GBCFT with flexibility (stretching) (36–40), 3D (41), and/or endurance (rapid or Nordic walking or walking in treadmill) (38–42).

Lastly, four comparisons involved a multicomponent intervention, one endurance and the other flexibility (stretching). Multicomponent interventions were two mixed exercises in combination

with education (42) or cognitive intervention (43), GBCFT exercises and supply of walking devices/footwear (44), Tai Chi and education (45) (**Table 1**). While a great number of interventions were delivered by trained instructors (61%), only about 20% of these were delivered by physiotherapists. Furthermore, about 60% of interventions analyzed were conducted in a gym or other sportive place, and of these, 19% were clinical contexts. Finally, 25% of exercises were practiced at home after training sessions (**Table 1**).

While exercises were largely compared with usual care (72%) or other types of exercises (15%), only 9% of control groups followed an educational program to prevent fall risk. Overall, five RCTs reported seven comparisons between two different types of exercises: in three trials, controls were mixed exercises composed by GBCFT, strength/resistance and flexibility (39,46,47), a flexibility exercise (48), and a GBCFT (49). Finally, we collected 65 measurements of outcomes during follow-up related to falls (43%), number of people fallen (32%), persons sustaining a fracture from a fall (12%), fear of falling (11%), and fracture-related falls (1 outcome collected) (**Table 1**).

Table 1- Characteristics of RCTs included. The table shows the frequency distribution of the country in which the trials were carried out, types of exercises observed by RCTs, professionals who delivered exercises, setting of interventions, types of controls, and outcomes collected for this SR and meta-analysis. Percentages were calculated on the subtotal of each distribution.

Country	Freq.	Percent
Europe	8	25.00%
North America	11	34.38%
South America	1	3.13%
East Asia	9	28.13%
Oceania	3	9.38%
Total	**32**	**100.00%**
Intervention		
3D	11	23.91%
Gait, balance, co-ordination and functional task exercises (GBCFT)	6	13.04%
Strength and resistance	6	13.04%
Endurance	1	2.17%
Flexibility	1	2.17%
Mixed exercises	17	36.96%
Multicomponent interventions	4	8.70%
Total	**46***	**100.00%**
Setting of intervention		
Home	8	25.00%
Gym, swimming pool and other	19	59.38%
Outdoor spaces	1	3.13%
Multiple setting	4	12.50%
Total	**32***	**100.00%**
Control		

Usual care/no intervention	33	71.74%
Education	4	8.70%
Counselling /advice, information	2	4.34%
Exercises	7	15.22%
Total	**46***	**100.00%**
Outcome		
Falls	28	43.08%
Fallers	21	32.31%
Fall-related fractures	1	1.54%
Persons sustaining a fall-related fractures	8	12.31%
Fear of falling	7	10.77%
Total	**65****	**100.00%**

* Sum is related to the total comparisons analyzed in this meta-analysis (N=46). There are missing data for information related to the professionals who delivered the exercises and the setting of interventions. ** Several outcomes were collected from the same studies.

Risk of Bias within Studies

As shown in **Table 2**, a great number of studies did not report enough information to evaluate the potential risk of bias, especially for the allocation concealment (selection bias), performance, and detection bias. However, 20 RCTs were evaluated at a low risk of bias for the randomization process, as well as 17 for their ability to reduce attrition bias related to lost and drop-out participants. Although a small number of RCTs were at a high risk of bias for selection, performance, detection, and attrition bias, many were judged negatively for the fidelity of their reports (articles) to the protocol, underlying the potential presence of results omission.

Table 2- Risk of bias of RCTs included. The table shows the evaluation of risk of bias extracted from the Cochrane SRs from which we collected our primary studies. The bias evaluation was performed according to the Cochrane tool to assess selection, performance, detection, attrition, and reporting bias. For performance and detection bias, having collected both objective and subjective outcomes, we reported the judgments of reviewers for both types of outcomes, when available.

Legend: Low risk of bias = + (green); Unclear = ? (yellow); High risk of bias = - (red)

Author, year	Selection bias (randomization)	Selection bias (allocation)	Performance bias (objective outcomes)	Performance bias (subjective outcomes)	Detection bias (objective outcomes)	Detection bias (subjective outcomes)	Attrition bias	Reporting bias
Brown 2002	+	+	?		?		-	-
Buchner 1997	+	?	?		?		?	?
Bunout 2005	+	?	?		?		?	-
Cerny 1998	+	-	?		?		+	-
Davis 2011	+	+	+		+		+	-
Davison 2005	+	?	?		+		+	+
Freiberger 2012	+	?	-		-		-	?
Gill 2016	+	+	?		+		?	-
Hamrick 2017	?	?	?		+		+	?
Huang 2010	?	-	?		?		-	-
Hinman 2002	?	?	-	-	-	-	+	?
Irez 2011	?	?	?		-		+	-
Kamide 2009	+	?	-		?		-	-
Karinkanta 2007	+	+	?		?		+	-
Kim 2014	+	?	?		+		+	-
Korpelainen 2006	+	+	?		+		+	-
Lehtola 2000	?	?	?		?		-	+
Lurie 2013	+	?	?		-		?	-
Means 2005	+	?	?		+		-	?
Nguyen 2012	?	?	-	-	-	-	-	?
Park 2008	+	?	?		?		+	-
Reinsch 1992	?	-	?		?		+	-
Robertson 2001	+	+	?	+	?	?	+	?
Steadman 2003	+	?	?	?	?	?	-	-
Suzuki 2004	?	?	?	?	?	?	?	?
Voukelatos 2007	+	?	?	?	?	?	+	?

Weerdesteyn 2006	?	?	?	?	?	?	+	?
Wolf 1996	+	?	?	?	?	?	+	-
Woo 2007	+	?	?	?	?	-	-	-
Wu 2010	?	?	?	?	?	-	+	-
Yoo 2010	?	?	-	-	-	-	-	?
Zhang 2006	?	?	-	-	-	-	+	?

Findings

Studies included in this SR and meta-analyses reported the effect of some exercises on fall risk, number of people fallen, fall-related fractures, people sustaining a fracture from a fall, and fear of falling.

(a) Falls. Overall, 19 RCTs (28 comparisons) showed the effectiveness of exercises for fall reduction (number of fall) (38,40,52–60,42,44,45,47–51). I2 indicated a medium level of heterogeneity (**Figure 2**). When observing by type of exercise, the most effective was 3D exercises. This was followed by strength/resistance, multicomponent, and mixed exercises. This analysis did not show any effect of GBCFT exercises, and there was only one RCT about flexibility (**Figure 2**). **Table 3** shows that I2 was only partially reduced by a meta-analysis of follow-up length and weekly minutes of exercise practiced. However, data showed that over 12 months from baseline, the intervention group was associated with a 28% lesser risk than the control group, whereas no effect emerged for the other types of exercises in the long-term follow-up. Similarly, a major effect emerged in the subgroup of studies, where exercises were practiced over 150 minutes in comparison to the subgroup, which practiced for fewer minutes per week, always in consideration of mixed and strength/resistance exercises (**Table 3**).
Excluding RCTs for which articles did not report enough details about health status to evaluate these populations as healthy people (**Table B1**), estimates did not change for strength/resistance (all RCTs were included), whereas MI, flexibility, and 3D exercises lost effectiveness. Mixed exercises (seven comparisons included) were effective only in subgroup studies with a longer follow up (over 12 months, Rate Ratio 0.75 95% CI 0.62, 0.92, n = 4) and in studies where exercises were practiced over 150 min per week (Rate Ratio 0.73 95% CI 0.57, 0.93, n = 2) (**Table B1**).

Figure 2- Forest plot for risk of fall by type of exercise. A meta-analysis was performed with a random effect using an estimate of Rate Ratio (RR) extracted from Cochrane SRs included (with their 95% CI). All types of exercises showed effectiveness in fall prevention, except GBCFT and flexibility exercises, whose estimates included 1 in their 95% CI. The dashed red line represents the overall mean of RR estimated with meta-analyses considering all types of exercises. Heterogeneity is medium-high.

Table 3- Subgroup meta-analyses for risk of fall by type of exercises. A meta-analysis was performed with a random effect using an estimate of Rate Ratio (RR) extracted from Cochrane SRs included (with their 95% CI). The table shows meta-analyses by follow-up length and weekly minutes. Effective interventions were mixed exercises, strength/resistance exercises, 3D, and multicomponent interventions. Mixed and strength/resistance exercises were effective in long-term follow-up and if practiced for a longer weekly time (over 150 min.).

	Comparisons	Estimate*	95% CI	I2 (%)	p-value
Mixed exercises					
Overall	10	0.69	0.52; 0.89	59.0	0.006**
By follow-up					
Over 12-months	5	0.72	0.58; 0.90	14.1	0.004**
Until 12-months	5	0.67	0.37; 1.19	76.2	0.173
By weekly minutes					
Until 150 min.	5	0.88	0.62; 1.25	47.8	0.48
Over 150 min.	5	0.53	0.36; 0.77	58.7	0.001**
Strength and resistance					
Overall	4	0.6	0.37; 0.99	71.0	0.046**
By weekly minutes					
Until 150 min.	3	0.82	0.65; 1.04	0.0	0.103
Over 150 min.	1	0.28	0.15; 0.54	-	0.000**
3D					
Overall	6	0.51	0.32; 0.8	70.5	0.004**
By follow-up					
Over 12-months	3	0.37	0.09; 1.54	71.9	0.173
Until 12-months	3	0.64	0.51; 0.80	0.0	0.000**
By weekly minutes					
Until 150 min.	4	0.47	0.28; 0.80	81.2	0.005**
Over 150 min.	2	0.75	0.24; 2.3	0.0	0.61
GBCFT					
Overall	4	0.94	0.68; 1.29	34.3	0.684
By weekly minutes					
Until 150 min.	3	1.05	0.8; 1.38	0.0	0.733
Over 150 min.	1	0.53	0.28; 1.00		0.051
Multicomponent					
Overall	3	0.63	0.41; 0.98	64.8	0.042**
By follow-up					
Over 12-months	2	0.54	0.16; 1.82	81.5	0.318
Until 12-months	1	0.64	0.57; 0.72		0.000**
By weekly minutes					
Until 150 min.	2	0.54	0.16; 1.82	81.5	0.318
Over 150 min.	-	-	-	-	-

* Rate Ratio; ** statistically significant estimate of meta-analyses.

(b) Number of people fallen. Seventeen RCTs presented results on the number of fallers for 21 comparisons analyzed: 12 comparisons were an effect of mixed exercises (37,39,40,42,50,51,55,61–64), and three observed multicomponent interventions (42–44), whereas Woo (2007a, 2007c) and Huang (2010) were focused on 3D and Woo (2007b) on strength/resistance (45,65). Furthermore, a flexibility (66) and GBCFT (57) exercises were analyzed by other two RCTs. Overall, participants in the exercise groups had a 23% lesser probability of registering this outcome during follow-up than those in the control groups. However, only 3D and mixed exercises appeared effective in reducing this outcome, with I2 having a low and considerable effect size (**Figure 3**): 46% and 31% lesser risk, respectively. Subgroup meta-analyses for mixed exercises reduced I2, except studies with a short follow-up (<12 months; **Table 4**). This analysis showed the effectiveness of studies with long-term endpoints (>12 months) and for exercises practiced over 150 min per week. In this case, participants in mixed exercises reported 51% lesser of risk than control participants (**Table 3**). When excluding analyses in RCTs with few details about health status at baseline, the results did not change except for 3D interventions (the only RCT remaining did not report a statistically significant effect: Risk Ratio 0.52 95% CI 0.02, 12.87) (**Table B2**).

Figure 3- Forest plot for the number of people who fell by type of exercise. A meta-analysis was performed with a random effect using an estimate of Risk Ratio (RR) extracted from Cochrane SRs included (with their 95% CI). Mixed exercises and 3D were the only two types of exercises that were effective in reducing the number of people who fell. Heterogeneity was lightly high, but acceptable (44.6%). The dashed red line represents the overall mean of RR estimated with meta-analyses considering all types of exercises. Heterogeneity is medium-low.
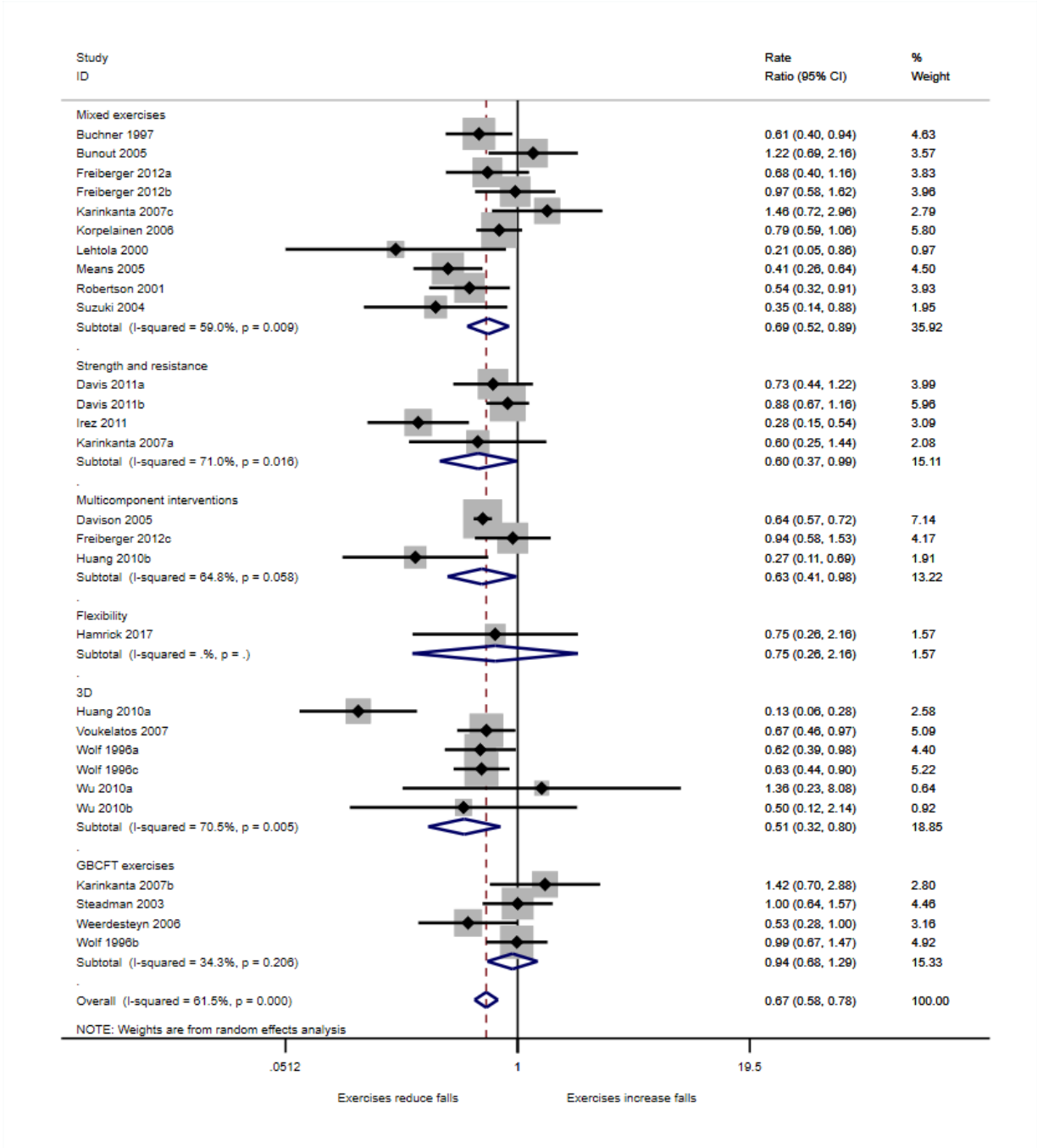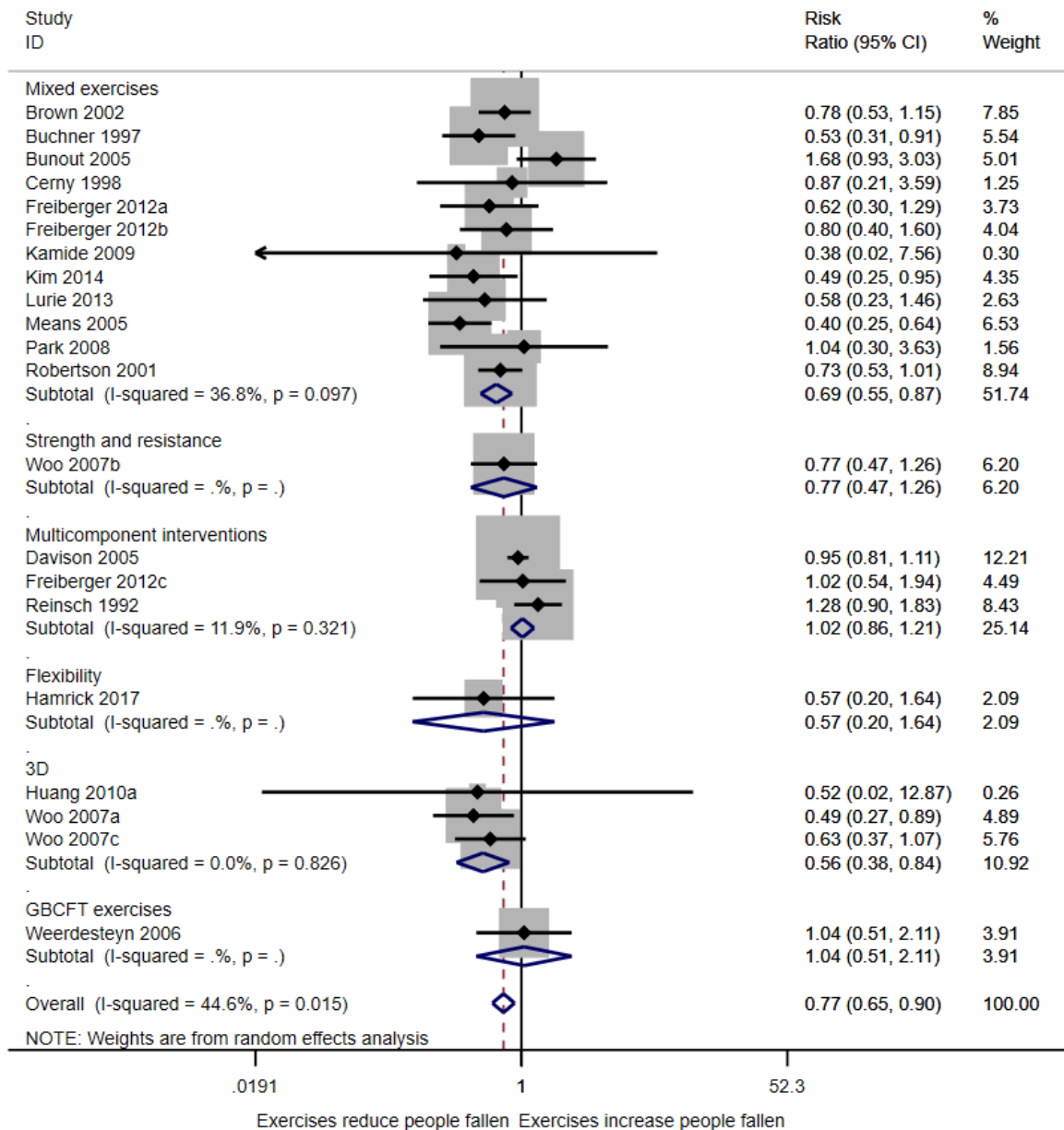
Table 4- Subgroup meta-analyses for the number of people who fell during mixed exercises. A meta-analysis was performed with a random effect using an estimate of Risk Ratio (RR) extracted from Cochrane SRs included (with their 95% CI). The table shows meta-analyses by follow-up length and weekly minutes. The general estimate for mixed exercises shows the effect of this type of exercises on the reduction of people who fell. The table presents the effectiveness of a subgroup of studies with longer follow-up length and greater time devoted to the practice of physical exercises.

	Comparisons	Estimate *	95% CI	I2 (%)	p-value
Overall	12	0.69	0.55; 0.87	36.8	0.002**
By follow-up					
Over 12-months	4	0.69	0.53; 0.90	0.0	0.007**
Until 12-months	8	0.7	0.48; 1.04	55.8	0.077
By weekly minutes					
Until 150 min.	6	0.82	0.63; 1.07	31.5	0.147
Over 150 min.	6	0.49	0.37; 0.66	0.0	0.000**

* Risk Ratio; ** statistically significant estimate of meta-analyses.

(c) People having sustained a fall-related fracture and number of fractures. Six RCTs presented results on a person sustaining a fracture for a fall, totalling 8 comparisons and reporting an estimate in favor of exercises for risk reduction of fracture-related falls (-30% risk). Five comparisons observed mixed exercises (36,41,44,54,55,63). In addition, one comparison focused on strength/resistance (54), another on GBCFT (54), and one on a multicomponent intervention (44). When considering singly type of exercise, none was effective for this outcome (**Figure 4**). A subgroup meta-analysis did not change the results (**Table B3**).

Only one RCT (41) reported an effect on the reduction of fractures from a fall, showing a protective effect of mixed exercises (Risk Ratio 0.29 95% CI 0.11, 0.77) (**Table A5**).

Figure 4- Forest plot for people who sustained fall-related fractures by type of exercise. A meta-analysis was performed with a random effect using an estimate of Risk Ratio (RR) extracted from Cochrane SRs included (with their 95% CI). While the overall estimate shows the effectiveness of exercises in reducing this outcome, considering a single type of exercise, none presents a statistically significant effect, visible in the graph observing 95% CI. Heterogeneity was about null, higher but at an acceptable level for mixed exercises (34%). The dashed red line represents the overall mean of RR estimated with meta-analyses considering all types of exercises. Heterogeneity is low.
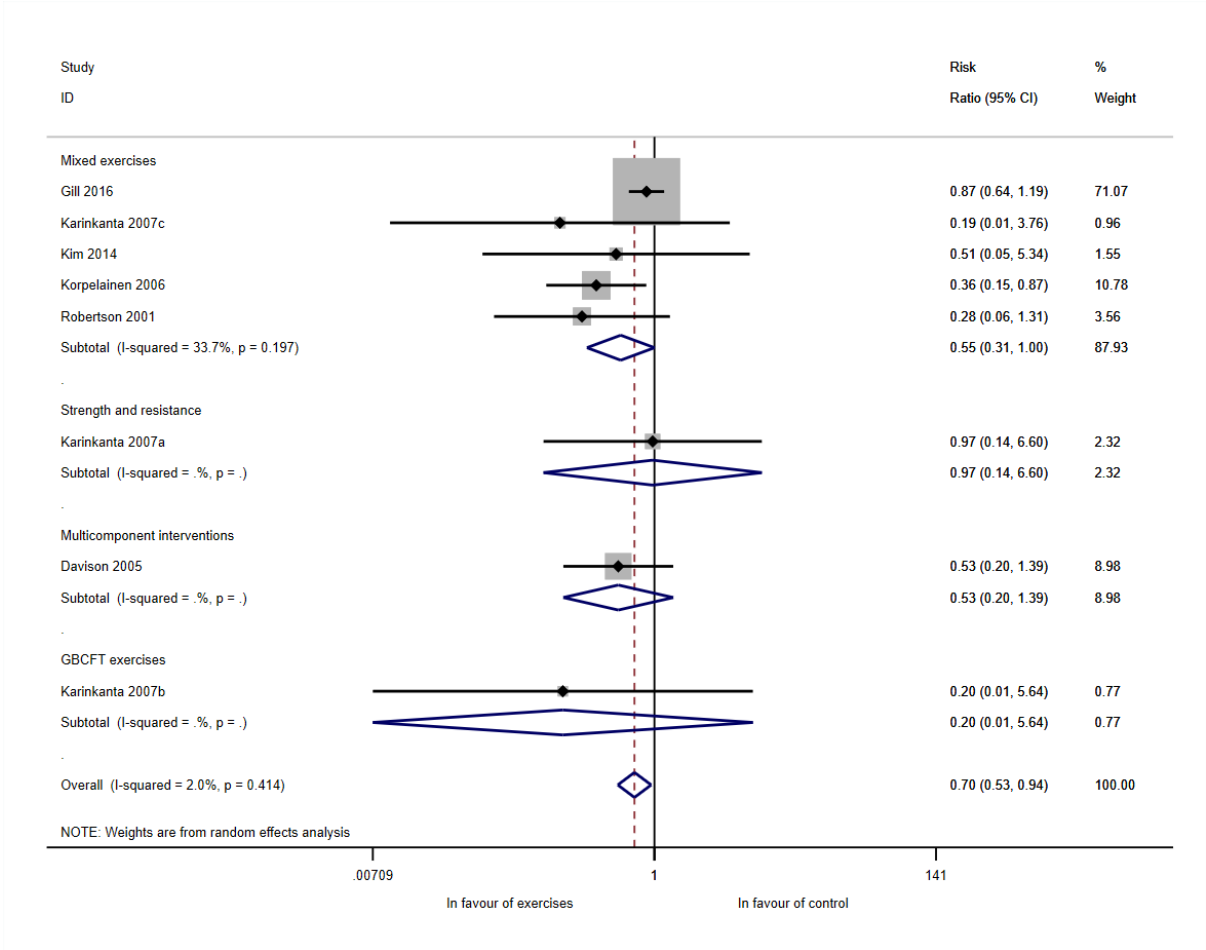
(d) Fear of falling. Five studies for seven comparisons reported an association between exercises and fear of falling and observed mixed exercises (42), strength/resistance (67), 3D exercises (68,69), GBCFT (67), and endurance activity (70). However, only endurance exercises were effective (Fig. 5). Finally, only one study reported sufficient details about the health status of participants at baseline (42), showing none effect of mixed exercises 24 months from the baseline.

Figure 5- Forest plot for fear of falling by type of exercise. A meta-analysis was performed with a random effect using an estimate of Standard Mean Differences (SMD) extracted from Cochrane SRs included (with their 95% CI). The scales used to measure fear of falling gave higher scores in the presence of less fear. No effect emerged from this analysis on fear reduction except in the presence of endurance activity. The dashed red line represents the overall mean of RR estimated with meta-analyses considering all types of exercises. Heterogeneity is high for the overall estimate and 3D.
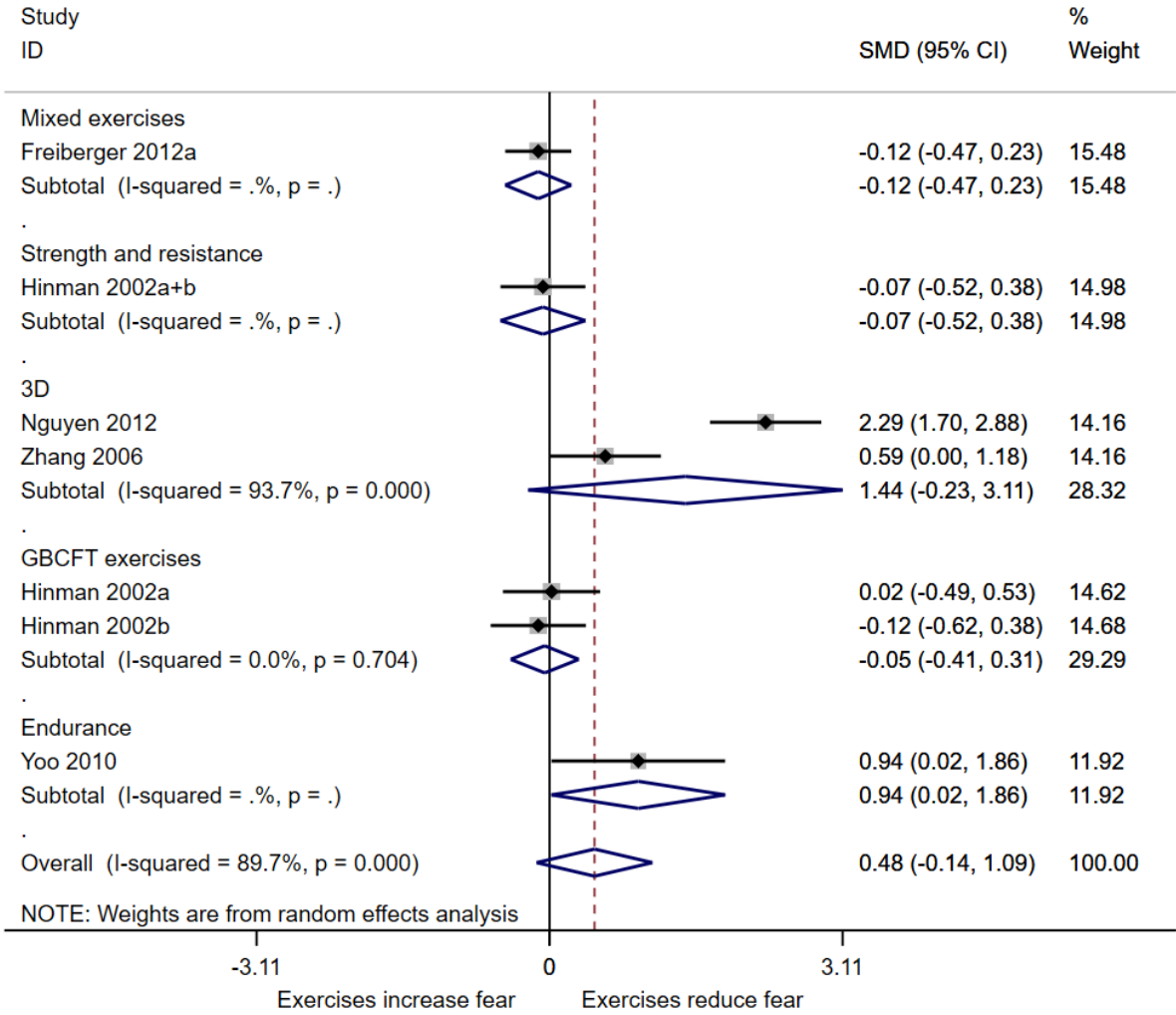

Risk of Bias across Studies: The small effect of studies

Peters' test did not reveal statistically significant bias for small-study effects, except for strength and resistance interventions and risk of fall (p=0.023). Egger's test for continuous data did not show statistically significant proof of a small-study effect of fear of falling and all types of interventions observed. However, funnel plots in Appendix B showed asymmetric distribution of effect estimates. Possible publication bias is visible in **Figure B4** showing the funnel plot by type of intervention for fall, with clear asymmetry for strength/resistance, 3D, and mixed exercises (higher concentrations of estimates in favor of exercises) and GBCFT exercises (higher concentrations in favor of control groups). 3D and mixed exercises appear mainly distributed in favor of exercises also for people who have fallen (**Figure B5**), and people having

sustained fall-related fractures (**Figure B6**), whereas GBCFT exercises are favored for people with a fear of falling (**Figure B7**).

Discussion

This SR aimed to determine which types of physical exercises are effective for fall risk reduction in adults over 50 by examining the RCTs reviewed by Cochrane SRs. From eligible Cochrane SRs, we selected RCTs that observed adults and adults over 60 through a comparison between exercises carried out by experimental groups and other interventions (or usual care) in control groups.

The primary outcomes were the number of falls, number of fallers, fractures, and number of people sustaining a fracture. Fear of falling was evaluated as a secondary outcome (31).

We identified five Cochrane SRs that analyzed 289 primary studies focused on evaluating the effect of preventive interventions on fall risk in adults. After the selection process, we included 32 RCTs on associations between exercises and falls, people who have fallen, people sustaining fall-related fractures, fall-related fractures, and fear of falling. The exercises analysed in these studies were mainly mixed exercise programs, 3D exercises, balance/coordination (GBCFT), and strength/resistance conducted in sportive structures or individually at home (after a brief training). In this meta-analysis, we included 46 comparisons extracted from the 32 RCTs between a type of exercise and no intervention. Only 7 RCTs were focused on comparisons between two types of exercises.

Our meta-analysis showed the effectiveness of 3D exercises, mixed exercises, and strength/resistance on reducing fall risk and fallers. In contrast to mixed exercises and strength/resistance, 3D exercises resulted in effective reduction in a short time (until 12 months follow-up) and if practiced less than 150 minutes per week, for both outcomes. GBCFT exercises did not present any effect, whereas flexibility and endurance were under-represented in this meta-analysis (only 1 RCT included on these types of exercises). Meta-analyses that only considered healthy populations showed the effectiveness in fall risk reduction only of strength/resistance (-40% of fall risk in the intervention group), followed by mixed exercises (-25% of fall risk of fall in the intervention group). Similarly, the number of fallers was reduced only by mixed exercises considering healthy people. Finally, while no single type of exercise showed a reduction in the number of persons sustaining a fracture, the number of fall-related fractures was reduced after intervention by only one RCT that observed mixed exercises in comparison to usual care.

It is worth considering that in an older population, physical activity as recommended by WHO guidelines (71) may - in some way and in some cases - be even harmful (72) and therefore able to trigger pathological processes related to poor physical functioning.

Furthermore, note that engaging in an intense physical activity (e.g., fast running) in old age can increase the risk of falling (73). Promoting adequate physical activity or exercises to improve muscle power, balance, and elasticity is one of the least expensive and most effective strategies for preventing falls in older people in the community. Activities such as walking outdoors or indoors on treadmills are the most accessible and feasible way to exercise to improve muscle strength, balance, and elasticity, leading to a reduction in the risk of falls (73). Although literature showed the significance of walking, flexibility, and GBCFT, our results are not consistent to support the lack of association between walking and flexibility (stretching) on

fall risk reduction if practiced as the only type of exercise during the week (only 2 RCTs included observed these types of exercises). We likewise did not find any association between GBCFT (balance/coordination and functional task) and the outcomes observed. However, if these types of exercises were practiced with strength/resistance, flexibility, or walking, the studies would have reported overall significant associations in their favor (see Results for mixed results).

Thus, the effectiveness of interventions on falls and motor balances/skills (3D, balance/coordination) practiced in insufficient quantities according to WHO recommendations (71) (less than 150 minutes a week) could be linked to the age of the population. It is possible that in populations most at risk of falls, such as the olders, even a minimum training intervention for balance and coordination is sufficient to have positive effects on the outcomes in question. Given the positive effects emerging from the experimental evidence, it could be possible to prescribe even a 3D exercise (i.e., Tai Chi training in these SRs).

The differences that emerge in terms of magnitude of the effect of the same exercise on different outcomes can be traced back to the fact that some outcomes (i.e., fall-related fractures, persons sustaining a fall-related fractures, fear of falling) were less observed than others by the RCTs included.

Moreover, if the effect on different outcomes (particularly on fall rate and number of people falling) was measured by the same study, then this difference may be due to the fact that a reduction in the rate of total falls over time is not necessarily associated with a reduction in the number of people falling. Specifically, the same individual may experience a reduction in the number of falls in the follow-up considered by virtue of physical exercise, but remain equal among those falling, because to measure this outcome, it is sufficient to have fallen only once during the follow-up.

In a recent work, Finnegan et al. (74) performed an SR and meta-analysis to explore the effects of long-term exercise interventions on preventing falls in community-dwelling older people. The results indicated that certain types of exercise programs are effective in fall prevention. Compared with their findings, our review was focused on which type of exercise is effective among apparently healthy older people. Similarly, we found that 3D exercises, as a single intervention, are the most effective in reducing the risk of falling.

Our results are consistent with findings from other systematic reviews. The recent work of Sherrington (75), an SR and meta-analysis that explored the benefits and harms of exercise for preventing falls in community-dwelling older people, indicated that exercise programs are effective in reducing the rate of falls and the number of people experiencing falls. Specifically, balance and functional exercises seem to be effective.

Our review attempted to respond to the suggestions of a recent SR (76) that included 23 cohorts and longitudinal studies. The review highlighted the positive impact of physical exercises on the healthy aging process and concluded by stating the effectiveness of physical activity. However, it also stated that future studies are needed to identify the type of physical activity and its optimal dose (76). With the meta-analyses herein presented, we can partially answer this question by underlining the benefits that resulted after a short period of regular 3D exercises practiced up to 150 minutes per week, as well as the benefits associated with mixed exercises

(GBCFT, strength/resistance, walking) and strength/resistance practiced over 150 minutes per week for a longer time (at least 12 months).

However, from the analyses of bias, a potential publication bias emerged in favour of exercises (excepted for GBCFT); for this reason, we could obtain an overestimated effect of mixed and 3D exercises, which could be an underestimated GBCFT association.

Another limitation is that this SR could be affected by a selection bias. Despite a double source of search (Cochrane Library and PubMed), only RCTs reviewed by Cochrane SRs were included in this review. However, Cochrane SRs reported complete data for each trial reviewed, with a rigorous method, and interventions were sufficiently described for our reclassification with Pro.Fa.NE taxonomy. In addition, if we did not find SRs in Cochrane Library, we searched the data by consulting original articles to find all data for meta-analyses. For this reason, this SR is based on rigorous evidence.

Additionally, although this SR included a wider range of ages (from 60 to 96 years), we were not able to consider the younger and senior samples separately and perform analyses by age because of insufficient details about the age range of the people observed for all studies. Accordingly, we were unable to construct valid age classes for meta-analysis.

Finally, the RCTs included were evaluated mainly at a low risk of bias for randomization, but not for their allocation to intervention and control groups. This could imply the presence of unbalanced groups at baseline for some confounders.

On the other hand, a strength of this SR is that we also conducted an analysis that excluded studies without sufficient details about the health status of the participants in order to summarize the effect of exercises in healthy and low-risk people.

The RCTs analyzed came from different countries (specifically US and European countries) but were carried out mainly in sportive centers and at home. Among the sportive centers, there were also clinical centers. Although these results could be generalizable to other contexts among older people, the effect of exercises on real fall reduction might be different for environmental characteristics in real contexts, thus reducing the effectiveness of exercises in fall risk reduction. We cannot assume that practicing the same exercises in outdoor places could lead to the same conclusions, given the, for instance, potential urban architectural barriers or quality of infrastructures.

Relevance for research and clinical practice

The results showed that general practitioners, geriatrics, nurses, and other health promoters could recommend regular exercises to adults and older people, better if these are mixed with a component of balance/coordination, strength/resistance, walking, and Tai Chi in order to improve their balance skills and muscle power during aging. According to the WHO, these exercises should be practiced with an almost daily frequency at least 150 minutes per week. The benefits of fall risk reduction can also emerge in a short time from the start of regular exercise practice.

However, considering the few settings in which RCTs were conducted, it is important to underline the effectiveness of practice exercises in a group with an instructor or a physiotherapist. Alternatively, exercises practiced individually at home were effective if practiced after a training period or in combination with a regular frequency of classes. Thus,

these aspects must be considered when a health promotion intervention is implemented or "prescribed."

Additionally, when hypothesizing any type of intervention that involves physical exercise, the gender differences of the participants must be considered. This is for two reasons: one, men and women differ in their biological, clinical, and anthropometric characteristics; and two, the effects can be maximized if the intervention is accepted favourably by the participant.

Our results indicate the importance of conducting primary prevention interventions. Family and community nurses are encouraged to promote physical activity, including ensuring the safety of the environment in which patients engage in activities of movement or daily living (77). Many interventions can also be carried out by volunteers who can be recruited from among the older adults themselves and trained on exercise practice. Participating in voluntary activities can help older people maintain an active life and outline a new social role for them within the community.

From this SR and meta-analyses emerges a lack of evidence in support of the benefits of exercises in healthy adults and older people. We found a large number of primary studies (289) analyzed by the most recent Cochrane SRs, but only a little proportion of these could be included following our criteria and mainly (109) for the unhealthy population. Although the probability of unhealthy people increases among older people, research attention must also be focused on healthy or apparently healthy adult people to find the best intervention and behaviours favourable for active and healthy aging.

It is likewise important to plan trials longer in terms of both intervention and follow-up length to identify the benefits of exercises in the long term and during the ageing process. Some research questions to address may be as follows: What is the amount of benefit achieved if exercises are practiced for several years starting from middle age (about 50 years old)? In a long-time period, will other types of exercises become effective in fall prevention and physical functionality maintenance?

In addition, research should differentiate the assessment of effects more according to the main mediators (age and gender) and possible confounders (social factors). Some social factors (e.g., gender, social class of belonging, accessibility to care, living environments, belonging to ethnic-religious-national minorities, etc.) could be confusing when estimating the effect of physical exercises on fall prevention. Hence, it is important to design trials that consider these mediators and confounders. In particular, the male gender was underrepresented in the RCTs included in this SR, and age, for example, restricted the analysis on younger or older people to identify the best age at which effectiveness is optimal.

Conclusion

The aim of this SR and meta-analyses was to assess what type of exercise is associated with fall risk reduction among apparently healthy adults aged 50 years and older. The implication for clinical practice includes regular programs with a mix of exercises. Further studies regarding the effect of physical exercises on fall prevention among healthy senior citizens are needed.

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CHAPTER 8

Effective, sustainable, and transferable physical exercise interventions for fall prevention among older people

Background

According to the World Health Organization (WHO), aging is a continuous process that results from interactions between genetic and environmental factors, which alter the structure and function of an organism (1). Frailty is the most problematic condition related to aging and increases the risk of adverse outcomes, including falls, delirium, and disability (2). Falls are multifactorial phenomena (3), and are defined as unexpected events in which the participant comes to rest on the ground, floor, or a lower level (4).

Falls have a major impact on health systems (5). Community-dwelling older people account for 28-35% of those who fall each year, and the incidence of falls is age-related (6, 7). In people aged 65 years and older, falls are the 11th leading cause of death in the United States of America, and the first cause of fatal or non-fatal injuries, emergency department admissions and hospitalizations (8).

The consequences for people who fall are both functional, such as disability and loss of autonomy, which increase nursing home admissions, and psychological, such as fears of falling again and loss of self-confidence (9, 10, 11). For society, the consequences include both direct and indirect costs (12). In 2015, in the United States, direct costs that were related to falls were estimated at approximately $50.0 billion, and indirect costs were considerably larger (13).

Interventions should be put into place to prevent falls, reduce fall-related injuries and costs, and save money (14, 15). Current literature suggests implementing preventive and multifactorial activities that address the specific risk factors and characteristics of the patients (16, 17).

Research has, for a long time, shown that regular physical exercise reduces falls and their consequences; it also improves physical and cognitive functions and quality of life and reduces the burdens on caregivers (18, 19). However, "physical exercise" should not be confused with "physical activity": in fact, the first means a planned, structured, repetitive, and targeted intervention, while the second refers to generic bodily movement (20).

Exercise should be individualized and related to patient's specific needs and abilities (21). However, exercise can be performed individually or in groups and undertaken freely or guided by an instructor (22).

According to the WHO, evidence-based exercise programs must be developed and implemented to reduce health care costs (23). Due to the wide variety in the types of exercises, durations, settings, and levels of supervision provided, the current literature shows inconclusive results about the most effective exercise programs and the best ways to implement them (24).

Evidence-based preventive interventions are needed, and they must be appropriate for the social settings, in order to involve people in making healthy decisions (25). The framework for the Interventions for fall Prevention that are Effective, Sustainable, and Transferable (IPEST) includes activities, actions, interventions, programs, and strategies that are focused on changing behaviors and promoting the health of communities (at national, regional, and local levels). This framework allows for the development of a tool that can guide local health authorities and help health professionals (26).

The aim of this study, then, is to develop a manual that can be used by professionals to support the implementation of physical exercise programs to prevent falls among older community-dwelling people.

Methods

We used the IPEST framework (26), a new method that can produce effective, sustainable, and transferable preventive interventions and is based on both evidence in the literature and consensus with clinical experts (**Figure 1**). This framework has two components.

Figure 1- IPEST framework process

First, we reviewed the scientific literature (guidelines, systematic reviews, and randomized controlled trials) to find the best evidence-based information about the types of physical exercises that can help to prevent falls among community-dwelling older people. In addition, we included only the highest quality information.

Second, we discussed these with a focus group of clinical experts to evaluate the best strategy for implementing the physical exercise. The interventions need to be sustainable in economic terms (cost-efficacy), social terms (with either a reduction or no increase in social inequalities related to socio-economic aspects, gender, nationality, etc.), and in terms of time (the effects of the intervention continue after the intervention is stopped). Moreover, the interventions should be transferable in a local contexts, with barriers and resources taken into consideration.

Finally, we developed a user manual for implementing such programs, to guide institutions and help health professionals.

The research process is described in the following seven phases:

Phase 1: Defining the health question

The questions we addressed are as follows:

- Which exercise programs are the most effective for reducing falls and the number of those who fall, as well as the fear of falling, in community-dwelling older adults?
- How should community-based exercise programs for the elderly be structured and delivered?

Phase 2: Search strategy

We searched for guidelines, systematic reviews, and randomized controlled trials (RCTs) that matched our research question, considering the pyramid of study designs and evidence of their effectiveness. This included searching the following: guidelines on the web pages of scientific societies, institutions, and associations and systematic reviews and RCTs on MEDLINE, EMBASE, Nursing and Allied Health (CINAHL), Physiotherapy Evidence Database (PEDro), Scopus, and the Cochrane Library Database (see **Appendix 1** for the search strategy).

Phase 3: Inclusion and exclusion criteria

We included studies published in Italian and/or English that focused on general populations aged 65 years and older who lived at home. In terms of guidelines, we included those that had been published after January 1, 2010. With regard to the systematic reviews, we established our search strategy the day after the most recent eligible guideline had been updated. For the randomized controlled trials, we established our search strategy the day after that for the most recent eligible systematic reviews. This was done so that we did not consider any evidence twice.

We excluded: narrative approaches, studies with uncertain or unclear results, studies that focused on pathological population subgroups, and studies cited in other works that were already included in this review, to ensure we did not consider them twice.

Phase 4: Study selection

According to the eligibility criteria, five reviewers and two reviewers independently searched for guidelines and reviews/RCTs, respectively. They read the titles and abstracts of the papers that had been identified and eliminated irrelevant studies. The studies that were found to be eligible for inclusion were then read in their entirety. Disagreements were managed by reaching a consensus, and when that was not possible for the reviews and RCTs, we consulted a third reviewer. Studies were selected following the hierarchy of evidence, and were then excluded according to the following criteria:

- guidelines— if already contained within other more recent guidelines;
- systematic reviews— if already contained within a guideline that was included;
- RCTs— if already included within guidelines or systematic reviews that were included.

Phase 5: Quality assessment

Guidelines were assessed with the Appraisal of Guidelines for Research & Evaluation Instrument (AGREE II) (27)-, an instrument that evaluates scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence, and which provides an overall guideline assessment.

Systematic reviews were evaluated with A Measurement Tool to Assess Systematic Reviews (AMSTAR) (28), and the results were modulated with both the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (29) and criteria that were established to determine the strength of the evidences. AMSTAR is an instrument that evaluates methods, results, discussion, and funding. Items obtained a level of "1" only when both items received a "YES" and the related PRISMA items obtained the maximum rating. Evaluation was done by

assigning either a "1" (if there was no information, the information was declared incomplete, or the review was not methodologically correct), a "2" (if there was information but it was not exhaustive), or a "3" (if the method was correct). Finally, the identified score (PRISMA + AMSTAR) had to be integrated with the criteria for the strength of the evidence, including adding a point if there was a low reporting bias or the review was done with an RCT, and also removing a point if errors influenced the results or were inconsistent, or if the outcome was indirect or subjective.

RCTs were assessed with the Cochrane risk of bias tool (30), which evaluates selection bias (random sequence generation and allocation concealment), performance bias, detection bias, attrition bias, and reporting bias (see **Appendix 2** for quality assessment tools).

We summarized the quality of evidence with a qualitative four-position scale (low, sufficient, good, and excellent), which represents the percentage of excellent quality criteria in relation to the totality of the criteria that has been evaluated (**Table 1**) (26).

Table 1- Rating for the quality assessment

Percentage of excellent quality criteria	Evaluation	Graphic representation
≤ 30%	Low	-
31% — 50%	Sufficient	+
51% — 75%	Good	++
> 75%	Excellent	+++

We included only the "excellent" studies. The quality was assessed by five reviewers independently, and disagreements were managed by consensus.

Phase 6: Data extraction and analysis
Two independent reviewers extracted the following data:
- for guidelines— society and year of publication, recommendations, strength of evidence, and references;
- for systematic reviews— author and year of publication, typology and number of studies included, objective and population target, and outcome and effect sizes;
- for RCTs— author and year of publication, typology of the study, objective and population target, and outcome and effect sizes.
The reviewers also extracted data about each intervention's sustainability and transferability.
Analyses and syntheses were conducted in a narrative manner.

Phase 7: The clinical experts' consensus
The narrative summary was discussed with an expert panel (IPEST Working Group) to assess the local transferability and sustainability. The focus group lasted 1½ hours and was conducted by an expert in qualitative research using a semi-structured ad hoc protocol. The panel was sampled by convenience and composed of the following health care professionals:

    - a nurse expert in gerontology, geriatrics, and primary care, representing two
      associations in these areas,

- a nurse in charge of territorial social assistance,
- a nurse coordinator of home nursing services,
- a nurse coordinator of home care facility,
- a family and community health nurse,
- a coordinating nurse and president of the Italian Association of Family and Community Nurses,
- a physiotherapist,
- a nurse coordinator,
- a medical director of geriatrics.

Verbal consent was obtained from all participants, and the focus groups were audio recorded and transcribed. The transcripts were read several times by two investigators and analyzed taking an inductive approach to identify the main themes (31). Bracketing was used to avoid bias (32).

The implementation manual to prevent falls among community-dwelling older adults using effective, sustainable, and transferable physical exercise was developed and approved by experts.

Results

Results of the search

On February 1, 2019, we identified five guidelines from the web pages of scientific societies, institutions, and associations, according to the eligibility criteria we had established. After a quality assessment had been conducted, we included two guidelines (33, 34) (**Figure 2**).

Figure 2- Selection of guidelines

Identification

Scientific Society:
- Canadian Task Force on the Periodic Health Examination
- The Community Guide U.S.A. Preventive Task Force (CGPTF)
- U.S. Preventive Services Task Force (USPSTF)
- U.S. Agency for Healthcare Research and Quality (AHRQ)
- Scottish Intercollegiate Guideline Network (SIGN)
- Centre for Evidence Based Medicine (CEBM) di Oxford
- The National Institute for Health and Care Excellence (NICE)
- Canadian Medical Association Infobase
- New Zealand Guidelines Group
- Haute Autorité de Santé
- Istituto Superiore di Sanità (ISS)
- U.S. Department of Health and Human Services (HHS)
- Registered Nurses' Association of Ontario (RNAO)
- World Health Organization (WHO)

Scientific society without guidelines:
N= 7

Guidelines identified:
N= 7

Screening

Excluded:
- ineligible intervention, participants or outcome measure:
N= 1 (SIGN, 2015)

Guidelines screened by title and abstract:
N= 6

Excluded:
- cited in a more recent guideline:
N= 1 (NICE, 2013)

Elegibility

Guidelines screened by full-text:
N= 5

Excluded:
- quality assessment "++":
N= 2 (HHS, 2018; ISS, 2009)
- quality assessment "+":
N= 1 (USPSTF, 2018)

Inclusion

Guidelines included: quality assessment "+++":
N= 2

For the reviews, we searched the databases that had been identified, from February 7, 2018, the date of the most recent eligible guideline update from the U.S. Preventive Services Task Force (USPSTF) (35), to July 23, 2019, and identified 1,301 studies (eight of which met the eligibility criteria). After a quality assessment had been conducted, we included one review (36) (**Figure 3**).

Figure 3- Systematic reviews selection
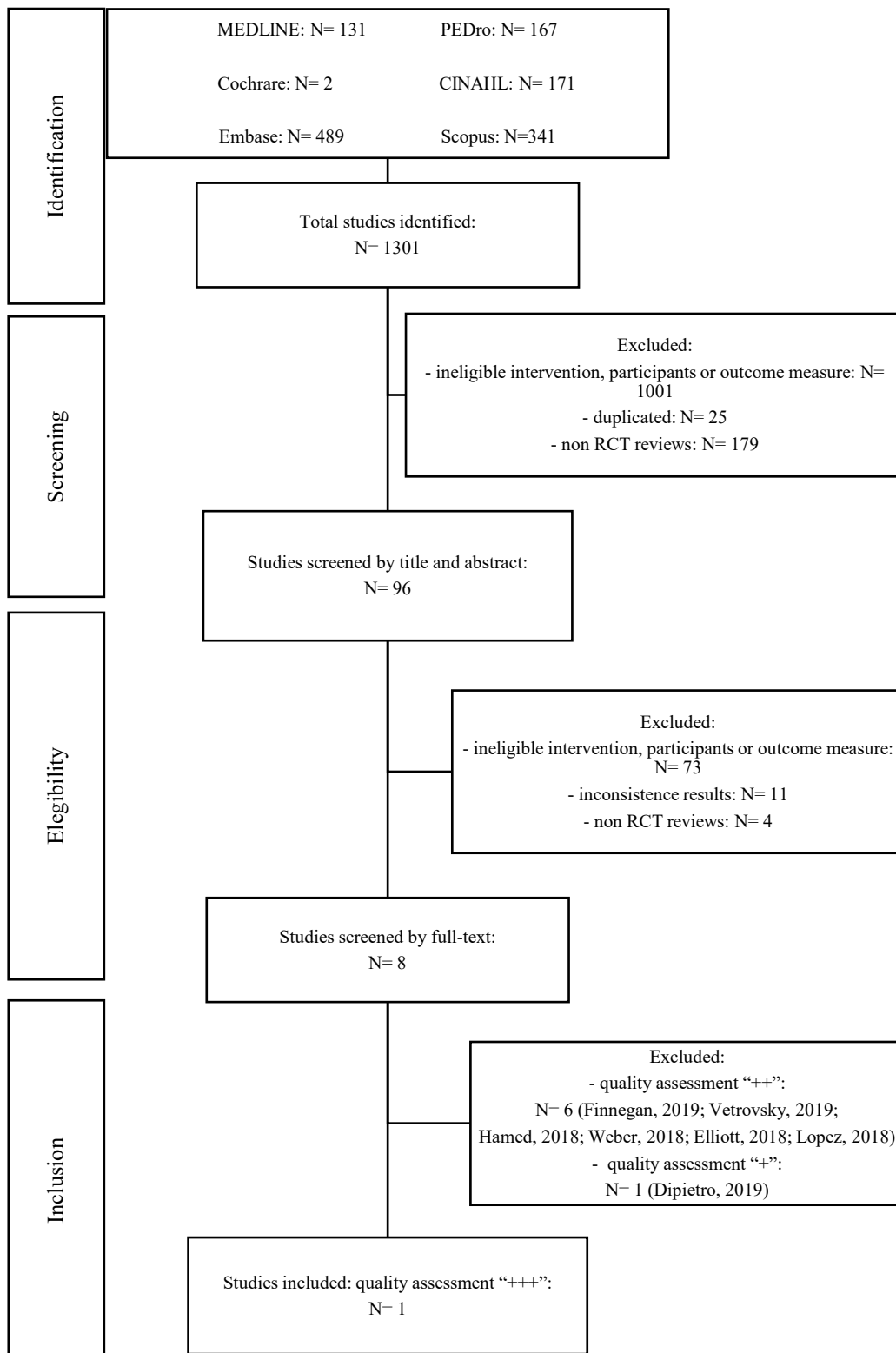
For the RCTs, we searched the databases that had been identified, from May 2, 2018, the date of the more recent eligible review update according to Sherrington (36), to July 23, 2019, and identified 1,175 studies (five of which met the eligibility criteria). After a quality assessment had been conducted (**Appendix 3**), we included one RCT (**Figure 4**).

Figure 4- Selection of the RCT

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┌─────────────┐  ┌──────────────────────────────────────────────────────────┐
│             │  │  MEDLINE: N= 106          PEDro: N= 167                   │
│  I          │  │                                                           │
│  d          │  │  Cochrare: N= 81          CINAHL: N= 148                  │
│  e          │  │                                                           │
│  n          │  │  Embase: N= 404           Scopus: N=269                   │
│  t          │  └──────────────────────────────────────────────────────────┘
│  i          │
│  f          │       ┌────────────────────────────────────────┐
│  i          │       │  Total studies identified:              │
│  c          │       │  N= 1175                                │
│  a          │       └────────────────────────────────────────┘
│  t          │
│  i          │
│  o          │
│  n          │
└─────────────┘
```

Identification

- MEDLINE: N= 106   PEDro: N= 167
- Cochrare: N= 81   CINAHL: N= 148
- Embase: N= 404   Scopus: N=269

Total studies identified:
N= 1175

Screening

Excluded:
- ineligible intervention, participants or outcome measure: N= 816
- duplicated: N= 48
- ineligible study design: N= 152

Studies screened by title and abstract:
N= 159

Elegibility

Excluded:
- ineligible intervention, participants or outcome measure: N= 101
- ineligible study design: N= 22
- inconsistence results: N= 31

Studies screened by full-text:
N= 5

Inclusion

Excluded:
- quality assessment "++":
N= 2 (Liu-Ambrose, 2019; Li, 2019)
- quality assessment "+":
N= 2 (Aibar-Almazan, 2019; Jimenez-Garcia, 2019)

Studies included: quality assessment "+++":
N= 1

Quality assessment

The quality assessment was conducted by five independent reviewers, and disagreements were resolved by consensus. The five guidelines that were assessed were of good quality overall (range 43%– 87%; mean 66.0). Two guidelines were excellent (overall scores: RNAO 85%; WHO 87%), two were good (overall scores: U.S. Department of Health and Human Services (HHS) 56%, Istituto Superiore Sanità (ISS) 59%); and one was sufficient (USPSTF 43%). Eight reviews were assessed (range 31%– 85%; mean 54.0): one was excellent (85%), four were good (1= 62%; 3= 54%), and three were sufficient (1= 31%; 2= 46%). Five RCTs were judged by risk bias and good quality overall (range 50%– 83%; mean 63.4): one was excellent (83%), two were good (67%), and two were sufficient (50%).

See **Appendix 3** for the quality assessment.

Best type of physical exercise for reducing falls

It was found that physical exercise reduces both the number of people who fall, regardless of their ages, and the number of falls, especially those that cause injuries. Furthermore, it reduces functional decline and fear of falling and increases social relations and quality of life (33, 34, 36).

In community-dwelling older adults, the physical exercises or training that are most effective include the following: multi-component (strength, flexibility, resistance, balance, and gait, etc.), three-dimensional (tai chi and qui gong, etc.), balance and functional, strength, and perturbation-based balance or stepping (33, 36). Individuals' risks of falling and their physical characteristics must first be identified, to develop an exercise program that aligns with their abilities and preferences. Home-based individual multi-component exercises are more effective for people who are at high risk of falling, and they should be managed by trained health personnel. Tai chi or group exercises are recommended for medium-low risk people (33, 34). Caution should be taken when recommending exercise to people who are at high risk of falling, because exercise may increase the risk (34).

It is difficult to establish a detailed exercise program, because studies often differ regarding the duration and frequency of an intervention (37). However, the greatest efficacy is found in people who have histories of recurrent falls or balance/gait deficits, including those affected by Parkinson's disease, multiple sclerosis or knee osteoarthritis as well as frail older adults. There is scant evidence about the effectiveness of exercise programs for people with dementia, cognitive impairment, or mental health conditions and those who have incontinence or have had a strokes (33). It is important to note that the effectiveness of physical exercise is amplified in a multifactorial intervention that includes risk evaluation, health education, environmental modification, examination of footwear, multi-faceted podiatry care, medication, and continence management (33).

Physical exercise was found to be extremely safe, and risk of falls in population that have been treated did not increase in relation to those of the general population. In addition, the trials found few adverse events (34, 36).

In terms of the transferability of physical interventions, we found that it is possible to implement a structured and effective program within a local context. It is necessary to use the primary care

network and common social places (e.g., churches and gyms) and to promote long-term adherence as well as to curtail the social isolation of the elderly (33, 37).

Finally, with regard to sustainability, we found that physical exercise programs can be implemented and also cost-effective, but only if participation is constant and continuous. Caregivers can reduce the total cost of the interventions and promote adherence (34). For people with medium-low risk of falls, costs can be reduced by using trained volunteers and having group exercises (33).

See **Appendix 4** for the data extraction table of the studies that were included.

Based on a summary of the evidence, a draft version of the user manual was created for submission to the members of the expert panel, who then discussed the entire document, focusing particularly on the sections on transferability, sustainability, and the implementation of the interventions.

Consensus among the clinical experts

After the expert panel had met, the manual was supplemented with the following indications:

- For low-risk individuals, group exercise is recommended over individual exercise because it has important social implications (reducing social isolation), and socialization should be encouraged.
- Risk assessment tools for falls complement clinical judgement, especially in high-risk people.
- the high-risk population's intervention team, as well as nurses and doctors, can include physiotherapists, occupational therapists, and motor science graduates; their programs must be specific and delivered individually.
- For greater sustainability, exercise programs in the low-risk population can also be conducted by trained volunteers recruited from among the participants and carried out within structures that are already present in local contexts (gyms, schools, religious buildings, associations, non-profit organizations, etc.).
- Daily life activities that require movement (i.e., cooking and gardening) can be promoted for those who either cannot or do not want to join structured programs.
- To guarantee diffusion and, most importantly, the economic and social sustainability of the programs, it is necessary to involve local institutional actors (municipalities, etc.) and social services.

The manual has been modified according to the recommendations of the experts, and its final version has been created. For the full text of the manual, see **Appendix 5**.

Discussion

The aim of this paper was to define which interventions for fall prevention are effective, sustainable, and transferable within the local context. The sources that were identified through the systematic review of the literature were selected according to the hierarchy of evidence and further filtered through quality assessment (reporting and bias, etc.). Recommendations for the prevention of falls through physical exercise were extracted from the studies that were included,

and using the recommendations an operating manual draft was developed and discussed with a panel of experts. The final IPEST manual was created with the consent of the experts.

However, in spite of the very high quality of the sources that were included through the literature review, the evidence on which they were based was not always of high quality. In addition the evidence was sometimes exposed to bias.

The terminology that was used to classify or report the types of physical exercise was not always clear and varied widely from one source to another. It is important to distinguish between interventions that combined different types of physical exercise and those that combined physical exercise with other interventions (e.g., modification of the home environment). Multifactorial interventions are more effective than a single intervention in the prevention of falls, but not in preventing fall-related fractures, falls requiring hospital admission or medical attention, and health-related quality of life (38).

One of the included guidelines (33) originally focused on older adults in hospital and long-term care settings. The version that we have included has been updated by extending the focus to the community; therefore, it can also be applied in primary care and home care settings.

The panel discussion focused mainly on the aspects of transferability, sustainability, and applicability of the interventions in Italy. The discussion emphasized the need to identify the target population clearly and to stratify individual risk levels through the use of instruments. However, while these instruments can integrate clinical judgements, they cannot replace them. The discussion with experts highlighted the fact that group physical activity is the first recommendation of health care providers in the medium-low risk population. Implementing an evidence-based intervention in the local Italian context requires a thorough knowledge of the characteristics of the territory and the habits of the population (39). Unlike in other countries, community centers in Italy are not common; therefore, group programs must be hosted in places where the populations can access them easily, such as school gyms, churches, and oratories. One of the most frequent barriers to the implementation of the programs is accessibility to the places where group exercises take place. Also, in more isolated settings with low population densities, such as in mountainous areas, people may need to be transported to the appropriate places. If no public transport is available, transportation could be offered by municipalities or volunteers.

With regard to social sustainability, the experts underlined the importance of involving local social services in planning these programs, to increase opportunities for those of lower social classes to attend and for women who are informal caregivers (e.g., for their husbands, grandchildren, or older parents). To reduce socio-economic inequalities, the planning involved in these programs must include consideration of how to facilitate access and adjust costs in relation to the income levels of the participants.

In addition, to reduce gender inequalities, social services must support women in their daily work (e.g., domestic and care activities) in a variety of ways, such as through volunteers, to allow these women to care for their health.

Furthermore, some people may not participate in the interventions because of a lack of knowledge regarding the benefits of physical activity and as a result of cultural resistance. Others may not join group programs for a variety of psychological reasons, such as embarrassment, sense of shame, fear of judgment by others, or depressive symptoms. These aspects should be investigated further. It is also important to note that caregivers of family

members can be a large target population for assisting with the implementation of the interventions, although they may need help from social workers to instruct them about providing care in a safe manner (40). This could include explaining how to mobilize patients safely by performing movements correctly and teaching relaxation techniques or simple exercises that patients can perform independently at home.

All activities of daily living that require movement (i.e., cooking and gardening) can be considered as alternative strategies if there is little or no adherence to exercise programs. This would, however, require individual educational interventions to personalize them, by helping the patient to recognize and integrate all activities that can benefit them through movement in their daily lives. In order for physical activity to be effective, it should include four components of balance (functional stability, dynamic stability, anticipatory control, reactive control) and flexibility (41). In addition, follow-up should be provided over time. Moreover, just walking is not an effective strategy to manage the risk of falls, especially in a high risk population. Instead, it should be integrated with a more specific intervention, each chosen according to individual objectives and capacities (42).

Scientific literature shows how aquatic exercises are an appropriate alternative to land exercises in helping improve the functional performance in older people, due to the physical proprieties of water in optimization of exercise. In fact, muscle activations patterns and movement kinematics are different, exercise intensity is higher, and there is no risk or fear of falling. However, aquatic exercises are less transferable in that they require expert physical therapists and clinical facilities with swimming pools (43).

The manual that has been produced contains indications that are considered transferable to different local contexts; however, these should be adapted to the local settings in which the interventions are to be implemented, including taking into consideration the needs of the population, the territorial and social contexts, the stakeholders, and the resources available.

There is an urgent need for healthcare professionals and community organizations to implement an effective fall reduction strategy into the routine care of older people, and a structured physical exercise program is suggested. These interventions are generally safe, but falls monitoring is necessary to avoid a rise in the number of falls due to this potential increase in physical activity (44).

Based on the competencies derived from the health policy framework for the European Region of the WHO, the multifaceted role of the family and community health nurse was introduced in Italy in recent years. These family nurses are responsible for implementing prevention and health promotion interventions to the population, including playing key roles in prevention and in effecting lifestyle changes (45). To reduce the risk of falls and actively prevent them, it is important for nurses to promote physical exercise, especially among the younger members of the elderly population, because it is important to encourage the adoption of healthy lifestyles as early as possible. Many interventions can also be carried out by volunteers who can be recruited from among the elderly themselves. Participating in voluntary activities can help older people to maintain active lives and outline a new social roles for them within the community.

IPEST has an important practical potential for evidence-based practice within the local context. However, the systematic selection of scientific evidence and the involvement of experts in the practical translation of interventions are crucial. The next step will be to test the effectiveness of the manual in practice.

Limitations

An important limitation to underline is the current lack of involvement by stakeholders (i.e., patient associations) in the process of developing the tool. Moreover, for the tool to be used effectively, it will be necessary to disseminate it at a national level. The guidelines were discovered through the use of a free combination of keywords, which may have extended the search but did not guarantee that all currently available guidelines were found.

Implications for research

Further studies should be carried out to assess the impact of fall prevention exercise programs, including the type and intensity of exercise to be recommended, any adverse effects, and the benefits of the interventions in relation to their costs. It is important that the interventions that were studied are classified according to the taxonomy for the Prevention of Falls Network Europe (46). Studies should also clearly state the type of intervention, its duration, and effort required.

Implications for practice

The manual that we have created from this work can be transferred to other contexts, but the general recommendations should be adapted to local needs and resources. Exercise programs should be differentiated according to the target population: it is recommended that people aged 65 years and older be stratified according to their risk factors. The types of exercise identified seem to be effective; however, some appear to be less effective than others, and this needs to be balanced in the design of the intervention.

Conclusion

Through the search for more recent evidence, our research highlights a possible way to integrate the guidelines for fall prevention among older people. The evidence obtained from this synthesis can guide the planning of intervention programs.

The tool that has been developed can be useful for guiding professionals in the implementation of prevention programs that are based on physical exercise. The recommendations that are provided in this work can be improved upon and adapted to local settings. The IPEST approach can be useful for obtaining the most up-to-date scientific evidence and translating into practice the evidence that is contained in the guidelines, systematic reviews, and primary studies. This methodology can be successfully applied to respond to other research focuses as well, such as home environmental modifications.

It is essential to take preventive action against age-related conditions and to balance priorities, needs, and resources. Raising awareness about frailty and age-related conditions in the elderly population is important for effective prevention and should lead to the promotion of lifelong healthy behaviors and lifestyles.

Abbreviations within the chapter

Acronym	Description
NICE	National Institute for Health and Care Excellence
IPEST	Effective, Sustainable, and Transferable Prevention Interventions
ISS	Istituto Superiore di Sanità
RCT	Randomized Controlled Trial
RNAO	Registered Nurses' Association of Ontario
WHO	World Health Organization
USPSTF	U.S. Preventive Services Task Force
HHS	(U.S. Department of) Health and Human Services

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CHAPTER 9

Home and environmental hazards modification for fall prevention among the elderly

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Background

Aging is a challenge for the global public health because it increase fall risk, disabilities, cognitive impairment, and comorbidities (1,2). Worldwide people aged 65+ that fall at home are 28-35% per year, people aged 70+ are 32-42% (3–6).

Falls are defined as unexpected events in which participants come to rest on a lower level (7). In adults, they are complex and feature multifactorial phenomena (8), related to environmental factors (31%), lack of physical exercise (17%), and dizziness (13%)(9).

Falls represent a major public health problem (10): they are consequences for people both physical (e.g., fractures or loss of mobility) and psychological (increasing fear of falling, loss of self-confidence, and social participation)(11,12). Older adults lose autonomy (13), experience a decrease in quality of life (14), and have increased nursing home admissions (15). Falls can have significant outcomes for the elderly population. According to the Centers for Disease Control and Prevention (16), in 2018 falls were the 11[th] leading cause of death and the first cause of fatal or non-fatal injury in people aged 65+ in the United States of America. Moreover, falls are the primary cause of emergency department admission and hospitalization. Falls incur both direct and indirect costs for society (17). For instance, according to the National Institute for Health and Care Excellence (NICE), in 2011, falls in the United Kingdom cost the NHS £2.3 billion per year (18).

Italy's elderly population is the largest in Europe and one of the largest in the world (19). Preventive activities, interventions, and strategies should be implemented to reduce the age-related disease burden and save money (20,21).

Preventive and multifactorial interventions should be implemented and focus on the individualized risk factors. They should not limit individuals' freedom, dignity, or quality of people's life (22). Research has long shown that home assessment and modification is an effective intervention to prevent falls and fall-related injuries: a well-designed environment protects people from home injuries and hidden fall hazards in daily activities (21). Aging decreases people's abilities, so home design must accommodate their characteristics, minimizing barriers and increasing participation in activities of daily living (23). International literature suggests installing zero-step entrances, short hallways, motion-sensor lightening, as well as removing rugs, adding grab bars or ramps, reorganizing furnishings, and similar interventions (24). According to a Cochrane review, the range of modifications and their costs are wide, and literatures is often inconclusive about the most cost-effective interventions and the best ways to implement them (25).

A prevention tool should be developed to guide local health authorities in delivering evidence-based interventions that improve the quality and the safety of care. The evidence-based manual should also support professionals in promoting healthy aging programs. This sets up the following framework: Effective, Sustainable and Transferable Preventive Interventions (IPEST) (26).

The aim of this study is to develop an implementation tool for effective, sustainable, and transferable home assessments and modification interventions to prevent falls and fall-related injuries in community-dwelling older people.

Research questions

The research questions (see the **Appendix 1** for further details), which were formulated according to the population, intervention, comparison, outcome (PICO) methodology (27), are as follows:

1. Is home assessment and modification effective in reducing the number of falls and fallers and the fear of falling in community-dwelling older adults?
2. Which home layout interventions are the most effective in reducing the number of falls and fallers in community-dwelling older adults?
3. How should these interventions be structured and delivered to community-dwelling older adults?

Methods

The IPEST framework (**Figure 1**) that can be used to develop effective, sustainable, and transferable preventive interventions, was applied in this study (26). The framework has two main components.

The first is a review of the scientific literature (guidelines, systematic reviews, and randomized controlled trials), including evidence-based activities, actions, interventions, programs, and strategies about home assessment and modification interventions to prevent falls and fall-related injuries in community-dwelling older people. This step include research of previous studies, review of inclusion and exclusion criteria, study selection, quality assessment, data extraction, and analyses. The extracted data have been summarized in a narrative way in the draft manual.

The second is to submit the draft manual to achieve a consensus among clinical experts about 1) sustainability in social terms (the intervention must not increase social inequalities related to gender, socioeconomic aspects, and cultural differences, among others), economic terms (e.g., cost efficacy), and in terms of time (positive effects should continue after the intervention has stopped), and 2) transferability in the local context given the barriers and resources. The draft manual has been modified according to the expert opinions, and the final manual has been created.

Figure 1- IPEST framework process

Literature review → Draft → Experts' consensus → Final manual

Literature Review

Study research

Following the hierarchy of the evidence pyramid, we looked for guidelines, systematic reviews, and randomized controlled trials (RCTs) that answered our research questions. We searched for guidelines on the websites of scientific societies, institutions, organizations, and associations. The MEDLINE, Embase, and Cumulative Index of Nursing and Allied Health Literature (CINAHL) databases were screened for systematic reviews and RCTs (see **Appendix 1** for the search strategy).

Inclusion and exclusion criteria

We included guidelines, systematic reviews and RCTs in Italian and/or English published between January 1, 2015 and July 15, 2019. We excluded studies with narrative or observational approaches, grey literature, editorials, expert opinions, reports, studies with inconclusive results, studies that were cited in already included papers, and studies that focused on populations with severe cognitive impairment or populations that were not self-sufficient.

Study selection

Guidelines were searched independently by four reviewers. Two reviewers independently looked for reviews and RCTs. First they read the titles and abstracts of the identified papers and eliminated irrelevant studies. Second, they read the papers in their entirety to identify those eligible for inclusion. The reviewers managed disagreements by reaching a consensus or consulting a third reviewer.

Studies were selected following the hierarchy of evidence of effectiveness, and then were excluded according to the following criteria:

- guideline, if already contained within other more recent guidelines;
- systematic review, if already contained within an included guideline;
- RCT, if already included within guidelines or systematic reviews included.

Quality assessment

Guidelines were assessed with the Appraisal of Guidelines for Research & Evaluation II (AGREE II) (28), a tool that evaluates scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence and provides an overall guideline assessment. The final score was calculated as the arithmetic mean of the results from each domain.

Systematic reviews were assessed with the following tools:

- Measurement Tool to Assess Systematic Reviews (AMSTAR) (29), integrated with
- Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (30) and criteria to quantify the strength of evidence.

First, we calculated the AMSTAR score. Reviews were given one point if each items received a "Yes" on an AMSTAR item and obtained the maximum rating (if the method was correct) on PRISMA. Second, the score was integrated based on the criteria for the strength of evidence. We added a point if there was a low reporting bias or if the review was done with RCTs. We

removed a point if the results were influenced by bias, if the results were inconsistent, or if the outcome was indirect or subjective.

RCTs were assessed with the Cochrane Risk of Bias Tool (31).

The quality of evidence was summarized with a qualitative four-position scale (low, sufficient, good, and excellent), which represents the percentage of excellent-quality evidence to the total evaluated evidence (**Table 1**) (26).

Table 1- Quality assessment rating

The table shows the percentages applied to classify the studies according to quality, and related graphic representation

Percentage of excellent quality criteria	Evaluation	Graphic representation
≤ 30%	Low	-
31% - 50%	Sufficient	+
51% - 75%	Good	++
> 75%	Excellent	+++

Only studies rated "excellent" were included. Five authors independently assessed the quality and managed disagreements by reaching a consensus.

Data extraction and analysis

Three authors independently extracted the data. For guidelines, the society and year of publication, recommendations, strength of evidence, and references were extracted. For systematic reviews, the author and year of publication, the typology and number of included studies, the objectives and target population, and the outcomes and effect size were extracted. For RCTs, the author and year of publication, the type of study, the objectives and target population, and the outcomes and effect size were extracted.

Data on the sustainability and transferability of each intervention were also obtained. See **Appendix 3** for the data extraction of the included guidelines. Analyses and narrative syntheses of the data obtained were carried out in order to create the draft manual.

Clinical experts' consensus

A draft of the user manual for implementing effective home assessment and modification interventions was developed based on the IPEST method (26). The manual was then discussed with an expert panel (IPEST Working Group) to assess the local transferability and sustainability.

The panel included the following health care professionals:

- a nurse expert in gerontology, geriatrics, and primary care
- a nurse in charge of territorial social assistance
- a nurse coordinator of home nursing services
- a nurse coordinator of home care structure
- a family and community health nurse

- a coordinating nurse and president of the Italian Association of Family and Community Nurses
- a physiotherapist
- a nurse coordinator
- a medical director of geriatrics.

All individuals participating in the consensus gave their verbal consent. Two authors informed all the participants about the study aim and that the results would be anonymous. The data were accessible only to the research team members (32).

A semi-structured interview as developed. The interview session lasted one hour and was audio recorded and transcribed. Two authors repeatedly read the transcript and identified the categories, followed by the themes (33,34). The authors organized the data by bracketing the information (35). Two authors made additions to the manual (see the **Appendix 4**) before submitting it back to the experts' judgment.

Results

On February 1, 2019, we identified 14 scientific societies, institutions, and associations that had published guidelines on fall prevention. Only two met the eligibility criteria and passed the quality assessment and therefore included in the study (**Figure 2**).

Figure 2- Guidelines selection

Identification

Scientific Society:
- Canadian Task Force on the Periodic Health Examination
- The Community Guide U.S.A. Preventive Task Force (CGPTF)
- U.S. Preventive Services Task Force (USPSTF)
- U.S. Agency for Healthcare Research and Quality (AHRQ)
- Scottish Intercollegiate Guideline Network (SIGN)
- Centre for Evidence Based Medicine (CEBM) di Oxford
- The National Institute for Health and Care Excellence (NICE)
- Canadian Medical Association Infobase
- New Zealand Guidelines Group
- Haute Autorité de Santé
- Istituto Superiore di Sanità (ISS)
- U.S. Department of Health and Human Services (HHS)
- Registered Nurses' Association of Ontario (RNAO)
- World Health Organization (WHO)

Scientific society without guidelines:
N= 10

Guidelines identified:
N= 4

Screening

Excluded:
- ineligible intervention, participants or outcome measure: N= 1 (SIGN, 2015)

Guidelines screened by title and abstract:
N= 3

Elegibility

Excluded:
- cited in a more recent guideline:
N= 1 (NICE, 2013)

Guidelines screened by full-text:
N= 2

Inclusion

Guidelines included: quality assessment "+++":
N= 2 (RNAO, 2017; WHO, 2017)

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On July 23, 2019, we identified 591 systematic reviews and RCTs. None of the reviews met the eligibility criteria (**Figure 3**), and none of the RCTs passed the quality assessment (**Figure 4**).

Figure 3- Systematic reviews selection

Figure 4- RCTs selection

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Identification
  ┌─────────────────────────────────────┐
  │  MEDLINE: N= 329                     │
  │                                      │
  │  CINAHL: N= 105                      │
  │                                      │
  │  Embase: N= 157                      │
  └─────────────────────────────────────┘
                    │
  ┌─────────────────────────────────────┐
  │  Total studies identified:          │
  │  N= 591                             │
  └─────────────────────────────────────┘

Screening
                    │         ┌──────────────────────────────────────────────┐
                    │         │  Excluded:                                   │
                    │         │  - ineligible intervention, participants or  │
                    ├─────────│    outcome measure: N= 509                   │
                    │         │  - duplicated: N= 29                         │
                    │         │  - ineligible study design: N= 34            │
                    │         └──────────────────────────────────────────────┘
  ┌─────────────────────────────────────┐
  │  Studies screened by title and      │
  │  abstract:                          │
  │  N= 19                             │
  └─────────────────────────────────────┘

Elegibility
                    │         ┌──────────────────────────────────────────────┐
                    │         │  Excluded:                                   │
                    │         │  - ineligible intervention, participants or  │
                    ├─────────│    outcome measure: N= 8                     │
                    │         │  - ineligible study design: N= 4             │
                    │         │  - inconsistence results: N= 6               │
                    │         └──────────────────────────────────────────────┘
  ┌─────────────────────────────────────┐
  │  Studies screened by full-text:     │
  │  N= 1                              │
  └─────────────────────────────────────┘

Inclusion
                    │         ┌──────────────────────────────────────────────┐
                    │         │  Excluded:                                   │
                    ├─────────│  - quality assessment "++":                  │
                    │         │  N= 1 (Pey June Tan, 2018)                   │
                    │         └──────────────────────────────────────────────┘
  ┌─────────────────────────────────────┐
  │  Studies included: quality          │
  │  assessment "+++":                  │
  │  N= 0                              │
  └─────────────────────────────────────┘
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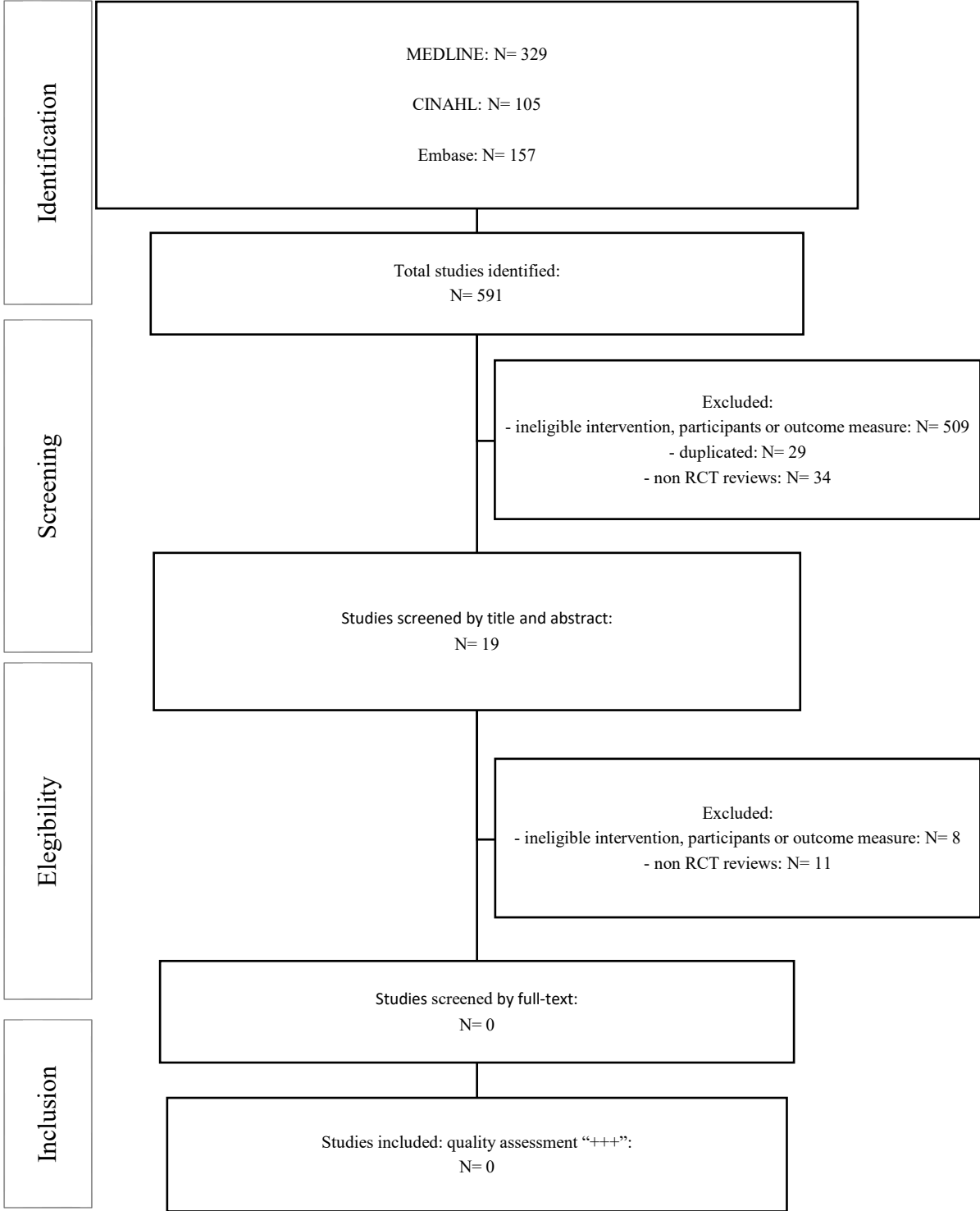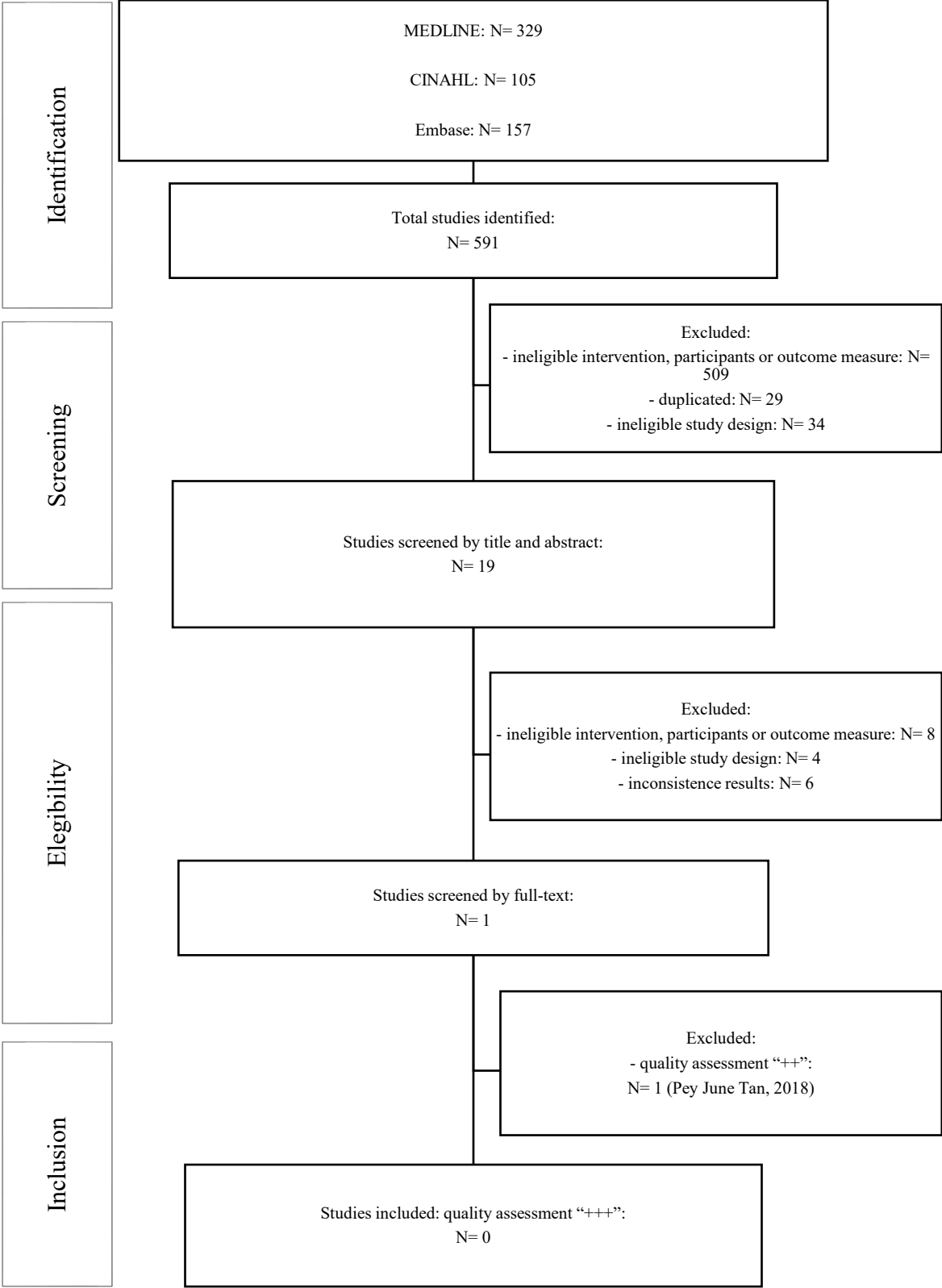
Two guidelines were selected, Registered Nurses' Association of Ontario (RNAO) and WHO. Either were rated "excellent", with respectively overall scores 85% and 87%. The RCT was assessed as "good" (Pey June Tan 66.7%) and was therefore excluded from the analysis (see **Appendix 2** for the quality assessment).

Best home modification to reduce falls
Home modification is an effective strategy for reducing the number of falls and fallers in community-dwelling older adults, mostly among those who are classified as having a high risk of falling. However, little evidence was found about the most effective combinations of interventions. Interventions should be tailored to individuals' needs. Individual risks must be identified before starting the program to produce targeted interventions and maximize their efficacy (36,37).

Home modification interventions should consider the following factors in the physical environment:

- appropriate flooring (e.g., slip-resistant flooring, dry surfaces, no parquet or carpets);
- adequate lighting (e.g., night light or supplemental lighting, easy to switch on);
- appropriate furniture (e.g., low bed/chair height, bed side rails, chairs with armrests and handrails in bathrooms and hallways);
- adequate layouts (e.g., sufficient room to move and use walking aids, all areas uncluttered and cleared of tripping hazards)(36).

The effectiveness of home modification is enhanced in multifactorial interventions that include risk evaluation, health education, environmental modification, the promotion of proper footwear, multifaceted podiatry care, medication reconciliation, and continence management (36,37).

In terms of sustainability, we found both barriers to and facilitators of successful implementation. Health professionals must address individuals' lack of a sense of urgency or motivation to change behaviors in order to raise their awareness of being at risk of falling. Every home modification must be discussed and approved by individuals and their caregivers to produce targeted and lasting change. Furthermore, the lack of financial resources could be a major barrier for both individuals and society (36).

Regarding transferability we found that trained professional (including doctors, occupational therapists, nurses, and physiotherapists) can carry out home hazard assessments and modifications (37).

A draft version of the user manual was created from a summary of evidence, and submitted to the expert panel to discuss the transferability, sustainability, and implementation of the intervention in the Italian context. The following findings and suggestions emerged from the consensus: First, fall-risk assessment tools are useful in completing clinical judgment. Second, interventions must be delivered by trained health professionals (e.g., nurses, doctors, occupational therapists, and physiotherapists) who should create a therapeutic alliance with people under their care. Third, it may be useful to deliver simpler and cheaper interventions first to make the environmental change more acceptable. Finally, local institutions (e.g., municipalities and social services) must be involved to ensure economic sustainability.

The manual was modified according to the experts' recommendations, and a final version was created (see **Appendix 4** for the full text of the manual).

Discussion

This study aimed to develop a user manual for the implementation of an effective, sustainable, and transferable home assessment and modification intervention, to prevent falls and fall-related injuries among community-dwelling older people. We reviewed the literature according to the hierarchy of evidence (guidelines – systematic reviews – RCTs) and then filtered the sources through a quality assessment. From the studies included, we extracted recommendations about the efficacy, sustainability and transferability of home modification programs. We developed an implementation manual draft and discussed it with a panel of experts. After that, a final IPEST version was created.

We found that home/environmental interventions can be effective in reducing the number of individuals who fall and the frequency of falls in community-dwelling people aged 65 and over. The literature suggests using slip-resistant flooring, adequate lightning, appropriate furniture, and an adequate and convenient layout (36,37).

Many variables are associated with falls of the elderly in the home environment, such as medical conditions, medications (38), and physical inactivity or reduced physical activity (39). Elderly patients experience more unstable balance as a result of important cardiovascular therapies that affect blood pressure and heart rate (40).

In addition, clothing and footwear also play an essential role in the incidence of falls in the elderly population (41).

Home assessment and modification is a low-cost, highly cost-effective, and high-return intervention (42). It produces health gains in terms of the quality of life among older adults. Moreover, a high fall burden is linked to an inadequate home environment; thus, preventive interventions should focus on accurate home modification (43). Before any scaling up an intervention, an efficient way to start the program is to target people at high risk of falls (44).

Such an interventions benefits all people staying in the modified homes, not just those at risk of falls. The effectiveness of the intervention is linked to the compliance of individuals at risk of falls and their caregivers (24,45). Thus, the literature and experts suggest making easy and feasible changes first to make the intervention more acceptable (36).

A multicomponent program to prevent falls in community-dwelling older adults is recommended to create an intervention focused on individual needs and offer additional benefits (e.g., group exercise programs that provide social contact) (46).

Similar studies have suggested implementing environmental modification after a comprehensive assessment of individuals' needs and demands. Education is a key step in creating a therapeutic alliance and successful intervention (47).

The economic situation and social interaction of the older adult also plays an essential role in the fall event. A relevant study by Pin and Spini (12) evaluated the interaction between falls and social participation as well as social support. Falls caused a decrease in social involvement and an increase in social support. This social impact of falls can be mitigated by preventive or rehabilitative interventions (12).

In the Italian context, family and community nurses can be the appropriate health professionals to assess the individual risk of falls and deliver targeted interventions. Nurses should first

evaluate the individual risk factors and then involve the person in a multifaceted intervention and a support network to deliver appropriate care. A network of primary care health professionals, hospital specialists, local institutions, and caregivers should be created to deliver the appropriate interventions and support people undergoing the change (e.g., home modification). Long-term sustainability of the intervention is linked to the support and trust of caregivers and the family. Local institutions must promote and finance the intervention, which can be costly.

Limitations of the Study

This study has a number of limitations. First, most of the evidence focused on environmental modifications of hospitals or long-term care settings. Nevertheless, some universal precautions may also be applicable to individual homes. Second, the literature does not specify the types of structural/home modifications that can maximize the effectiveness of the program. It was hard to find papers that studied home modifications as a single intervention and not as part of a multicomponent one. Third, although we included only high-quality sources, the evidence they found was not always of high quality and was often exposed to bias. For instance, we assessed the quality of guidelines with AGREE II, which evaluates the methodological rigor and transparency but not the quality of the recommendations. Fourth, the fall risk of the included populations was assessed with different or unspecified tools, so it was hard to make comparisons. Fifth, the populations of the included studies often excluded persons with specific diseases (e.g., Parkinson's and Alzheimer's disease) that are common in older adults. Sixth, the follow-up period used in most of the included studies was too short, making it difficult to evaluate the long-term effectiveness of the interventions. Finally, the studies did not demonstrate that home modifications reduce falls and fall-related injuries.

Implications for research

Further studies may be carried out to assess the impact of home modification on other risk-reduction interventions so that an appropriate cost-benefit program can be developed. To the best of our knowledge, no studies have compared the effectiveness of individual interventions related to environmental change, especially in relation to the difficulty in making them applicable in everyday practice. However, some studies comparing the effectiveness of environmental modification with other interventions took into account different aspects of home modification (e.g., removing obstacles and installing handrails).

It would be interesting to compare the effectiveness of various types of environmental modification interventions, such as no-cost interventions (e.g., removal of carpets and obstacles or the use of walking aids), low-cost interventions (e.g., reorganizing lighting systems and using handrails and chairs with armrests), and high-cost interventions (e.g., changing the layout and installing elevators). Moreover, it is important for future studies to demonstrate that environmental modification can reduce falls and fall-related injuries.

Implications for practice

The manual that we created can be used to implement home modification programs to reduce the number of falls and fallers among community-dwelling older adults. The IPEST methodology is useful in producing user-friendly evidence to support health workers in

everyday practice. This IPEST manual has not yet been widely implemented, so there is still little experience in this area. The operating manual needs strategies for transferability and implementation in local contexts.

Conclusion

Home modification is an effective preventive program in reducing falls and fallers among older community-dwelling adults aged 65 and over. The IPEST user manual can help clinicians, health professionals and stakeholders to implement environmental change interventions. However, promoting healthy aging remains the most effective strategy for reducing costs and morbidity in the elderly population.

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CHAPTER 10

The prevention of falls in patients with Parkinson's disease with in-home monitoring using a wearable system: a pilot study protocol

"Everyone has duties to the community in which alone the free and full development of his personality is possible."

(Article 29- 1, United Nations, *Universal Declaration of Human Rights*)

Introduction

Parkinson's disease (PD) is a chronic, and progressive neurodegenerative condition that is caused by the loss of neurons that produce dopamine, the chemical responsible for communication between motor neurons (1, 2). Though the exact causes of neurodegeneration are not yet fully understood, several factors do need to be considered. In addition to the classical motor phenotype, which is characterized by bradykinesia, rest tremors and postural instability, patients often complain of several non-motor-related symptoms, including cognitive impairment, depression, hallucinations, gastrointestinal dysfunction, and sleep disturbances, all of which have a significant impact on both patients' and their caregivers' lives (3).

PD is the second most common neurodegenerative disease, after Alzheimer's-caused dementia; the prevalence of PD varies globally; estimates range from 15/100,000 inhabitants of China to 150-200/100,000 inhabitants of Europe and North America. In Italy, PD has a prevalence rate of 193.7/100,000; about 5% of these individuals are under the age of 50, while 70% are over the age of 65 (4, 5).

Onset occurs at an average of around 60 years of age, and the disease is slightly more frequent in males, with a 1.5-2 higher rate of incidence. In terms of prevalence, the disease occurs in 1-2% of those over 60 and 3-5% of those over 85. Due to the increasing age of the general population, the prevalence of the disease is estimated to double by 2030 (5, 6). Dopaminergic treatment has shown clinical benefits at early stages of Parkinson's, but several complications can occur as the disease progresses, including motor fluctuations, postural deformities, and cognitive decline, which respond less to current therapeutic options. Also, the effect of rehabilitation on reducing dyskinesia was studied (7).

Some complications, such as postural instability and dementia, have a mean onset time of approximately 5 and 10 years from diagnosis, respectively, although this is highly variable due to individual characteristics (8). Previous studies have identified several risk factors for future

falls in patients with Parkinson's, such as slowness, freezing of gait, loss of balance and mobility problems, cognitive impairments, and a history of previous falls (9). Falls occur frequently in patients with Parkinson's; incidence rates vary from 35% to 90% for falls and from 18% and 65% for recurrent falls (10). PD patients are also prone to near-falls; main risk factors of these include jerky movements and postural instability (11). It has been estimated that 30% of people over 65 years old experience one fall per year (12), and it is also worth noting that day-to-day activities can represent risk factors for falls because they can be influenced by reduced motor ability (13).

The results of an umbrella review suggest that in PD patients' virtual reality rehabilitation improves gait performance (14), thus a possible reduction in the risk of falling as well. In other patient population, the use of the telemedicine and e-health technology has been described (15 – 20).

The use of sensors that can quickly identify the event of a fall has been documented in the literature (21). The bracelet (see **Figure 1**) in question here (called TED by the research team to facilitate communication with patients) is an advanced technological device developed by the 4Sec company (www.4secsrl.com) that is equipped with an accelerometer capable of detecting up to 200 samples per second concerning the acceleration of gravity across the x, y, and z axes. The device was developed to adapt to an individual's biological variables. As such, it is totally programmable and its performance can be optimized for each patient. All data received by the device is sent to the cloud collection system, both continuously (with the goal of monitoring the function of interest) and in cases of specific events included in the monitoring plan, such as a fall. The data is then processed by machine learning systems that can extrapolate elements of knowledge and learning of the device from the data, using the most modern deep learning algorithm. The device shown to be sensitive to breathing movement in infants (22).

Although fall detection and prevention has been a research topic since the mid-2000s, there is a gap in the literature regarding studies of PD fall prevention systems, specifically when applied to individuals in their homes.

This study aims to investigate the feasibility of a full-scale research project that uses the TED bracelet to identify whether individuals with Parkinson's disease are at risk of falling. Specifically, the study will have the following objectives:

- to estimate the prevalence of falling among PD patients;
- to evaluate study participants' adherence to the device, gait characteristics and their variations, the adequateness of diary keeping;
- to compare a group of patients with PD's gaits and risk of falling with those of a group of older citizens who are not affected by any gait or mobility altering conditions;
- to collect and store biomaterial and clinical information and store it in the Biobank of Università of Piemonte Orientale (UPO Biobank) for further research.

Methods
Study design
This will be a pilot prospective observational study.

Study setting and participants
The study will be conducted at both at the Movement Disorders' Center (Neurological Unit) of the University Hospital "Maggiore della Carità" (Novara, Italy) and at the homes of the enrolled patients.

Inclusion and exclusion criteria
The inclusion criteria for PD patients will be: a) subjects > 65 years old suffering from Parkinson's at an intermediate stage as defined by Hoeen and Yahr (H&Y) 1.5-3; b) the ability to understand and provide informed consent; c) preserved cognitive skills, tested as defined by a mini mental state examination (MMSE) score of > 24.

The inclusion criteria for healthy controls without gait problems will be: a) subjects > 65 years old; b) not suffering from any disease that could alter their gait; c) ability to understand and provide informed consent; c) preserved cognitive skills, as defined by a MMSE score of > 24.

The following conditions will be the exclusion criteria:
a) hospitalized subjects or nursing home residents; b) bedridden subjects; c) PD patients undergoing advanced therapy (apomorphine infusions, deep brain stimulation implants, levodopa carbidopa intestinal gel treatments); d) subjects with severe choreic dyskinesias; e) subjects with a concomitant disease that could increase their risks of falling (e.g., neuropathies, osteopenia, osteoporosis); f) subjects with neurological disorders other than idiopathic PD; g) subjects affected by atypical Parkinsonism, psychiatric disorders, or any other condition that, in the researchers' opinion, could compromise the eligibility for the present study (e.g., having an implanted pacemaker).

Participants' recruitment
Participants will be recruited at the Movement Disorders Center (neurological unit) by the principal investigator and neurologists from the team. Any subject that meets the inclusion criteria will be included in the study cohort and followed up with for a maximum of 12 months. The enrollment phase will last about three months.

The investigators will provide any information required by the eligible participants to define the purposes, methods, device features, risks, and benefits of the study, and will also offer useful contacts. Participants will be invited to sign the informed consent form and to give an additional consent for the collection of peripheral blood for biobanking at the UPO Biobank. This will not affect their potential involvement in the study.

Sample size calculation
After setting a first type error of 0.10 (pilot study), a prevalence of falls of 0.10, and a half-width of the confidence interval of 0.10, we were able to define the sample size of this study as 26 PD subjects. Each PD subject will be matched with an older citizen who is unaffected by any gait-altering conditions.

Data collection

Enrollment phase

At the enrollment, the following information will be collected/assessed using a datasheet:

- age, gender, work, education level, size of family, and daily life habits (for example, whether he/she lives alone);
- characteristics of the home;
- pharmacological treatments;
- comorbidities;
- cognitive function (MMSE) (23);
- motor function using the Movement Disorder Society's revision of the United Parkinson's Disease Rating Scale (MDS-UPDRS) and related subscales (24);
- quality of life (Quality of life in Parkinson's disease patients - PDQ-39-IT) (25);
- fear of falling (Falls Efficacy Scale International - FES-I) (26);
- motor and movement disorders (freezing of gait questionnaire) (27).

Monitoring phase

The monitoring phase will last a maximum of 12 months; all information will be collected both electronically (through the TED device (**Table 1**)) and manually by falls diary. Study participants will be instructed to complete a diary recording on days where falls or near-falls occur. The following information will also be collected: a) time and place of the fall or near-fall; b) caregiver (or family member) witnesses; c) causes as well as physical, personal, and environmental conditions; d) activities undertaken; e) description of the dynamics of the falls/near-falls; f) consequences.

Table 1- Gait characteristics monitored by TED

Gait characteristics	Variables	Unit of measurement	Notes
Step Cadence	Numeric	Average steps/minute	Estimated average cadence every 10 minutes
Estimated walking speed	Numeric	Meters/second	Estimated average speed every 10 minutes
Swing	Episode	TBD	Evaluation of swinging amplitude. Database timestamp event record.
Gait festination	Episode	Timestamp	Database timestamp event record.
Fall*/Near Fall**	Episode	Timestamp	Database timestamp event record.
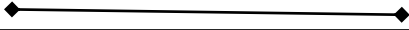
* Definition of a fall: "To inadvertently reach the ground, floor, or other lower level, excluding intentional changes in position to lean against furniture, walls, or other objects," (20).

**Definition of a near-fall: "Stumbling, sliding, or missteps involving a loss of balance that does not translate into a fall because corrective action is taken to recover balance," (21, 22).

The TED device will automatically record the characteristics of the participants' gaits during the study period. At the end of the monitoring phase, the dataset will be accessible to authorized researchers. **Table 2** shows the study time schedule.

Table 2- Study Time Schedule

	STUDY PERIOD			
	Movement Disorder Center		**Home**	**Close-out**
TIMEPOINT	$-t_1$	t_0	t_3 *(12 months)*	t_4
ENROLLMENT				
Eligibility screen	X			
Informed consent	X			
Device delivery and instruction provision		X		
MONITORING PHASE				
TED device			•————————•	
Falls diary			•————————•	
ASSESSMENTS				
CLINICAL VARIABLE & LIFESTYLE				
Demographic characteristics	X			
Daily lifestyle habits	X			
Home features	X			
Pharmacological treatment	X			
comorbidities	X			
MMSE	X			
MDS-UPDRS	X			
PD-39-IT	X			
FES-I	X			
Freezing of Gait Questionnaire	X			
GAIT CHARACTERISTICS				
Step cadence			•————————•	

Estimated walking speed			←————————→	
Swing			←————————→	
Gait festination			←————————→	
Fall/near fall			←————————→	
Characteristics of the fall*				
Gait pattern				X

TED device

The TED device is safe, assembled in a shock-resistant plastic case, and is very small and easily transportable. The radio transmission complies with the regulations in force in terms of EMC emissions. Although the device's sensors possess a high level of adequacy and sensitivity (except when it comes to the measuring of falls), the application to detect the near falls, the measurement of the cadence of the step, of the walking speed, and the oscillation was used only in the context of experimental testing.

Study outcomes

The following outcomes will be considered:
- The number of falls and near-falls that occurred during the study will be counted using numbers recorded by both the TED bracelet and the participants' diaries. The double counting will verify data coherence between TED device recordings and the fall events reported in the diary. Furthermore, the adequacy of diary keeping will be verified too.
- Consistent use of the TED devices will be measured as follows. The absence of gait characteristic measurements for a period exceeding 24 hours will be considered an interruption in the use of the device. The interruption will be considered temporary if the use of the device is resumed by the end of the observation period and final if it is not. In the event of a temporary interruption, the number of outage events that occurred during the observation period will be counted.
- The gait characteristics associated with falls and near-falls in Parkinson's patients will also be examined. At the end of the observation period, the TED device's actual data transmission will be evaluated, and the trends in the parameters (pace, walking speed, oscillation, festination) will be analyzed. Subsequently, these data will be related to the falls / near-falls.

Statistical analysis

Descriptive statistics will be utilized to describe patients' characteristics. Mean and standard deviation (SD) will be used to describe continuous variables with normal distribution. Continuous variables that are not normally distributed will be expressed using median and interquartile range. Absolute and relative frequencies will be presented for categorical variables.

Consistent use of the device will be defined as the ratio of the number of subjects who never experienced interruption to the total number of participating subjects and by counting the

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number of interruptions each individual experiences. For the first indicator, the confidence interval will be 95%. Diary-keeping adequacy will be assessed by calculating the proportion, and the corresponding 95% CI, of the number of days where the diary was correctly filled in as compared to the number of days on which the bracelet was worn. Cohen's Kappa will be used to assess the level of agreement between the TED device and the diary in terms of fall detection. Units of interest will be days (or daily time bands); data points will include either both instruments identifying a fall (agree) or one recording an event that the other has not (disagree). The clinician and the subject will resolve any unclear cases by comparing the data from the TED device with the diary. Trends in gait patterns will be displayed graphically and analyzed through specific models for repeated measurements. The gaits' characteristics (exposure) will be evaluated for various time frames of different lengths to represent the period before the fall/near-fall (outcome).

Logistic regression models will be also used to verify the association between the variables used to determine gait patterns and the risk of falling. Furthermore, the predictive power of each variable on the risk of falling will be determined by calculating the mean values of various parameters during the 15, 30, 45, and 60 minutes leading up to the fall, for the events, and in the same time frame, for the non-events, identified randomly during the observation period.

Specific conditional logistic regression models will be used to compare the association between gait patterns and risk of falling between individuals suffering from Parkinson's disease and individuals not suffering from any pathologies that could alter gait. In these models, in addition to the variables used to determine the patterns, a variable identifying the disease state (Parkinson's vs. absence of a pathology that could alter gait) and an interaction term between pattern and disease state will be included.

Discussion

Twenty-six patients with intermediate PD who are being treated at the Movement Disorders' Center, and 26 participants over 65 years old not affected by diseases that could alter their gait (the control group) will be enrolled in the pilot study. The results of this study could be helpful in the evaluation of the feasibility of a more extensive study.

This study will be the first to be conducted using the TED device in PD patients. However other studies using similar devices have shown promising results (21, 31), leading us to believe in the potential of the TED device. Notably, the TED device is a bracelet that can be worn with a level of comfort that is similar to a bracelet or watch. Therefore, we expect a high level of wearability (adherence), acceptability, and gradeability from the subjects. This device is also easy to use and can be operated independently by either the user or caregiver, meaning that people living alone can be monitored while maintaining their independence and privacy. This study could be useful in implementing a gait monitoring system in practice for people with PD or other neurodegenerative diseases that affect physical function and mobility, such as Alzheimer's dementia. Preventing falls and their related issues (e.g. disability) could have a significant impact on both PD patients' and their caregivers' quality of life.

Lastly, this study highlights biobanking's key role in fostering scientific research by allowing for the discovery and validation of disease markers and novel therapeutic strategies, the adherence to standard laboratory practices, and the quality of results and ethical requirements (32). Furthermore, biobanking encourages both government agencies and international

infrastructure to recognize the best ethical, scientific, and legal practices and guidelines for providing healthcare (33). Thus, it effectively supports health studies, not solely via relevant biospecimens collection linked to relevant personal and health information (health records, family history, lifestyle, genetic information), but via the implementation of new factors like imaging biobanks and data on diagnostic interventions (32, 33).

This study does not include the elderly population who use walking aids and wheelchairs.

The TED device can detect movement in space – if it is worn on the wrist, it will detect one's position based on where one's wrist is. The device is able to detect a wheelchair user's fall, but for accurate detection, it would have to be worn at chest level. In this case, the recorded fall time would be shorter than for a person who fell while standing. It is necessary to establish a person's basic posture beforehand. In the case of a wheelchair, the parameters of the algorithm that detect the fall would have to be changed according to the sitting position. From our experience, we believe that the most suitable device for detecting falls in wheelchair users is one worn on the chest. We are not aware of any published studies on wheelchair users. The detection of falls in wheelchair users and people using walking aids could be a topic for further research.

Should the results of our project support the validity of the TED device in its ability to identify gait patterns predictive of falling or near falling, the device could be used to stratify the risk level in frail patients at high risk of fracture (e.g. osteoporotic). The device could also be used in the general population to establish risk factors for falls and near falls, both in the home and in structured care settings (e.g. residential facilities and hospitals).

To complement the assessment carried out by the TED device, it is considered appropriate to combine an assessment of home risk factors (34). Further fall prevention interventions could be assessed and implemented based on the physical capabilities of the assessed person (35). For example, exercise is one such intervention (36).

This study's protocol may have a limitation in its design that would make it impossible to determine *a priori* if the overall cost of the monitoring system is convenient and sustainable over time.

In conclusion, the development of a gait monitoring system for people with PD or other neurodegenerative diseases that impact physical functions and mobility, such as dementia or Alzheimer's is undoubtedly useful. Preventing falls will offer a major advancement in home care assistance for both patients with Parkinson's disease and their caregivers, significantly improving their quality of life.

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CHAPTER 11

Cross-border validation of a home falls detection form

Campani D, Viganò A, Levati S, Regazzi O, Mion A, Signorotti L, Pratillo S, Zennaro S, Prandi C, Cross-border validation of a home falls detection form, Article under review

Preface
- The use of a validated falls and near-falls reporting form makes it possible to describe the characteristics, dynamics, and causes associated with falls in the home;
- properly recording data on falls enables timely collection and analysis of data on the phenomenon and longitudinal and comparison studies, as well as prevalence and incidence studies;
- through data analysis, sets of interventions can be planned to decrease the risk of falls or near-falls and guide care practice;
- the cross-border validation carried out represents a first step in achieving a higher level of regional integration and cross-border coordination to improve care and relationships between neighboring regions through shared solutions and synergies that start with the analysis of larger databases.

Introduction
Unintentional injuries are the fifth leading cause of death in the elderly (after cardiovascular disease, cancer, stroke and lung disease). Falls account for two-thirds of these deaths constituting a common and significant problem among older people, with increased morbidity and mortality related to it (1). Most falls are associated with one or more identifiable risk factors, for example, weakness, unsteady gait, confusion, and the use of certain medications. Studies have shown the importance of these factors whose assessment can significantly reduce fall rates (1).
In the United States, about one-third of older people (65 years or older) living at home fall each year, and about half of them, will have an episode of future falls (2).
Although not all falls lead to complications, about 10% cause serious injuries that require medical care, sometimes with diagnostic investigations and specialist visits provided in emergency rooms or in the hospital through more or less lengthy hospitalizations. All this has negative repercussions on the quality of life and independence of these people. In addition, previous studies show that the risk of falling is directly related to age (2). Falls and related injuries are common in the elderly and are associated with significant economic costs that are borne by individuals, the community, and the health care system as a whole (3).
The increase in the elderly population with chronic diseases poses a greater challenge for the health care system in finding effective and feasible interventions to achieve a good quality of life for these people living at home (3). Due to the continuous increase in life expectancy in recent decades, the elderly population becomes increasingly at high risk for falls. Therefore, it is advisable to carry out an increasingly targeted fall risk assessment and put more attention on the planning and intervention steps in order to minimize the adverse event (2).

Important risk factors for falls in the elderly are impaired sense of balance and ambulation, multiple therapy, malnutrition, and a history of previous falls. Common consequences of falling are activity limitations, loss of mobility and independence, and fear of falling again (3).

More than 400 risk factors for falls have been identified. These risk factors are described and classified in various ways, including as modifiable (i.e., amenable to intervention) and nonmodifiable (i.e., unchangeable, such as age). Other classifications include intrinsic and extrinsic (environmental), behavioral, social and economic factors. Regardless of classification, it is important to note that for many people, the factors are complex and interconnected (4).

Factors within healthcare organizations can also increase the risk of falls, for example, problems associated with inconsistent assessment processes and interventions (5).

The nature of falls is complex, so its assessment is also complex. The optimal approach involves interdisciplinary collaboration in assessing and identifying and applying interventions, particularly assessment of exercise, coexisting medical conditions, and the environment in which the person lives (1).

Fall prevention interventions may include single component interventions (e.g., exercise) or multiple interventions of two or more types (e.g., exercise and medication review) (6, 7, 8). The various fall prevention interventions, whether single or multiple, in most cases are associated with fewer future falls (9). These interventions can be customizable to the individual person or standardized in the elderly population (10).

Many falls are predictable and preventable; however, some falls cannot be avoided; in these cases, the focus should be on proactive prevention by decreasing the frequency of falls. Fall prevention is a shared responsibility within the health care team (11).

Finds a distinct importance for fall prevention, education of the patient, caregiver, and social and health care personnel who care for the patient on a daily basis (12).

Despite fall prevention interventions, it is impossible to totally reduce this risk. In this case, optimal and correct recording of the event on special forms is of utmost importance, so that new assessments and subsequent more targeted interventions can be made for that person. Hence the need in care services to have a specific and validated fall detection card.

In recording falls, great dissimilarity often prevails among care services due to the different types of records used. The recording of falls and near-falls in the primary care setting, particularly during home care, is a practice that may not be as widespread as in other more institutional settings such as residences for the elderly and hospitals. This would result in a serious underestimation of the phenomenon, which could then be studied and prevented before it occurs resulting in access to the emergency department.

Therefore, the objectives of this paper are to review and update a falls report card already in use, making it understandable and decodable for operators, user-friendly and cross-border validated. Using unvalidated forms can lead to unfocused assessments and possible oversights, and as a result, subsequent planning and intervention would be incomplete or even incorrect. All this leads to negative consequences for the person as they would still be at high risk of falling.

From this, the importance of using a proper home falls detection form emerges, so that an individualized program can be created for the individual person, based on their deficits and comorbidities.

Objective

The objective of the study was to construct and validate a falls reporting form capable of detecting and describing falls and near-falls in the population living at home in cross-border territory (Italian and Swiss).

Materials and Methods

This is a delphi method validation study. Preliminarily, a retrospective study had been carried out on three years' data (2018-2020) regarding home falls collected by health care providers of a "spitex" (a general term used in the German language for home care and nursing, i.e., "out-of-hospital care") operating in the Locarno area of Canton Ticino. From the results of the study, it was found that the form currently in use for detecting falls at home had some critical issues (ex. incomplete data for the understanding of the falls phenomenon, dissimilarities in the compilation), in the face of a procedure already in place and widespread reporting of the incident by operators and service attention with respect to this issue. Starting from this tool, through the use of the Delphi method, a multidisciplinary working group was created that analyzed and modified the form on the basis of the evidence sought through a review of the literature and considerations emerging from the analysis of the previous dataset. The form was then blindly forwarded via e-mail to eight experts, four Swiss and four Italian professionals chosen on the basis of their respective multidisciplinary expertise, specialties and experience, to receive their initial individual evaluation.

With a 100% response rate, the form was then analyzed and modified by the working group based on the experts' opinions. It was then sent for a second round of evaluation, to which no further changes were made.

Description of the Multidisciplinary Working Group

The multidisciplinary Working Group (WG) was composed by uniting nine experts[1] with diverse educational backgrounds and expertise in the fields of nursing, education, research and organization.

Thus, the WG included:
- A Researcher
- A Health Director
- An expert in information systems
- One assistant health director, quality contact person
- A clinical nurse specialist in Geriatrics and Gerontology.
- A scientific collaborator of the Prevention Service
- A District Manager
- A university lecturer
- PhD student.

Description of the Panel of Expert Evaluators

The multidisciplinary panel of Expert Evaluators (EVs) was selected, similar to the WG, by including stakeholders and experts with proven expertise in the field.

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[1] The masculine was used to indicate the roles of various group members of each gender.

The EV group thus included eight evaluators, four from Italy and four from Switzerland, including:
- Two physical therapists
- An occupational therapist/ergotherapist
- A Geriatrician
- A nurse in charge of home care projects
- A statistician
- One ADI nursing coordinator
- A Family Nurse Practitioner.

Description of the instrument

The **original** home fall detection form (**Figure 1**), consisted of 7 main frames:
- *Operator panel*
- *User data framework*
- *Fall data framework*
- *Framework narrative description of the fall*
- *Framework outcomes of the fall*
- *Framework narrative description of the outcomes of the fall*
- *Post-fall detection framework, procedures and preventive measures.*

Figure 1- The original form

MODULO DI RILEVAZIONE CADUTE A DOMICILIO

Compilato il	Compilato da	Funzione

DATI UTENTE

Cognome_____ Nome_____ Data di Nascita_____
SESSO ☐ M ☐ F

Deambulazione antecedente la caduta	☐ Solo ☐ Con ausili ☐ Con l'aiuto di terzi
Stato di coscienza antecedente la caduta	☐ Orientato ☐ Disorientato

Terapia Farmacologica in atto	☐ Diuretici ☐ Antiparkinsoniani ☐ Neurolettici
	☐ Ansiolitici ☐ Antipertensivi/vasodilatatori ☐ Lassativi
	☐ Antidolorifici ☐ Antidepressivi ☐ Ipnotici
	☐ Anticoagulanti ☐ Altro _____

DATI CADUTA

Data della caduta_____Ora_____

Tempo di permanenza a terra_____

Luogo	☐ Camera ☐ Bagno ☐ Corridoio ☐ Cucina ☐ Soggiorno ☐ Sala ☐ Giardino ☐ Cantina ☐ Altro _____
Testimoni	☐ No ☐ Si, quali _____
Attività svolta durante la caduta	☐ Alzarsi/sedersi ☐ Deambulazione con/senza ausilio ☐ Coricarsi ☐ Girarsi ☐ Piegarsi ☐ Eseguire transfert ☐ Altro _____
Tipo di caduta	☐ Scivolato ☐ Inciampato ☐ Capogiro/svenimento ☐ Perdita di equilibrio ☐ Spinto da terzi ☐ Non ricorda ☐ Altro _____
Direzione della caduta	☐ Avanti ☐ Indietro ☐ Di lato ☐ Non rilevabile
Impatto	☐ Pavimento ☐ Parete ☐ Sanitari ☐ Mobilio ☐ Altro _____

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Descrizione:	
Causa della caduta	☐ Inciampo/collisione ☐ Cambio improvviso di direzione ☐ Malore ☐ Perdita di coscienza ☐ Rottura ausilio ☐ Perdita di forza ☐ Movimenti troppo rapidi ☐ Mancata richiesta di aiuto ☐ Abbigliamento/calzature ☐ Errata valutazione della distanza ☐ Uso inadeguato degli ausili (specificare): _____ ☐ Inadeguatezza ausili (specificare): _____ ☐ Fattori ambientali (specificare): _____ ☐ Altro _____

Esiti della caduta	☐ Nessuna lesione evidente ☐ Contusioni ☐ Ferite ☐ Trauma cranico ☐ Fratture (anche sospette) ☐ Dolori, sede _____
Descrizione esiti	

Deambulazione post caduta	☐ Solo ☐ Con ausili ☐ Con l'aiuto di terzi
Stato di coscienza post caduta	☐ Orientato ☐ Disorientato

PROCEDURE MESSE IN ATTO	☐ Informato i parenti, quali _____ ☐ Informato medico Dr. _____ ☐ Altro _____
MISURE PREVENTIVE PREVISTE	

Overall, most of the questions were closed-ended.

There was a field related to the data of the person filling out the form and one related to the data of the user. Then it was possible to investigate the different items pertaining to the specific and technical characteristics of the user, the fall, and the outcomes about it.

The first assessment (**Figure 1**) investigated:

      - the "pre-fall gait"

- the "state of consciousness prior to the fall"
- the "drug therapy in place."

After these data, "fall data" were collected, investigating:
- date, time of the fall and the time on the ground
- the "location" of the fall
- whether "witnesses" had been present and which witnesses
- "the activity performed during the fall"
- the "type of the fall"
- the "direction of the fall"
- "the impact" of the fall (e.g., floor", "wall", etc.)
- the narrative "description" of the fall
- the "cause of the fall" (e.g., "tripping/collision," "sudden change of direction," "clothing/footwear")
- the "outcomes of the fall" (e.g., "bruises," "injuries," "fractures")
- a narrative description of the outcomes
- the "post-fall ambulation" (e.g., "alone" or "with aids")
- the "post-fall state of consciousness"
- the "procedures put in place" (e.g., "informed the doctor")
- the "preventive measures planned."

See the **Figure 1** for more details.

Description of the phases of the study

The study was conducted in five phases (**Figure 2**) and four times as follows:
- T0 or preparatory phase: retrospective data analysis and literature review
- Phase T1: proposed changes by the WG.
- Phase T2: first round of EV evaluation
- Phase T3: changes by the WG.
- Phase T4: Second round of EV evaluation and validation.

Figure 2- Study phases

Fasi dello studio

T0	T1	T2	T3	T4

- Analisi di dati retrospettivi di cadute a domicilio
- Analisi della scheda originaria di reporting delle cadute
- Revisione di letteratura
- Costituzione del GdL
- GdL: prima modifica della scheda originaria di reporting delle cadute
- Costituzione del panel EV
- Invio al panel EV
- GdL: raccolta e sintesi delle modifiche suggerite
- GdL: seconda modifica della scheda originaria di reporting delle cadute
- Invio al panel EV
- GdL: raccolta esiti
- Approvazione finale

Results

The original board was evaluated by a multidisciplinary working group, and following an evaluation of the evidence through a literature review, initial changes were made to the board. The changes made to the form fall within three conceptual levels:

- At the first level, changes were made regarding the technical and scientific content of the module through consultation with experts on the subject of falls.
- The second level involved identifying operating instructions to guide the computerized implementation of the module in order to create a correct and functional dataset.
- In the third level, complementing and supplementing the previous two, methodological notes for statistical and research purposes are described.

Modifications of the original tool

Operator panel

The compilation date was introduced in the format DD/MM/YYYYY by forcing the operator's response to this one format.

In the "compiled by" field, the possibility of introducing only one name of compiler, i.e., the one who makes the report and is responsible for it, has been restricted. In the "operator function" field, the professional function of the person who reports the fall by filling in the form is specified. Therefore, only one function was left to be reported, limiting the choice to a few professional categories (e.g., nurse, OSS, caregiver, etc.). Regarding falls possibly recorded by students/students, only the qualification of the professional responsible for reporting is always reported, and even in the case of reports of falls made by more than one figure (e.g., OSS + Nurse), the field reports only one qualification namely that of the person making the recording/reporting.

User data framework

In the "user data" section, the term "sex" has been replaced with "gender."

A new "previous falls" section was introduced, with two dichotomous closed-ended "yes" or "no" questions. They are, "Has the user fallen before?", "Has the user ever been in danger of falling in the last month (near-fall)?"

Another new item is introduced: "eyesight" through a question, "Do you use glasses or contact lenses?" answered with "yes" or "no."

Whether the fall was caused by "environmental factors" is assessed, answered with "yes" or "no," and in the case of a positive answer, the cause is assessed: "lighting," "obstacles," "stairs," or "uneven floors." Answers related to "pre-fall walking" are replaced with: "autonomous," "occasionally with aids/third-party help," "always with aids/third-party help."

The part about "current drug therapy investigates "how many drugs the user habitually takes" by removing some drug categories, i.e., leaving only: "diuretics," "antihypertensives/vasodilators," "anxiolytics," "hypnotics," "painkillers," "laxatives," "antidepressants," and "antiparkinsonian drugs."

Fall data framework

The section on "fall data" has also been modified: this section has items for the person filling out the form, such as knowing the "date of the fall," "the time," with three possible answers: "morning (6-12)," "afternoon (12-20)" or "night (20-6)" and the " time on the ground" with answer "no time on the ground-a few seconds," "a few minutes," "more than half an hour- up to an hour," or "more than an hour (even more than one hour)."

"Fall location" responses were changed, leaving only: "bedroom," "bathroom," "kitchen," "living room/living room," "passage areas," or "outdoor places."

Closed answers were introduced in the case of a positive answer to the question of whether "witnesses" were present during the fall event, specifying: "home help staff-carers," "family member," or "outside person."

The item "Who reports the fall?" was added: "assisted person" or "witness." In the question "type of fall," the response "pushed by third party" and "does not remember" was removed, and "undetectable" was added next to "does not remember."

The item of "direction of fall" has been removed and the word "wall" has been replaced with the word "wall" in the item concerning "impact." The item "cause of the fall" and the resulting closed responses is completely removed as it is considered redundant.

Framework narrative description of the fall

The field requires describing the dynamics of the fall in a narrative manner. This response field is mandatory, involves free text entry, and has not been modified by experts, i.e., it has been confirmed.

Framework outcomes of the fall

In "fall outcomes" next to the word "bruises," "hematomas" is added.

A new aspect is investigated, concerning "fear of falling" by dichotomous "yes" or "no" response.

Framework narrative description of the outcomes of the fall

In accordance with the field "Narrative description of the fall," this box has not been changed by the experts, i.e., it has been confirmed.

Post-fall detection framework, procedures and preventive measures

Responses regarding "post-fall ambulation" are changed to: "independent," "temporarily with aids/third-party help," and "permanent with aids/third-party help."

Responses to "procedures put in place" are also replaced with, "notified doctor and a family member" or "notified others."

"Planned preventive measures," from open-ended question, becomes multiple-choice with the following possible answers: "Environmental modification interventions," "physical therapist, rehabilitation, exercise," "Pharmacological review," "Teleallarm, technological devices," "interview, education, instruction," "other interventions" the latter to be specified.

First round of evaluation

At this point the new version of the board was sent to the experts in the first round, who proposed the following changes:
- In the "previous falls" section, the following phrase was added to the question "Has the user fallen before?": "in the past 12 months."
- To the next question, "Has the user ever been at risk of falling in the past month (near-fall)?" the following questions were added: "Does the user perceive insecurity while standing or walking?", "Is the user able to get up by himself?"
- In the "eyesight" section, after the question "Do you use glasses or contact lenses?" a sub-question was added, "If yes, were you wearing them at the time of the fall?", also answered with a dichotomous "yes" or "no."

The part regarding the responses of "environmental factors," are changed with additions: "poor or inadequate Lighting," "obstacles (furniture, carpets, etc.)," "stairs," or "uneven and/or wet floors or other barriers (e.g., bathtub)." Responses of "pre-fall ambulation" are changed to the following assessments: "independent," "occasionally independent with aids/third-party aids," in which case it is sought whether "used them at the time of the fall?" by dichotomous answer "yes" or "no," "always dependent with aids/third-party aids," and whether "used them at the time of the fall?" by answering "yes" or "no," "not ambulatory."

The item "state of consciousness before the fall" is replaced with "space-time orientation," the answers remain the same. It is added whether or not cognitive impairment is present?" answering "yes" or "no." An assessment of "nutritional status" is added with two possible answers: "correct" or "has nutritional deficiencies." In the "witnesses" section, the name "caregivers" is moved to the "family member" response. The item "activity performed during the fall" is replaced with "motor functions," the possible answers remain the same. Responses related to "activity performed during the fall" are replaced by indicating only one of the following responses: "B/ADL," "I/ADL," "leisure activities." Answers related to "post-fall ambulation" are replaced with: "independent," "occasionally independent with aids/third-party help," "always dependent with aids/third-party help," or "not ambulatory (bedridden, etc.)." "Post-fall state of consciousness" is replaced with "space-time orientation," responses remain unchanged. A new item is added, "were there any premonitory signs?" with "yes" or "no"

response. In the section "planned preventive measures," the response "physiotherapist, rehabilitation, exercise" is replaced with "Activation of specialized rehabilitation pathway (Physiotherapy / Ergotherapy)."

Second round of evaluation
Subsequently, the revised form was again emailed to the experts for the second round of blind evaluation.

At this stage, only the addition of the category "beta-blockers" was proposed in the "current drug therapy" section, but this proposal was not accepted.

After this last step, having obtained 100% consensus among experts, the form was validated as a specific and accurate tool for investigating falls at home.

There was a good degree of agreement among the experts in the study, and the new form is found to be useful in implementing a new system for detecting falls at home, particularly related to the fall and near-fall event.

The final version of the card is shown in **Figure 3**.

Figure 3- Final template

MODULO DI RILEVAZIONE CADUTE A DOMICILIO		
Compilato il *(GG/MM/AAAA)*	**Compilato da** *(un solo operatore)*	**Funzione operatore**

DATI UTENTE

Cognome_____ Nome_____
Data di Nascita *(GG/MM/AAAA)* _____ GENERE ☐ **F**   ☐ **M**

Precedenti cadute L'utente è già caduto in precedenza? (negli ultimi 12 mesi) L'utente ha mai rischiato di cadere nell'ultimo mese (quasi-caduta)? L'utente percepisce insicurezza in piedi o camminando? L'utente è in grado di rialzarsi da solo?	SI/ NO SI/NO SI/NO SI/NO
Vista Utilizza occhiali o lenti a contatto? Se si, li indossava al momento della caduta?	SI/NO SI/NO
Fattori ambientali Se sì, quali?	SI/NO
	Illuminazione scarsa o inadeguata ostacoli (mobili, tappeti, ecc.) scale pavimenti irregolari e/o bagnati o altre barriere (es. vasca da bagno)

Deambulazione antecedente la caduta	indipendente
	occasionalmente indipendente con ausili/aiuto terzi- li utilizzava al momento della caduta?
	    o SI/NO
	sempre dipendente con ausili/aiuto terzi- li utilizzava al momento della caduta?
	    o SI/NO
	non deambulante

Orientamento spazio-tempo	☐ Orientato ☐ Disorientato
E' presente un deterioramento cognitivo?	SI/NO

Terapia Farmacologica in atto Quanti farmaci assume abitualmente l'utente?	_____ *(numero farmaci)*
Quali tipi di farmaci assume il paziente?"	diuretici antipertensivi/vasodilatatori ansiolitici ansiolitici, ipnotici, antidolorifici lassativi antidepressivi antiparkinsoniani
Stato nutrizionale	corretta presenta carenze alimentari

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DATI CADUTA

Data della caduta *(GG/MM/AAAA)* _____	
Orario caduta	mattino (6-12) pomeriggio (12-20) notte (20-6)
Tempo di permanenza a terra	nessun tempo a terra- pochi secondi pochi minuti più di mezz'ora- fino a un'ora più di un'ora (anche più ore)

Luogo della caduta	camera da letto bagno cucina soggiorno/sala zone di passaggio luoghi esterni
Testimoni	☐ No ☐ Si, quali personale aiuto domiciliare familiare- badanti persona esterna
Chi riferisce la caduta?	persona assistita testimone
Funzioni motorie	deambulare alzarsi/sedersi, coricarsi, transfert girarsi piegarsi altro
Attività svolta durante la caduta (indicare una sola risposta)	B/ADL I/ADL Attività di tempo libero
Tipo di caduta	perdita equilibrio inciampo scivolamento capogiro/svenimento mancanza forze, perdita di forze negli arti inferiori, cedimento altro non ricorda, non rilevabile
Impatto	pavimento mobili muro sanitari altro

Descrizione:

Esiti della caduta	☐ Nessuna lesione evidente 　　Contusioni/ematomi ☐ Ferite　　　☐ Trauma cranico ☐ Fratture (anche sospette)　　☐ Dolori, sede _____
Paura di cadere	SI/ NO
Descrizione esiti	

Deambulazione post caduta	indipendente occasionalmente indipendente con ausili/aiuto terzi sempre dipendente con ausili/aiuto terzi non deambulante (allettato, ecc.)
Orientamento spazio-tempo	☐ Orientato　　　☐ Disorientato
Ci sono stati segni premonitori?	SI NO

PROCEDURE MESSE IN ATTO	Avvisato medico e un familiare Avvisati altri
MISURE PREVENTIVE PREVISTE 　　Interventi modifica ambientale 　　Attivazione di percorso riabilitativo specialistico (Fisioterapia / Ergoterapia) 　　Revisione farmacologica 　　Teleallarm, dispositivi tecnologici 　　colloquio, educazione, istruzioni 　　altri interventi *(specificare)* _____	

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Discussion

The purpose of this study was to create and validate an applicable falls and near-falls reporting tool in the home resident population in cross-border territory.

Date fields

All dates entered in the form have been standardized to the DD/MM/YYYYY format, forcing operators to use a single date mode that can then flow uniformly into a dataset. This is also because sometimes the date entered may refer to the date of compilation but not necessarily coincide with the date of the fall, and, especially in cases where operators find themselves using the paper format, subsequent transcription of this data may be the cause of errors or discrepancies.

Drug therapy

During the creation of this card, the section on drug therapy provoked discussion among experts. While we believe it is very important to have information on the medications taken by the patient, recording this data is difficult to apply with a card of this type, given the infinite variety of molecules available and the equal possibility of therapeutic combinations. In any case, the information can be deduced from patients' medical records. However, it might be interesting to create a system that is able to automatically record drug intakes in order to cross-reference them with fall episodes. The topic of drug therapy is very multifaceted, and the solution adopted about the inclusion of drug categories was based on data from the literature and the practicality of reporting (nurses and other caregivers). If necessary, data can be cross-referenced with the therapy record (detail of prescriptions), in case a particular correlation phenomenon is to be studied. A few experts had requested the introduction of antiepileptics, natural sleeping pills, insulin, anticancer medicines, and beta blockers. The first four were not included because they were forking and/or had little clinical correlation; the pharmacological category of beta blockers was denied because they were already included among antihypertensives.

The role of the practitioner's clinical reasoning

Within the "Narrative Description of the Fall" frame, the fill-in operator is asked to describe the dynamics of the fall narratively through free text. In this case, it is necessary to report in a concise and direct manner the events that occurred, providing only the details considered relevant to understanding the dynamics of the fall, the risk factors, and anything that might be useful for taking personalized fall prevention actions.

Similarly, the "Description of Fall Outcomes" framework requires the inclusion of a brief description of the consequences of the fall and the implications on the user's personal, family and social life.

In both cases, the presence of free-text fields, and thus the absence of standardization of possible answers, induces the practitioner to have to select through his or her own clinical judgment the information to be entered, filtering those considered essential and important, from those that are incidental or secondary.

Implications for practice

The validated card can be used in care practice for reporting falls and near-falls in the home resident population, both to document the phenomenon and to guide and modify care practice as well as preventive interventions implemented. The form lends itself to computerization and integration with information systems in use, with the opportunity to create ad hoc applications for computerized management of data compilation and recording. Care staff must be trained in the proper use of the form as well as in the basics of fall prevention and risk factor modification. The advantage offered by free text inclusion is maximum flexibility and customization of descriptions; however, this could also result in the loss of some potentially useful information. There is therefore a need to balance synthesis with analysis, and this aspect could be governed through staff training sessions. Orientatively, the outline for descriptions should answer these five questions (5 W rule): who? (who?), what? (what?), when? (when?), where? (where?), why? (why?). Taking into account the answers entered in the overall compilation of the form, free-text fields provide an additional opportunity to enter data deemed important that have not already been documented elsewhere.

Implications for research

Further studies are needed to better investigate the level of effectiveness completeness of the indices reported in the final form, as well as studies assessing the impact of the reporting form on practice, organization, and health outcomes. The form thus defined was designed for use in the local area, however, its implementation in other settings should not be ruled out.

Limits

The present study was conducted on the basis of literature evidence and the opinion of a group of international experts in order to provide the best possible guidance about falls reporting, however, the indices and domains included in the final validated form may not be exhaustively descriptive of the falls and near-falls phenomenon.

Conclusions

With this study, a falls and near-falls reporting form was created and validated for the home care resident population. After this phase, it was possible to train the various professionals working in home care and nursing services in Canton Ticino and at ASL Novara in the use of the card. The future perspective is the creation of a cross-border dataset for the study of falls and related preventive interventions. The creation of an app or adaptation of current information systems can also be envisioned.

Through the implementation of this card in care practice, it is possible to guide practice and create a personalized program for the individual person, based on his or her deficits and comorbidities, to prevent or decrease fall recurrence. The data collected with this card allow for the creation of a dataset describing the critical points in the everyday life of the person who has fallen or nearly fallen so that care can be supported by orienting it to prevention and the implementation of targeted and personalized interventions to avoid future events.

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CHAPTER 12

General discussion

The journey thus far has shown how necessary and essential it is to (a) study new organizational and care models for the elderly and (b) implement the best scientific evidence in practice. This concerns all possible care settings, from hospital to home care. Addressing frailty, disability, and chronicity is only possible through the development of care processes that integrate the clinical with the care, social, and psychosocial spheres.

The prevention of falls is a topic yet to be explored; many more evidence-based interventions need to be implemented and studied. The involvement of government departments, as well as voluntary and third-sector associations, should be fostered so that effective and transferable interventions are also able to be sustained over time and separated from the direct intervention of health professionals. This could be the result of shared policies at the community level, from a network perspective in which a true culture of prevention has developed over time. The community is a valuable resource, and each individual can contribute to community building. Increasing population health literacy is certainly a priority, as is measuring the impact and outcomes of the new models implemented. In this sense, health outcomes are central to the evaluation of care processes.

Ethical considerations

The nursing profession has undergone profound changes over the years in terms of activities, responsibilities, and professional autonomy. The transformations that have taken place over time have led to the renewal of educational paths and organizational and professional models. In addition, the changes that have occurred in the legal field through the enactment of a series of laws that have framed the professional figure in a general way and they have specified the areas of nursing activity. The Code of Ethics represents the ethical part of the professional identity (1, 2), and the ethical core of the nursing profession hinges on the nurse's relationship with the person being cared for.

In recent years, there has also been a profound change in the sociocultural context in which health professionals work. Important and rapid technological innovations have prompted practitioners to reexamine their behaviors with the aim of developing more evidence-based behaviors. Responding to health demands requires an increase in financial and non-financial resources, with consequent difficulties in being able to guarantee equity in resource allocation. The health care setting is openly "secular and pluralistic," and stakeholders (caregivers, family members, physicians, nurses, and other professionals) may have different moral views, all of which are worthy of respect. Caregivers increasingly demand greater protection in the defense of their fundamental rights, which include the right to information, to decision-making about

their health status, to confidentiality, to protection of personal data, and to continuity of care between hospital and home care (3).

Bioethics, which can be defined as "the systematic study of human behavior in the life sciences and health care, as such behavior is examined in the light of moral values and principles" (4), provides a method for finding answers to the new problems arising from the relationship between the caregiver and the patient in a social-health context. This relationship has become complex and can no longer be governed by self-referral but requires first and foremost the recognition of the centrality of the person being cared for and the needs of this person, as well as the opinions held and *ideas of the good* maintained by this person.

The daily practice of health care and patient care obliges nurses, physicians, and all social and health care personnel to make decisions in which personal values, the principles contained in the constitutional charter, norms and codes of ethics, and the preferences of the patients themselves come into play (5). In light of the new technologies available, it is good to listen to the patient in order to (a) understand his or her preferences and (b) possibly even propose actions to support digital literacy (3). In fact, health care personnel should take into account patient's preferences and involve caregivers. Preventing falls through exercise, the modification of the home environment, and the use of new technologies and other types of interventions can only be successful if the feelings of the person being cared for are taken into account, while respecting his or her privacy and aspects related to the principle of self-determination.

Therefore, in care practice, it is important that there be a true and good therapeutic alliance between professionals and patients (e.g. patient engagement), who are then the real protagonists of their own health. Involving families, and caregivers in general, adds indispensable value to this alliance (3).

Future developments

Caring for people is a complex activity that involves the collective action of several professions. Interprofessional collaboration, which involves health professionals acting together to achieve common goals in caring for and supporting patients, has been the subject of numerous studies that highlight its positive effects in terms of quality of care, adherence to guidelines, patient satisfaction, and reduction of errors in health care (6). Future research work will be needed to further investigate the impact of new organizational models and best practices in terms of preventing falls. With respect to the models presented in this paper, further studies will also be needed to investigate the impact on the health, organizational, and satisfaction outcomes of patients, caregivers, and health care personnel.

It is also important to study new strategies to foster work in multi-professional teams. Barriers to interprofessional collaboration include misunderstanding (a) each other's professional terms of reference, and (b) the potential of teamwork. It is also important to investigate new strategies to encourage work in multi-professional teams and foster communication among various health care professionals (e.g. nurses, medical doctors, physiotherapists, psychologists, social workers, etc.). One such strategy could be to adopt joint training programs, such as mentioned above. The literature highlights that the education of future health professionals must increasingly take place in an interprofessional education setting: "a setting in which two or more students from different professions learn from each other or with each other or even learn about each other's professional specifics and scope of autonomy and responsibility" (7).

Organizational models that foster interdisciplinarity (e.g. ACE model, primary nursing, intentional rounding, family and community nursing) are thus the future on which to base health care organizations.

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Conclusion

The scientific rationale that guided this path was based on a thorough understanding of the issues related to the aging population and the demographic and social changes that have occurred in recent years. Additionally, in the wake of the pandemic, it was necessary to focus on new organizational models and preventive interventions.

Research has long shown that many therapeutic treatments (e.g., for osteoporosis) prove ineffective or achieve less satisfactory results if they are not accompanied by supportive care interventions. In some population groups, this effect seems to be particularly important. In people with neurodegenerative diseases, such as Parkinson's disease, interventions to support drug therapies, such as exercise and home environmental risk reduction, appear to be critical to ensuring a better quality of life. These aspects can be equally applied to elderly people living at home alone, who may be more or less affected by chronic diseases. In this sense, the use of wearable technology devices could be an even greater innovative resource to support best clinical and care practices. New models of territorial governance should therefore include technology as a tool available to support interventions, while best practices should also be widely implemented and supported at the policy level for better management of healthcare spending and greater appropriateness in the choice of care settings for personal care.

Advanced management models for the health of the elderly population and the implementation of evidence-based clinical and care practices were studied during this research track. Particular emphasis was placed on fall prevention because falls are considered a nursing-sensitive outcome. Thus, they could be considered an outcome of interest for both the evaluation of organizational models and the implementation of best practices.

Although some studies are still ongoing and some issues require further study, this report summarizes the research that has been conducted to date.

APPENDICES

APPENDICES CHAPTER 4

Table A- Attribution of percentages to the causes of the problem

Area	Description	Weight/percentage	% cumulative
A	Organizational model in use	12%	12
	Inefficient distribution of economic resources	2%	14
	Long hospital stay times	3%	17
	Diagnostic therapeutic setting of acute cases	9%	26
B	Resistance to change by staff	7%	33
	Poor information/training in patient pathway management	6%	39
	Poor social case management skills	4%	43
C	Absence of direct protocols for admission of the elderly person	3%	46
D	Multipathological and elderly population	32%	78
	Structural causes	22%	100
Total		**100**	**100**

Table B- Stakeholder engagement evaluation matrix

Stakeholders	Unconscious	Resistant	Neutral	Favorable	Guide
Corporate Management					CD
Geriatrics				CD	
Neighboring Hospitals	C				
Neighboring public/private facilities	C				
Staff		C	C	CD	
ASL/Territory	C				
Patients/citizens	C				
Project Management Group					CD

Legend:
C indicates current involvement;
D indicates the desired involvement.

Figure 1- Stakeholder importance matrix

		Stakeholder importance			
		Level of importance unknown	Little or no importance	Some importance	Significant importance
Stakeholder influence	Significant influence	C		A	
	Some influence				
	Little or no influence	D		B	
	Level of influence unknown				

Table C- Stakeholder influence matrix

Stakeholders	A	B	C	D
Corporate Management	x			
Geriatrics	x			
Neighboring Hospitals				x
Neighboring public/private facilities				x
Staff		x		
ASL/Territory			x	
Patients/citizens				x
Project Management Group	x			

Figure 2a- Floor plan of the facility

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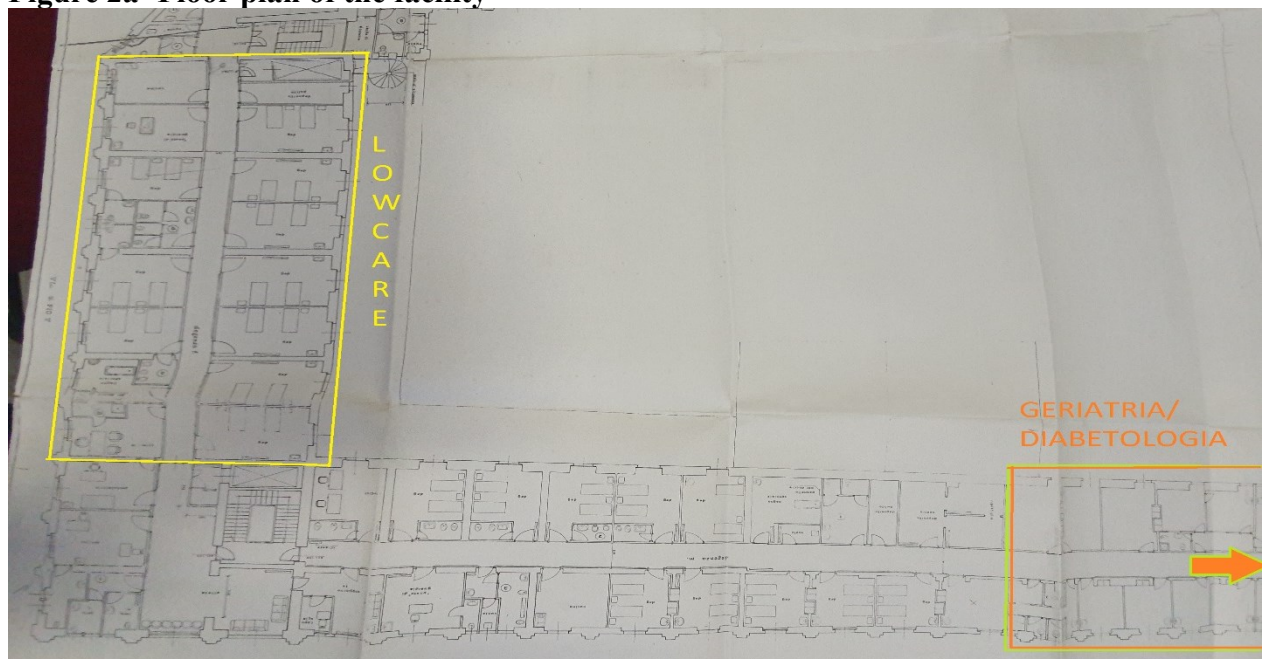
Paragraph 1. Analysis of proposed solutions

All resources were calculated based on the expected volume of services, balancing standards to resources and the Italian context. For a detailed description, please refer to the economic budget explained in Paragraph 2.

To carry out the feasibility analysis (**Table D**), 4 levels of judgment were considered: economic, managerial, strategic, and managerial. All were weighted on three criteria: urgency (in terms of time), importance (to the citizen and caregivers), and criticality (how crucial it is to the company); each criterion was given a score from 1 to 10.

The calculation of feasibility is obtained by the following formula: (urgency score* importance score* criticality score)/ No. 5 voters.

By averaging these scores, a value emerged that represents the feasibility of the proposals.

Table D- Organizational Proposal for Implementation of ACE Unit

A. STRUCTURAL ASPECTS (adequacy of premises, structural and technological requirements)

	ECONOMIC	*MANAGEMENT*	*STRATEGIC*	*MANAGERIAL*
URGENCY	9	8	9	9
IMPORTANCE	8	4	2	6
CRITICALITY.	10	9	9	10
FEASIBILITY.	144	57,6	32,4	108
Average total project feasibility: 85,5				

B. ORGANIZATIONAL ASPECTS (human resources, processes, productivity)

	ECONOMIC	*MANAGEMENT*	*STRATEGIC*	*MANAGERIAL*
URGENCY	6	7	8	9
IMPORTANCE	6	6	5	7
CRITICALITY.	6	7	8	8
FEASIBILITY.	43,2	58,8	64	100,8
Average total project feasibility: 66,7				

The feasibility obtained is high overall because the identified proposals are both strategic for the implementation of the Unit under study.

Applying the Eisenhower matrix (**Table E**) and in consideration of feasibility, the most important and urgent actions to be implemented are identified.

The weighted trade-off on criteria of criticality, importance and urgency was not reported in the matrix, although from the assessment carried out, the proposed implementation of the ACE Unit is nevertheless confirmed.

Table E- Eisenhower matrix

Important	Urgent (to be done immediately)	Not urgent (to be done at a later date)
	Application for permits and start of work Adjustment of structural requirements	Staff recruitment Staff training Creation of admission criteria
Not important	**To be delegated**	**To be postponed**
	Review/drafting of protocols Communication plan	Project evaluation Creating work plans

Figure 3- Diagram representation of OBS
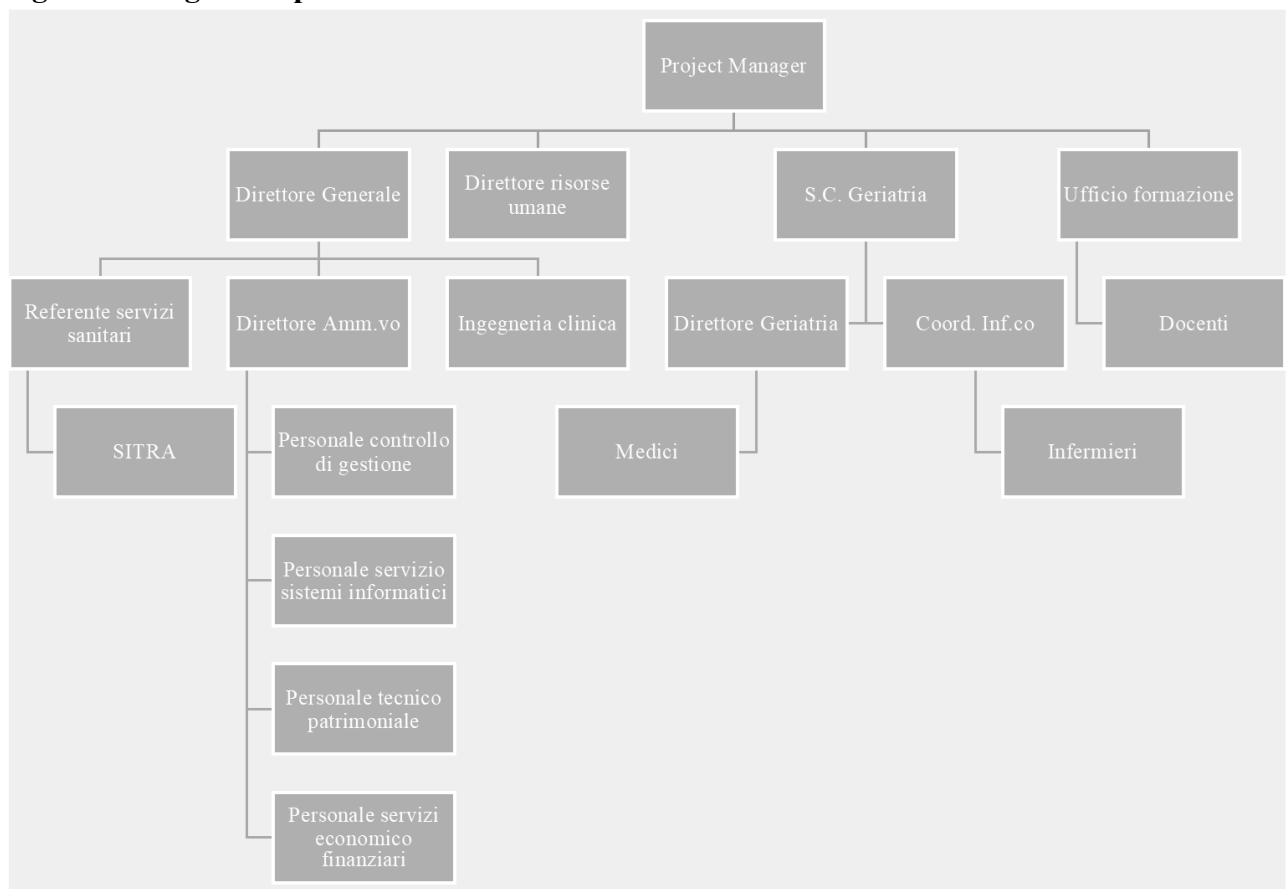
Table F- RAM

WBS Element \ OBS Element	PROJECT MANAGER	STRATEGIC SUMMIT*	DIPSA	TEAM SOFTWARE ENGINEERS	HUMAN RESOURCES.	DIRECTOR OF GERIATRICS	MEDICAL EQUIPMENT.	COORD. INF.CO	CPSI	CLINICAL ENGINEERING	IRFI	TEACHERS
1. AUTHORIZATION AND DELIBERATIVE ASPECTS												
1.1 Resolution to open ACE Unit, assets and personnel	V	A	E	V	V	V	V	V	V	V	V	
1.2 Resolution for local restructuring, information system, technology and communication	V	A	E	V	V	V		V		V		
1.3 Internal mobility notices and competitions	V	A	E		V	V	V	V	V			
1.4 Place profile creation	SV	A	E		V	S		S				
2. COST CENTER												
2.1 Economic and financial management	V	A	E		V	SV		V				
3. RESOURCE ALLOCATION												
3.1 Bursar's office materials procurement/acquisition of goods and services	V	A	E			V	A	V				
3.2 Restructuring	SV	A	E			V	V	SV				
3.3 Warehouse	V	A	V	E		V	V	S				
3.4 Information system	SV	A	V			V	V	E				
4. CLINICAL ENGINEERING												
4.1 Drafting technical specifications	V	A	V			V				E		
4.2 Drafting of special contract specifications.	V	A	V			V				E		
4.3 Drafting tender specifications for new equipment procurement	V	A	V			V				E		

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Activity												
4.4 Purchase of new equipment	V	A	V			SV		V		E		
4.5 Delivery and testing	V	SV	A			SV		V		E		
5. HUMAN RESOURCES.												
5.1 Recruiting	V	A	SV	E	V		S				V	
5.2 Allocation of personnel	SV	A	V	E	V	V	V	V			V	
6. TRAINING												
6.1 Creating training courses	SV		A		S		S				E	E
6.2 Define teachers	S				V		V				E	V
6.3 Delivering training	V		A		V	V	V	V				E
7. INFORMATION SYSTEM AND COMMUNICATION												
7.1 Information system	V	SV	A	E	V	S	V					
7.2 Intake and inpatient process	S	V	SV	V	SV	E	SV	V				
7.3 Creation of the computerized medical record	SV	A	SV	E	SV	S	SV	S				
8. QUALITY SYSTEM												
8.1 Facility Accreditation	V	SV	A		V	S	V	V				
8.2 ISO Certification	V	A	SV		V	E	V	V				
8.3 Quality standards and checklist creation	V	V	A		V	V	V	V				
8.4 Indicator system	SV	V	A		V	V	V	V				

Paragraph 2. Economic estimate

The implementation of the economic budget is carried out schematically divided into 5 macro areas of expenditure. The figures given are purely descriptive and indicative of the expenditure assumption for the implementation of the project. A more accurate and real evaluation can be carried out only in the presence of the cost estimates provided by the contractors.

- **PLANNING**, **COORDINATION** and **SECRETARIAT** (cost item may not exceed 15% of total cost) **(A)**

DESCRIPTION	UNIT OF COST	TOTAL
Nursing executive personnel to carry out the call for applications	€ hour x tot hours	€ *omissis*
Administrative staff (documentation preparation, computer data processing, ...)	€ *omissis*	€ *omissis*
External consultant	€/hr *omissis*	€ *omissis*

- **STAFF (B)**

QUALIFY	ENTITY OF AFFILIATION	OCCUPATION PERFORMED	HOURLY COST.
Geriatricians			
C.P.S.S. (Experienced health professional collaborator) with master's degree in coordination	Geriatrics Coordinator	Personnel management, work organization, research, training	€ (monthly salary €) *omissis*
C.P.S.I. (Collaborating professional health nurse)		Nursing care manager, research, education	€ (monthly salary €) *omissis*
OSS			€ (monthly salary €) *omissis*
Administrative staff		Administrative part management	€ (monthly salary €) *omissis*

- **FURNITURE, EQUIPMENT (C)**

DESCRIPTION	UNIT OF COST	TOTAL
Inpatient unit furniture (beds, chairs, armchairs, bedside tables, cabinets)	Already present in the structure	*Omissis*
Furnishing service spaces Furnishing common areas (living room patients) Computer equipment (computers, printers, copier, etc.).		*Omissis* *Omissis* *omissis*

- **RENOVATION OF PREMISES, OPERATING EXPENSES (D)**

DESCRIPTION	UNIT OF COST	TOTAL
Studio/room	Already present in the structure	0 € (any additional maintenance costs)
Adjustment of facilities (air conditioning, medical gas facilities, electrical system, etc.).		*Omissis*
Adjustment of premises Toilet and utility room renovation		*Omissis* *Omissis*
Painting		*Omissis*
Miscellaneous supplies (electricity, heating, water, telephone, ...)	Already present	0 € (any additional maintenance costs)

- **MISCELLANEOUS (JOB GRANTS, ETC.) (E)**

DESCRIPTION	UNIT OF COST	TOTAL
Company does not allocate additional resources	*Omissis*	€ *Omissis*

TOTAL COST A € + **B** € per year (C.P.S.I. + administrative: total € monthly) + **C** € + **D** € + **E** 0 € = **€** per year.

Costs related to organizational processes (training and protocols) were not included as isorresources.

Relationships between estimated and expected costs

The accuracy of the project cost estimate should be based on the probable cost i.e., the cost of the activity, based on a realistic assessment of the effort for the work required and any expenses required; inconsideration of this, it is necessary to compare the expected results of the project and the made cost estimate (total value). With the implementation of an ACE Unit (taking into account cost estimates and contigency reserves) the actual costs would be amortized, as the reduction in the number of inappropriate admissions positively impacts the economic as well as the clinical aspect. In order to compare expected results and estimated costs, we will be able to make use of the construction of the project cost baseline broken down by time steps net of any management reserves, which can be changed only through formal change control procedures. **Table G** shows the components of the total budget and the estimated costs, broken down into the different time phases. The budget defined as an estimate, will later have to be redistributed according to the cost estimates of the companies that won the tenders.

Table G- Project budget components

Total amount	Project budget 100%	Management reserve 15%.			
		Cost baseline 85%	Reserve for contingency 10%		
			Estimated cost of Work Packages 75%	Renovation	
				Supplies	
				Staff	
				Training	

In view of the estimates made, the total estimated costs amount to:
- Estimated cost of activities: *omissis* €;
- Asset contingency reserve: *omissis* €:
- Estimated cost of the Work Packages: *omissis* €;
- Management reserve: *omissis* €;
- Cost baseline: *omissis* €;
- Project budget: *omissis* €.

Costs are expected to be amortized over the 5-year period following project implementation in terms of productivity, waste reduction and redefinition of organizational processes.

APPENDICES CHAPTER 5

Figure A - ASST Nord Milano territorial social-health network
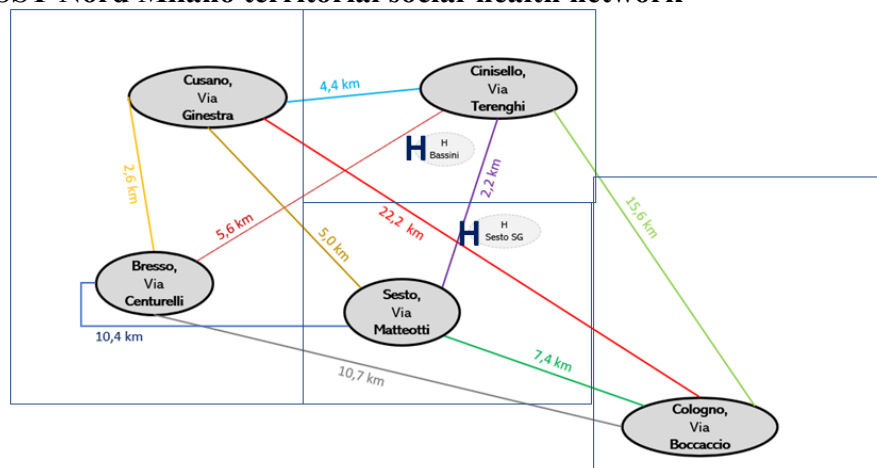
Table 1 - project organizational structure

Phases	Activities	Units involved	Responsible
1. Reorganization of activities at PO	1.A- Reorganization of care by levels of intensity of care (low intensity, medium intensity, high intensity)		
	1.B- Introduction of innovative organizational-care models: primary nursing, ACE model, IFeC		
	1.C- Identification of hospital-based specialist outpatient clinics.		
2. Introduction of new figures	2.A- Introduction of hospital IFeC and territorial IFeC figure with definition Job description		
	2.B- Introduction of the figure of Bed Manager with Job description definition		
3. Definition of procedures	3.A - Reporting frailty cases to hospital IFeC using agile screening tools (e.g., Sunfrail scale)		
	3.B- case reassessment by hospital IFEC through more specific intake tools (e.g., Tilburg scale)		
	3.C- Referral to the relevant territorial IFeC for taking charge in the territory.		
4. Network Creation	4.A- link with Primary Care Medicine and PLS for PRESST.		
	4.B- Interconnection with network of municipalities and social services		
	4.C- Links with third sector		
5. Introduction of new activities	5.A- publishing internal/external hours		
	5.B- setting up technology and operator training for telemedicine startup		
	5.C- Service model design (hours, opening gg) of area network nodes		

Table 2 - Gantt Diagram

Objective	Activities	Month 1	Month 2	Month 3	Month 4	Month 5
1. Reorganization of activities at PO	1.A- Reorganization of care by levels of intensity of care (low intensity, medium intensity, high intensity)	▓	▓			
	1.B- Introduction of innovative organizational-care models: primary nursing, ACE model, IFeC	▓	▓			
	1.C- Identification of hospital-based specialist outpatient clinics.		▓	▓		
2. Introduction of new figures	2.A- Introduction of hospital IFeC and territorial IFeC figure with definition Job description	▓	▓	▓		
	2.B- Introduction of the figure of Bed Manager with Job description definition	▓	▓	▓		
3. Definition of procedures	3.A - Reporting frailty cases to hospital IFeC using agile screening tools (e.g., Sunfrail scale)			▓	▓	
	3.B- case reassessment by hospital IFEC through more specific intake tools (e.g., Tilburg scale)			▓	▓	▓
	3.C- Referral to the relevant territorial IFeC for taking charge in the territory.			▓	▓	▓
4. Network Creation	4.A- link with Primary Care Medicine and PLS for PRESST.	▓	▓	▓	▓	
	4.B- Interconnection with network of municipalities and social services			▓	▓	
	4.C- Links with third sector					
5. Introduction of new activities	5.A- publishing internal/external hours	▓	▓			
	5.B- setting up technology and operator		▓	▓	▓	

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	training for telemedicine startup					
	5.C- Service model design (hours, opening gg) of territorial network nodes					

Paragraph 1- Risk evaluation

During the course of implementation, situations could occur that slow down or hinder the actual development of the project. In order to anticipate possible critical issues, an analysis of the risks and timelines against which they might occur was carried out. The timing analysis of the main risks identified is shown in **Table 3**.

The possible risks identified are:
- Long project implementation time related to covid management;
- unanticipated costs;
- Resistance from staff;
- Delays due to bureaucratic aspects;
- structural limitations;
- Delays due to staff recruitment or training.

Table 3- Representation of the Timing of Risk versus Project.

Risk analyzed	Timing of risk versus project*	
Long project implementation time	RI	RT
Unanticipated costs		RT
Resistance from staff		RT
Delays due to bureaucratic aspects	RI	
Structural limitations	RI	RT
Delays due to staff recruitment	RI	

*Legend: RI- immediate risks; RT- late-onset risks.

APPENDICES CHAPTER 7

Appendix A

- Table A.1 search strategy
- Table A.2 List of Cochrane systematic reviews included
- Table A.3 List of RCTs selected by Cochrane systematic review
- Table A.3/bis RCTs included by Cochrane systematic reviews (SRs) from which RCTs were selected and data were collected
- Table A.4 Tables of studies included

Table A.1- Search strategy

Source**: Cochrane Library** String no. **1** Date **01/20/2017 (95 Results); 10/04/2019 (100 Results)**	
ID	Search
#1	"sport".ti,ab,kw or "leisure time activities".ti,ab,kw or "bycicling".ti,ab,kw or "golf".ti,ab,kw or "gymnastic".ti,ab,kw (Word variation has been searched)
#2	"tai chi".ti,ab,kw or "mountaineering".ti,ab,kw or "tennis".ti,ab,kw or "running".ti,ab,kw or "joggin".ti,ab,kw (Word variation has been searched)
#3	"ski".ti,ab,kw or "swimming".ti,ab,kw or "walk".ti,ab,kw or "movement therapies".ti,ab,kw or "fitness".ti,ab,kw (Word variation has been searched)
#4	"exercise".ti,ab,kw (Word variation has been searched)
#5	"healthy".ti,ab,kw (Word variation has been searched)
#6	"healthy aging".ti,ab,kw (Word variation has been searched)
#7	"healthy adult".ti,ab,kw (Word variation has been searched)
#8	"healthy population".ti,ab,kw (Word variation has been searched)
#9	"healthy people".ti,ab,kw (Word variation has been searched)
#10	Mesh descriptor: [Adult] (Explode all tree)
#11	Mesh descriptor: [Middle aged] (Explode all tree)
#12	#1 or #2 or #3 or #4 and #5 or #6 or #7 or #8 or #9 and #10 and #11
Source**: Cochrane Library** String no. **2** Date **01/20/2017 (165 Results); 10/04/2019 (7 Results)**	
ID	Search
#1	"physical activity" (Word variations have been searched)
#2	"sport" (Word variations have been searched)
#3	primary prevention (Word variations have been searched)
#4	"diabetes mellitus" (Word variations have been searched)
#5	diabetes mortality (Word variations have been searched)
#6	"treatment" (Word variations have been searched)
#7	secondary prevention (Word variations have been searched)
#8	#1 or #2 and #3 and #4 or #5 and #6 and #7
Source**: Cochrane Library** String no. **3** Date **01/20/2017 (182 Results); 10/04/2019 (178 Results)**	
ID	Search

#1	"physical activity" (Word variations have been searched)
#2	sport (Word variations have been searched)
#3	primary prevention (Word variations have been searched)
#4	obesity (Word variations have been searched)
#5	obesity mortality (Word variations have been searched)
#6	"mortality" (Word variations have been searched)
#7	secondary prevention (Word variations have been searched)
#8	"treatment" (Word variations have been searched)
#9	#1 or #2 and #3 and #4 and #5 and #6 and (not #7 not #8)

Source: Cochrane Library String no. 4 Date 01/20/2017 (87 Results); 10/04/2019 (269 Results)

ID	Search
#1	"physical activity" (Word variations have been searched)
#2	"prevention" (Word variations have been searched)
#3	"pulmonary disease" (Word variations have been searched)
#4	"chronic obstructive pulmonary disease" (Word variations have been searched)
#5	"pneumonia" (Word variations have been searched)
#6	pulmonary disease mortality (Word variations have been searched)
#7	"primary prevention study" (Word variations have been searched)
#8	"treatment" (Word variations have been searched)
#9	secondary prevention study" (Word variations have been searched)
#10	"sport" (Word variations have been searched)
#11	#1 or #10 and #2 and #3 or #4 or #5 and #6 and #7 and #8 and #9

Source: Cochrane Library String no. 5 Date 01/20/2017 (92 Results); 10/04/2019 (0 Results)

ID	Search
#1	"physical activity" (Word variations have been searched)
#2	sport (Word variations have been searched)
#3	primary prevention (Word variations have been searched)
#4	neurological disease (Word variations have been searched)
#5	neurological disease mortality (Word variations have been searched)
#6	mortality (Word variations have been searched)
#7	secondary prevention:ti,ab,kw (Word variations have been searched)
#8	treatment (Word variations have been searched)
#9	(#1 or #2 and #3 and #4 and #5 and #6) not #7 not #8

Source: Cochrane Library String no. 6 Date 01/20/2017 (65 Results); 10/04/2019 (263 Results)

ID	Search
#1	adult :ti,ab,kw (Word variations have been searched)
#2	tumor :ti,ab,kw (Word variations have been searched)

#3	cancer:ti,ab,kw (Word variations have been searched)
#4	neoplasms:ti,ab,kw (Word variations have been searched)
#5	physical activity :ti,ab,kw (Word variations have been searched)
#6	sport :ti,ab,kw (Word variations have been searched)
#7	exercise :ti,ab,kw (Word variations have been searched)
#8	mortality :ti,ab,kw (Word variations have been searched)
#9	primary prevention study :ti,ab,kw (Word variations have been searched)
#10	secondary prevention study :ti,ab,kw (Word variations have been searched)
#11	treatment :ti,ab,kw (Word variations have been searched)
#12	#1 and #2 or #3 or #4 and #5 or #6 or #7 and #8 and #9 and(not #10 not #11)

Source: Cochrane Library String no. 7 Date 01/20/2017 (21 Results); 10/04/2019 (638 Results)

ID	Search
#1	Exercise
#2	Physical activity
#3	Physical activities
#4	Mesh Descriptor: [heart failure] (esplode all trees and with qualifier (S): [Prevention and control - PC]
#5	Mesh Descriptor: [heart disease] (esplode all trees and with qualifier (S): [Prevention and control - PC]
#6	Mesh Descriptor: [cardiovascular disease] (esplode all trees and with qualifier (S): [Prevention and control - PC]
#7	Secondary prevention
#8	treatment
#9	Healthy people:ti,ab,kw (Word variations have been searched)
#10	Mesh Descriptor: [primary prevention] (esplode all trees)
#11	#1 or #2 or #3 and #4 or #5 or #6 and #7 or #8 and #9 and #10

Source: PubMed String no. 8 Date 01/20/2017 (1269 Results); 10/04/2019 (85 Results)

ID	Search
#1	("adult"[MeSH Terms] OR "adult"[All Fields] OR "over 50"[All Fields] OR "healthy"[All Fields] OR "aged"[MeSH Terms] OR "aged"[All Fields] OR "geriatric"[All Fields] OR "frail"[All Fields] OR "elder"[All Fields] OR "older"[All Fields]) AND ("exercise"[MeSH Terms] OR "exercise"[All Fields] OR "motor activity"[MeSH Terms] OR "motor activity"[All Fields] OR "activity"[All Fields] OR "locomotion"[MeSH Terms] OR "locomotion"[All Fields] OR "locomotor activity"[All Fields] OR "aerobic"[All Fields] OR "sports"[MeSH Terms] OR "sports"[All Fields]) AND ("aging"[MeSH Terms] OR "aging"[All Fields] OR "ageing"[All Fields]) AND ((Review[ptyp] OR Editorial[ptyp]) AND "2012/02/02"[PDAT] : "2017/01/30"[PDAT]) AND (Review[ptyp] AND ("2017/02/01"[PDAT] : "2019/10/04"[PDAT]) AND "humans"[MeSH Terms])

Table A.2- List of Cochrane systematic reviews included

Gillespie LD, Robertson MC, Gillespie WJ, et al. *Interventions for preventing falls in older people living in the community*. Cochrane Database Syst Rev. 2012 Sep 12;(9):CD007146
Hopewell S, Adedire O, Copsey BJ, et al. *Multifactorial and multiple component interventions for preventing falls in older people living in the community*. Cochrane Database Syst Rev. 2018 Jul 23;7(7):CD012221
Howe TE, Shea B, Dawson LJ, et al. *Exercise for preventing and treating osteoporosis in postmenopausal women*. Cochrane Database Syst Rev. 2011 Jul 6;(7):CD000333
Kendrick D, Kumar A, Carpenter H, et al. *Exercise for reducing fear of falling in older people living in the community*. Cochrane Database Syst Rev. 2014 Nov 28;2014(11):CD009848
Sherrington C, Fairhall NJ, Wallbank GK, et al. *Exercise for preventing falls in older people living in the community*. Cochrane Database Syst Rev. 2019 Jan 31;1(1):CD012424

Table A.3- List of RCTs selected by Cochrane systematic review

Brown 2002 Brown, A. I. (2002). *Functional Adaptation to Exercise in Elderly Subjects*. Curtin University of Technology
Buchner 1997 Buchner, D. M., Cress, M. E., de Lateur, B. J., Esselman, P. C., Margherita, A. J., Price, R., & Wagner, E. H. (1997). The Effect of Strength and Endurance Training on Gait, Balance, Fall Risk, and Health Services Use in Community-Living Older Adults. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*, *52A*(4), M218–M224.
Bunout 2005 Bunout, D., Barrera, G., Avendaño, M., Maza, P. de la, Gattas, V., Leiva, L., & Hirsch, S. (2005). Results of a community-based weight-bearing resistance training programme for healthy Chilean elderly subjects. *Age Ageing*, *34*(1), 80–3
Cerny 1998 Cerny, K., Blanks, R., Mohamed, O., Schwab, D., Robinson, B., Russo, A., & Zizz, B. S. (1998). The effecr ofd multldnnenslonal elerclse program on strength, range of mohan. balance sod gait in the ire11 elderly. *Gait & Posture*, *7*, 144–190
Davis 2011 Davis, J. C., Marra, C. A., Robertson, M. C., Khan, K. M., Ashe, M. C., & Liu-ambrose, T. (2015). Economic evaluation of dose-response resistance training in older women : a cost effectiveness and cost utility analysis, *22*(5), 1355–1366. https://doi.org/10.1007/s00198-010-1356-5

Davison 2005
Davison, J. (2004). Patients with recurrent falls attending Accident & Emergency benefit from multifactorial intervention — a randomised controlled trial, 162–168

Freiberger 2012
Freiberger, E., Häberle, L., Spirduso, W. W., & Rixt Zijlstra, G. A. (2012). Long-Term Effects of Three Multicomponent Exercise Interventions on Physical Performance and Fall-Related Psychological Outcomes in Community-Dwelling Older Adults: A Randomized Controlled Trial. *Journal of the American Geriatrics Society*, *60*(3), 437–446. https://doi.org/10.1111/j.1532-5415.2011.03859.x

Gill 2016
Gill Thomas M, Pahor Marco, Guralnik Jack M, McDermott Mary M, King Abby C, Buford Thomas W et al. Effect of structured physical activity on prevention of serious fall injuries in adults aged 70-89: randomized clinical trial (LIFE Study) *BMJ* 2016; 352 :i245

Hamrick 2017
Hamrick, I., Mross, P., Christopher, N., & Smith, P. D. (2017). Complementary Therapies in Medicine Yoga ' s e ff ect on falls in rural , older adults. *Complementary Therapies in Medicine*, *35*(April), 57–63. https://doi.org/10.1016/j.ctim.2017.09.007

Huang 2010
Huang, H.-C., Liu, C.-Y., Huang, Y.-T., & Kernohan, W. G. (2010). Community-based interventions to reduce falls among older adults in Taiwan - long time follow-up randomised controlled study. *Journal of Clinical Nursing*, *19*(7–8), 959–968. https://doi.org/10.1111/j.1365-2702.2009.02834.x

Hinman 2002
Hinman MR. Comparison of two short-term balance training programs for community-dwelling older adults. *Journal of Geriatric Physical Therapy* 2002;25(3):10–5

Irez 2011
Irez, G. B., Ozdemir, R. A., Evin, R., Irez, S. G., & Korkusuz, F. (2011). Integrating Pilates exercise into an exercise program for 65 + year-old women to reduce falls, (February 2010), 105–111

Kamide 2009
Kamide, N., Shiba, Y., & Shibata, H. (2003). Effects on Balance , Falls , and Bone Mineral Density of a Home-based Exercise Program without Home Visits in Community-Dwelling Elderly Women : a Randomized Controlled Trial. https://doi.org/10.2114/jpa2.28.115

Karinkanta 2007
Karinkanta, S., Nupponen, R., Heinonen, A., Pasanen, M., Sievänen, H., Uusi-Rasi, K., … Kannus, P. (2012). Effects of Exercise on Health-Related Quality of Life and Fear of Falling in Home-Dwelling Older Women. *Journal of Aging and Physical Activity, 20*(2), 198–214. https://doi.org/10.1123/japa.20.2.198

Kim 2014
Kim, H., Yoshida, H., & Suzuki, T. (2014). Falls and fractures in participants and excluded non- participants of a fall prevention exercise program for elderly women with a history of falls : 1-year follow-up study, 285–292. https://doi.org/10.1111/ggi.12095

Korpelainen 2006
Korpelainen, R., Keinänen-Kiukaanniemi, S., Heikkinen, J., Väänänen, K. and Korpelainen, J. (2006), Effect of Exercise on Extraskeletal Risk Factors for Hip Fractures in Elderly Women With Low BMD: A Population-Based Randomized Controlled Trial. J Bone Miner Res, 21: 772-779. doi:10.1359/jbmr.060116

Lehtola 2000
Lehtola_S, Hanninen_L, Paatalo_M. The incidence of falls during a six-month exercise trial and four-month followup among home dwelling persons aged 70-75 years [Kaatumistapaturmien ilmaantuvuus 70-75-vuotiailla oululaisilla liikuntaintervention ja sen jälkeisen seurannan aikana]. Liikuntatiede 2000;6:41-6

Lurie 2013
Lurie et al.: Pilot comparative effectiveness study of surface perturbation treadmill training to prevent falls in older adults. BMC Geriatrics 2013 13:49

Means 2005
Means KM, Rodell DE, O'Sullivan PS. Balance, mobility, and falls among community-dwelling elderly persons: effects of a rehabilitation exercise program. *Am J Phys Med Rehabil*. 2005;84(4):238-250. Doi:10.1097/01.phm.0000151944.22116.5a

Nguyen 2012
Nguyen MH, Kruse A. A randomized controlled trial of Tai chi for balance, sleep quality and cognitive performance in elderly Vietnamese. *Clin Interv Aging*. 2012;7:185-190. https://doi.org/10.2147/CIA.S32600

Park 2008
Park, H., Kim, K. J., Komatsu, T., Park, S. K., & Mutoh, Y. (2008). Effect of combined exercise training on bone, body balance, and gait ability: a randomized controlled study in community-dwelling elderly women. *Journal of Bone and Mineral Metabolism*, 26(3), 254–259. https://doi.org/10.1007/s00774-007-0819-z

Reinsch 1992
Reinsch, S., MacRae, P., Lachenbruch, P. A., & Tobis, J. S. (1992). Attempts to Prevent Falls and Injury: A Prospective Community Study. *The Gerontologist*, 32(4), 450–456. https://doi.org/10.1093/geront/32.4.450

Robertson 2001
Robertson_MC, Devlin_N, Gardner_MM, Campbell_AJ. E&ectiveness and economic evaluation of a nurse delivered home exercise programme to prevent falls. 1: Randomised controlled trial. *BMJ* 2001;322(7288):697-701

Steadman 2003

Steadman, J., Donaldson, N., & Kalra, L. (2003). A Randomized Controlled Trial of an Enhanced Balance Training Program to Improve Mobility and Reduce Falls in Elderly Patients. *Journal of the American Geriatrics Society*, *51*(6), 847–852. https://doi.org/10.1046/j.1365-2389.2003.51268.x

Suzuki 2004

Suzuki_T, Kim_H, Yoshida_H, Ishizaki_T. Randomized controlled trial of exercise intervention for the prevention of falls in community-dwelling elderly Japanese women. *Journal of Bone and Mineral Metabolism* 2004;22(6):602-11

Voukelatos 2007

Voukelatos, A., Cumming, R. G., Lord, S. R., & Rissel, C. (2007). A Randomized, Controlled Trial of tai chi for the Prevention of Falls: The Central Sydney tai chi Trial. *Journal of the American Geriatrics Society*, *55*(8), 1185–1191. https://doi.org/10.1111/j.1532-5415.2007.01244.x

Weerdesteyn 2006

Weerdesteyn, V., Rijken, H., & Geurts, C. H. (2006). A Five-Week Exercise Program Can Reduce Falls and Improve Obstacle, 131–141. https://doi.org/10.1159/000091822

Wolf 1996

Wolf, S. L., Barnhart, H. X., & Kutner, N. G. (1996). Reducing Frailty and Falls in Older Persons: An Investigation of Tai Chi and Computerized Balance Training, 489–497

Woo 2007

Woo, J., Hong, A., Lau, E., & Lynn, H. (2007). A randomised controlled trial of Tai Chi and resistance exercise on bone health, muscle strength and balance in community-living elderly people. *Age and Ageing*, *36*(3), 262–268. https://doi.org/10.1093/ageing/afm005

Wu 2010

Wu, G., Keyes, L., Callas, P., Ren, X., & Bookchin, B. (2010). Comparison of Telecommunication, Community, and Home-Based Tai Chi Exercise Programs on Compliance and Effectiveness in Elders at Risk for Falls. *Archives of Physical Medicine and Rehabilitation*, *91*(6), 849–856. https://doi.org/10.1016/j.apmr.2010.01.024

Yoo 2010

Yoo, E. J., Jun, T. W., & Hawkins, S. (2010). The Effects of a Walking Exercise Program on Fall-Related Fitness, Bone Metabolism, and Fall-Related Psychological Factors in Elderly Women. *Research in Sports Medicine*, *18*(4), 236–250. https://doi.org/10.1080/15438627.2010.510098

Zhang 2006

Zhang, J.-G., Ishikawa-Takata, K., Yamazaki, H., Morita, T., & Ohta, T. (2006). The effects of Tai Chi Chuan on physiological function and fear of falling in the less robust elderly: An intervention study for preventing falls. *Archives of Gerontology and Geriatrics*, *42*(2), 107–116. https://doi.org/10.1016/j.archger.2005.06.007

Table A.3- RCTs included by Cochrane systematic reviews (SRs) from which RCTs were selected and data were collected

Cochrane SRs	Number of studies included in Cochrane SRs	Number RCTs included in this meta-analysis	List of RCTs included in this meta-analysis
Gillespie et al. 2012	159	19	Brown 2002 Buchner 1997 Bunout 2005 Cerny 1998 Davis 2011 Davison 2005 Huang 2010 Kamide 2009 Korpelainen 2006 Means 2005 Reinsch 1992 Robertson 2001 Steadman 2003 Suzuki 2004 Voukelatos 2007 Weerdesteyn 2006 Wolf 1996 Woo 2007 Wu 2010
Hopewell et al. 2018	62	2	Davison 2005 Huang 2010
Howe et al. 2011	43	2	Karinkanta 2007 Korpelainen 2006
Kendrick et al. 2014	30	8	Hinman 2002 Nguyen 2012 Reinsch 1992 Resnick 2008 Yoo 2010 Weerdesteyn 2006 Wolf 1996 Zhang 2006
Sherrington et al. 2019	108	26	Brown 2002 Buchner 1997 Bunout 2005 Cerny 1998 Davis 2011 Gill 2016 Hamrick 2017 Huang 2010 Irez 2011

			Kamide 2009
			Karinkanta 2007
			Kim 2014
			Korpelainen 2006
			Means 2005
			Lehtola 2000
			Lurie 2013
			Park 2008
			Reinsch 1992
			Robertson 2001
			Steadman 2003
			Suzuki 2004
			Voukelatos 2007
			Weerdesteyn 2006
			Wolf 1996
			Woo 2007
			Wu 2010

Table A.4- Tables of studies included

First author, year	Brown 2002
Country	Australia
Participants	
Participants (% Females)	149 (79,2%)
Exp (n) / Control (n)	50 / 49
Lost at followup	28
Analysed exp. group	39 subjects with mean age n.a. (SD n.a.; range n.a. - n.a.)
Analysed control group	32 subjects with mean age n.a. (SD n.a.; range n.a. - n.a.)
Risk for	n.a.
Number of arms analysed / Total	2
Intervention	Mixed exercises: 10 minutes of warm-up activities and stretches; strengthening component of shoulder, elbow, trunk, hip, knee and ankle (with elastic tubing and sand or rice bags); balance exercises altering base of support and standing surface to dynamic activities as stepping up a small step, obstacle and combined balance and neck movements and altered walking patterns; endurance activities (marching combined with arm movements and dancing); co-ordination activities (hand-eye activities as bat and ball games, batting ballons, etc.); concluded with stretching
	Delivered by: Physiotherapist
	Intensity level: Low
	Weekly minutes: 120
	Setting: Clinical gym and other
Control	No intervention
Compliance	mean attendance: 85% (22 - 26 sessions), range of 62 - 100% (16 sessions)
Outcomes and Results	Fallers RR 0,78 95% CI 0,53; 1,15

Follow-up (months)	14
Sensibility analyses	Yes

First author, year	Buchner 1997
Country	US
Participants	
Participants (% Females)	181 (50,83%)
Exp (n) / Control (n)	75 / 30
Lost at followup	n.a.
Analysed exp. group	70 with mean age 75 (SD n.a.; range n.a. - n.a.)
Analysed control group	30 subjects with mean age 75 (SD n.a.; range n.a. - n.a.)
Risk for	previous falls, light impairment on mobility
Number of arms analysed / Total	4 / 4
Intervention	Mixed exercises: 3 EXERCISES GROUPS (EG, SG, EG+SG): EG practiced 6-month endurance with cycles per 30-35 minutes at moderate intensity level; SG practiced 6-month strength exercises using weight machines (10 repetitions per 2 sets, 1 set at lower intensity and 1 set at moderate intensity level) for upper body (incline press, rowing), rotary torso, ankle (strapping the foot to a metal plate with weights), lower body (leg press, extension, curl, hip adduction and abduction); EG+SG practiced 6-month endurance (20minutes) and 1 set of strength at moderate intensity level
	Delivered by: n.a.
	Intensity level: Moderate
	Weekly minutes: 180
	Setting: Clinical gym and other
Control	No intervention
Compliance	Exercise groups: participants who remained in the study attended 95% sessions
Outcomes and Results	Fallers All exercise groups vs. Ctrl RR 0,53 95% CI 0,31; 0,92
	Falls All exercise groups vs. Ctrl RR 0,61 95% CI 0,4; 0,94
Follow-up (months)	18
Sensibility analyses	Yes

First author, year	Bunout 2005
Country	Chile
Participants	
Participants (% Females)	298 (71,14%)
Exp (n) / Control (n)	111 / 130
Lost at followup	57
Analysed exp. group	111 with mean age n.a. (SD n.a.; range n.a. - n.a.)
Analysed control group	130 subjects with mean age n.a. (SD n.a.; range n.a. - n.a.)
Risk for	light impairment on mobility

Number of arms analysed / Total	2 / 2
Intervention	Mixed exercises: Functional weight bearing exercises: warming up and three levels of chair stands (5 sets of 10 repetitions), three levels of modified squats (5 sets of 10 repetitions), three levels of step ups in a stair (10 sets of 10 repetitions), arm pull-ups using rubber bands (6 sets of 15 repetitions). After each 12/15 repetitions resistance were increased (Borg scale: from light to hard). Walking of 15 min before and after resistance training.
	Delivered by: Instructor
	Intensity level: Low
	Weekly minutes: 120
	Setting: Gym, swimming pool and other
Control	Usual activity
Compliance	42% non-compliant (attended < 50% sessions)
Outcomes and Results	Fallers RR 1,68 95% CI 0,93; 3,03
	Falls RR 1,22 95% CI 0,69; 2,16
Follow-up (months)	12
Sensibility analyses	Yes

First author, year	Cerny 1998
Country	US
Participants	
Participants (% Females)	28 (0%)
Exp (n) / Control (n)	15 / 13
Lost at followup	0
Analysed exp. group	15 with mean age n.a. (SD n.a.; range n.a. - n.a.)
Analysed control group	13 subjects with mean age n.a. (SD n.a.; range n.a. - n.a.)
Risk for	light impairment on mobility
Number of arms analysed / Total	2 / 2
Intervention	Mixed exercises: Progressive resistive strengthening, stretching, aerobic and balance exercises, and brisk walking over various terrains.
	Delivered by: n.a.
	Intensity level: Moderate
	Weekly minutes: 270
	Setting: Multiple setting
Control	No intervention
Compliance	n.a.
Outcomes and Results	Fallers RR 0,87 95% CI 0,21; 3,57
Follow-up (months)	6
Sensibility analyses	No

First author, year	Davis 2011
Country	Canada
Participants	

Participants (% Females)	155 (100%)
Exp (n) / Control (n)	Davis 2011a (54) Davis 2011b (52) / 49
Lost at followup	0
Analysed exp. group	54 subjects in Davis 2011a, 52 in Davis 2011b with mean age n.a. (SD n.a.; range n.a. - n.a.)
Analysed control group	49 subjects with mean age n.a. (SD n.a.; range n.a. - n.a.)
Risk for	
Number of arms analysed / Total	3 / 3
Intervention	
Davis 2011a	Strength and resistance: resistance training program used a progressive, high intensity protocol.
	Delivered by: Instructor
	Intensity level: High
	Weekly minutes: 60
	Setting: Gym, swimming pool and other
Davis 2011b	Strength and resistance: resistance training program used a progressive, high intensity protocol.
	Delivered by: Instructor
	Intensity level: High
	Weekly minutes: 120
	Setting: Gym, swimming pool and other
Control	Mixed exercises (GBCFT, Strength/resistance, Flexibility). balance and tone classes: consisted of stretching exercises, range-of-motion exercises, basic core-strength exercises including kegels (pelvic floor exercises), balance exercises, and relaxation techniques.
	Intensity level: Moderate
	Weekly minutes: 120
	Setting: Gym, swimming pool and other
Compliance	n.a.
Outcomes and Results	Falls Int.a vs. ctrl RR 0,73 95% CI 0,44; 1,22; Int.b vs. Ctrl RR 0,88 95% CI 0,67; 1,16
Follow-up (months)	9
Sensibility analyses	Yes

First author, year	Davison 2005
Country	UK
Participants	
Participants (% Females)	313 (72,2%)
Exp (n) / Control (n)	159 / 154
Lost at followup	20
Analysed exp. group	144 subjects with mean age 77 (SD 7; range n.a. - n.a.)
Analysed control group	149 subjects with mean age 77 (SD 7; range n.a. - n.a.)
Risk for	
Number of arms analysed / Total	2 / 2

Intervention	Multicomponent interventions: Home-based physiotherapy and occupation therapy: 9 components of gait and 13 components of balance. Intervention was by gait re-education, and a functional training programme + supply of assistive devices and footwear
	Delivered by: Physiotherapist
	Intensity level: Low
	Weekly minutes:
	Setting: Home
Control	usual care
Compliance	n.a.
Outcomes and Results	Fallers RR 0,95 95% CI 0,81; 1,11
	Falls RR 0,64 95% CI 0,57; 0,72
	Persons sustaining a fracture for fall RR 0,53 95% CI 0,2; 1,38
Follow-up (months)	12
Sensibility analyses	No

First author, year	Freiberger 2012
Country	Germany
Participants	
Participants (% Females)	280 (43,57%)
Exp (n) / Control (n)	200 / 80
Lost at followup	73
Analysed exp. group	49 subjects in Freiberger 2012a 49 subjects in Freiberger 2012b 48 subjects in Freiberger 2012c with mean age 76,4 (SD ,1), 75,3 (SD 3,6), and 75,6 (SD 4,3) respectively
Analysed control group	52 subjects with mean age 76,8 (SD 4,1; range n.a. - n.a.)
Risk for	previous falls
Number of arms analysed / Total	4 / 4
Intervention	
Freiberger 2012a	Mixed exercises: Strength and balance + endurance training: walking with change of pace and direction and Nordic walking
	Delivered by: Instructor
	Intensity level: Moderate
	Weekly minutes: 120
	Setting:
Freiberger 2012b	Mixed exercises: Strength and balance
	Delivered by: Instructor
	Intensity level: Moderate
	Weekly minutes: 120
	Setting:
Freiberger 2012c	Multicomponent interventions: Multifaced group: strength and balance + fall risk education
	Delivered by: Instructor
	Intensity level: Moderate

	Weekly minutes: 120
	Setting:
Control	No intervention
Compliance	n.a.
Outcomes and Results	Fear of falling (higher score indicate less fear) Int.a vs. Ctrl SMD -0,12 95% CI -0,47; 0,23
	Falls Int.a vs. Ctrl RR 0,68 95% CI 0,4; 1,16; Int.b vs. Ctrl RR 0,97 95% CI 0,58; 1,62; Int.c vs. Ctrl RR 0,94 95% CI 0,58; 1,53
	Fallers Int.a vs. Ctrl RR 0,62 95% CI 0,3; 1,3; Int.b vs. Ctrl RR 0,8 95% CI 0,4; 1,6; Int.c vs. Ctrl RR 1,02 95% CI 0,54; 1,95
Follow-up (months)	24
Sensibility analyses	Yes

First author, year	Gill 2016
Country	US
Participants	
Participants (% Females)	1635 (67,16%)
Exp (n) / Control (n)	818 / 817
Lost at followup	0
Analysed exp. group	818 with mean age 78,7 (SD 5,2; range n.a. - n.a.)
Analysed control group	817 subjects with mean age 79,1 (SD 5,2; range n.a. - n.a.)
Risk for	hypertensive, hyperglycemia, previous falls,
Number of arms analysed / Total	2 / 2
Intervention	Mixed exercises: Walking, strength, flexibility, and balance
	Delivered by: Instructor
	Intensity level: Moderate
	Weekly minutes: 300
	Setting:
Control	Education: Health education: negotiating the healthcare system, traveling safely, and preventive services + a five to 10 minute instructor led program of stretching exercises.
Compliance	63% of the scheduled sessions: median 71% (interquartile range 50-83%)
Outcomes and Results	Persons sustaining a fracture for fall RR 0,87 95% CI 0,64; 1,19
Follow-up (months)	31
Sensibility analyses	Yes

First author, year	Hamrick 2017
Country	US
Participants	
Participants (% Females)	43 (79,07%)
Exp (n) / Control (n)	21 / 22
Lost at followup	5

Analysed exp. group	19 with mean age 69,8 (SD n.a.; range 60 - 88)
Analysed control group	19 subjects with mean age 70 (SD n.a.; range 61 - 81)
Risk for	previous falls
Number of arms analysed / Total	2 / 2
Intervention	Flexibility: Yoga Home Exercise and Relaxation:physical postures (asana), body awareness and mindfulness, regulation of the breath (pranayama) and centering/relaxation (meditation)
	Delivered by: Instructor
	Intensity level: Low
	Weekly minutes: 120
	Setting: Gym, swimming pool and other
Control	Flexibility: Home Relaxation-Only: participants were instructed to practice the yoga home poses for 10 minutes with 5 minutes of relaxation
	Intensity level: Low
	Weekly minutes: 30
	Setting: Home
Compliance	Attendance in the 16 yoga sessions was 92%
Outcomes and Results	Falls RR 0,75 95% CI 0,26; 2,16
	Fallers RR 0,57 95% CI 0,2; 1,65
Follow-up (months)	6
Sensibility analyses	Yes

First author, year	Hinman 2002
Country	US
Participants	
Participants (% Females)	97 (62,89%) with mean age 72 (range 63 - 87)
Exp (n) / Control (n)	58 / 30
Lost at followup	30
Analysed exp. group	28 subjects in Hinman 2002a, 30 subjects in Hinman 2002b
Analysed control group	30 subjects
Risk for	previous falls
Number of arms analysed / Total	3 / 3
Intervention	
Hinman 2002a	Gait, balance, co-ordination and functional task ecxercises: computerized balanced training: balance exercises
	Delivered by: Physiotherapist
	Intensity level: Low
	Weekly minutes: 60
	Setting: Home
Hinman 2002b	Gait, balance, co-ordination and functional task ecxercises: home exercize program: balance exercises
	Delivered by: n.a.
	Intensity level: Low

	Weekly minutes: 60
	Setting: Home
Control	Usual care
Compliance	90%
Outcomes and Results	Fear of falling (higher score indicate less fear) SMD 0,02 95% CI -0,5; 0,53
Follow-up (months)	1
Sensibility analyses	No

First author, year	Huang 2010
Country	Taiwan
Participants	
Participants (% Females)	184 (29,89%)
Exp (n) / Control (n)	134 / 50
Lost at followup	21
Analysed exp. group	31 subjects in Huang 2010a, 56 in Huang 2010b with mean age 71,4 (SD 0,49) and 71.50 (SD 1.02), respectively
Analysed control group	47 subjects with mean age 71,5 (SD 1,01)
Risk for	hypertensive, hyperglycemia, light impairment on mobility
Number of arms analysed / Total	3 / 4
Intervention	
Huang 2010a	3D: Tai Chi Chuan
	Delivered by: Instructor
	Intensity level: Low
	Weekly minutes: 120
	Setting: Gym, swimming pool and other
Huang 2010b	Multicomponent interventions: 3D (Tai Chi Chuan) + Education
	Delivered by: Instructor
	Intensity level: Low
	Weekly minutes: 120
	Setting: Gym, swimming pool and other
Control	No intervention
Compliance	n.a.
Outcomes and Results	Fallers Int.a vs. Ctrl RR 0,52 95% CI 0,02; 12,25
	Falls Int.a vs. Ctrl RR 0,13 95% CI 0,06; 0,27; Int.b va. Ctrl RR 0,27 95% CI 0,11; 0,71
Follow-up (months)	18
Sensibility analyses	Yes

First author, year	Irez 2011
Country	Turkey
Participants	
Participants (% Females)	60 (100%)
Exp (n) / Control (n)	30 / 30
Lost at followup	0

Analysed exp. group	30 with mean age 72,8 (SD 6,7; range n.a. - n.a.)
Analysed control group	30 subjects with mean age 78 (SD 5,7; range n.a. - n.a.)
Risk for	overweight
Number of arms analysed / Total	2 / 2
Intervention	Strength and resistance: Pilates classes: progressive exercises with equipments (Thera-Band elastic resistance band, balls)
	Delivered by: Instructor
	Intensity level: Moderate
	Weekly minutes: 180
	Setting: Gym, swimming pool and other
Control	No intervention
Compliance	completed 32/36 sessions (92% participation rate)
Outcomes and Results	Falls RR 0,28 95% CI 0,15; 0,55
Follow-up (months)	3
Sensibility analyses	Yes

First author, year	Karinkanta 2007
Country	
Participants	Finland
Participants (% Females)	149 (100%)
Exp (n) / Control (n)	112 / 37
Lost at followup	5
Analysed exp. group	37 subjects in Karinkanta 2007a, 35 subjects in Karinkanta 2007b, 36 subjects in Karinkanta 2007c with mean age 72,7 (SD 2,5), 72.9 (SD 2.3), 72.9 (SD 2.2), respectively
Analysed control group	36 subjects with mean age 72 (SD 2,1; range n.a. - n.a.)
Risk for	hypertensive, hyperglycemia
Number of arms analysed / Total	4 /* 4
Intervention	
Karinkanta 2007a	Strength and resistance: Resistance training group: tailored resistance exercises for large muscle groups using machines (raising from a chair using a weight vest, squatting, leg presses, hip abduction, hip extension, calf rise, and rowing) tailored up to 70 - 80% of 1RM
	Delivered by: Other
	Intensity level: Moderate
	Weekly minutes: 150
	Setting: Gym, swimming pool and other
Karinkanta 2007b	Gait, balance, co-ordination and functional task ecxercises: Balance-jumping training group: balance, agility, and impact exercise. Static and dynamic balance and agility training sessions, jumps and other impacts, and changes of direction with music. Exercises were performed with step board. Exercises were aerobics or

	step aerobics alternating every 2 weeks in 12-week period exercises
	Delivered by: Other
	Intensity level: Moderate
	Weekly minutes: 150
	Setting: Gym, swimming pool and other
Karinkanta 2007c	Mixed exercises: Combination of resistance and balance-jumping training group
	Delivered by: Other
	Intensity level: Moderate
	Weekly minutes: 150
	Setting: Gym, swimming pool and other
Control	No intervention
Compliance	mean attendance rate 74%
Outcomes and Results	Falls Int.a vs. Ctrl RR 0,6 95% CI 0,25; 1,45; Int.b vs. Ctrl RR 1,42 95% CI 0,7; 2,87; Int.c vs. Ctrl RR 1,46 95% CI 0,72; 2,96
	Persons sustaining a fracture for fall Int.a vs. Ctrl RR 0,97 95% CI 0,14; 6,49; Int.b vs. Ctrl RR 0,2 95% CI 0,01; 7,96; Int.c vs. Ctrl RR 0,19 95% CI 0,01; 3,92
Follow-up (months)	12
Sensibility analyses	Yes

First author, year	Kim 2014
Country	Japan
Participants	
Participants (% Females)	105 (100%)
Exp (n) / Control (n)	52 / 53
Lost at followup	2
Analysed exp. group	51 with mean age 77,83 (SD 4,21; range n.a. - n.a.)
Analysed control group	52 subjects with mean age 77,83 (SD 4,15; range n.a. - n.a.)
Risk for	hypertensive, previous falls
Number of arms analysed / Total	2 / 2
Intervention	Mixed exercises: Muscle strength and balance training: 5-min warm-up, 30 min of strengthening exercise, 20 min of balance training and 5 min of cool-down performed in progressive sequence and resistance (exercises were chair, resistance band, ankle-weight exercises and balance training). After the 3-month exercise classes (twice a week for 1-h), participants attend 1-h exercise classes once a month and were encouraged to carry out two to three sets of each exercise at least three times a week
	Delivered by: Other
	Intensity level: Moderate
	Weekly minutes: 180
	Setting: Clinical gym and other

Control	Education: Health education: 60 minutes class once a month for 3 months on undernutrition, cognitive function and oral hygiene
Compliance	mean attendance rate during intervention, 75% (range 64 – 86%); mean frequency home exercises 3.4 a week; mean exercise time 24.9 minutes
Outcomes and Results	Fallers RR 0,49 95% CI 0,25; 0,93
	Persons sustaining a fracture for fall RR 0,51 95% CI 0,05; 5,48
Follow-up (months)	12
Sensibility analyses	Yes

First author, year	Korpelainen 2006
Country	Finland
Participants	
Participants (% Females)	160 (100%)
Exp (n) / Control (n)	84 / 76
Lost at followup	48
Analysed exp. group	54 with mean age 72,9 (SD 1,1; range n.a. - n.a.)
Analysed control group	58 subjects with mean age 72,8 (SD 1,2; range n.a. - n.a.)
Risk for	hypertensive
Number of arms analysed / Total	2 / 2
Intervention	Mixed exercises: 15-minute warm-up and 45 minutes of strength, balance, and jumping exercises, including walking, rapid walking, walking with arm movements, knee bends, leg lifts, heel rises and drops, dancing, stamping, stepping sideways, forward, and backward, stair climbing, stepping up and down from benches, and jumping. Balance exercises were done with music. Exercise classes: hour-long training sessions once a week, supervised by a qualified physiotherapist, for a 6-month period + 20-min daily of exercise at home
	Delivered by: Physiotherapist
	Intensity level: Moderate
	Weekly minutes: 180
	Setting: Multiple setting
Control	No intervention
Compliance	77% during the first supervised 6-month period, mean frequency of performing home programme was 3 a week
Outcomes and Results	Falls RR 0,79 95% CI 0,59; 1,06
	Fractures for falls RR 0,29 95% CI 0,11; 0,78
	Persons sustaining a fracture for fall RR 0,36 95% CI 0,15; 0,87
Follow-up (months)	30
Sensibility analyses	Yes

First author, year	Lehtola 2000
Country	Finland

Participants	
Participants (% Females)	131 (80,15%)
Exp (n) / Control (n)	92 / 39
Lost at followup	0
Analysed exp. group	92 with mean age 72,3 (SD 1,6; range n.a. - n.a.)
Analysed control group	39 subjects with mean age 72,4 (SD 1,6; range n.a. - n.a.)
Risk for	
Number of arms analysed / Total	2 / 2
Intervention	Mixed exercises: Group-based balance, flexibility, walking: 60-minute class, 1 a week for 20 weeks; walking with sticks 20 minutes, > 3 a week for 24 weeks; home exercises 20 minutes, > 3 a week for 24 weeks
	Delivered by: Other
	Intensity level: Moderate
	Weekly minutes: 180
	Setting: Multiple setting
Control	No intervention
Compliance	Active participants: 52 participants; Passive: 20 participants
Outcomes and Results	Falls RR 0,21 95% CI 0,05; 0,84
Follow-up (months)	10
Sensibility analyses	No

First author, year	Lurie 2013
Country	US
Participants	
Participants (% Females)	64 (59,38%)
Exp (n) / Control (n)	31 / 33
Lost at followup	5
Analysed exp. group	26 with mean age 81,1 (SD 6,53; range 66 - 94)
Analysed control group	33 subjects with mean age 79,2 (SD 7,65; range 65 - 96)
Risk for	light impairment on mobility
Number of arms analysed / Total	2
Intervention	Mixed exercises: Balance, strength and flexibility plus walking in treadmill
	Delivered by: Physiotherapist
	Intensity level: Moderate
	Weekly minutes: 0
	Setting: Clinical gym and other
Control	Mixed exercises: Balance, strength and flexibility
	Intensity level: Low
	Setting: Clinical gym and other
Compliance	n.a.
Outcomes and Results	Fallers RR 0,58 95% CI 0,23; 1,45
Follow-up (months)	3
Sensibility analyses	No

First author, year	Nguyen 2012
Country	Vietnam
Participants	
Participants (% Females)	96 (50%)
Exp (n) / Control (n)	48 / 48
Lost at followup	0
Analysed exp. group	48 with mean age 69,23 (SD 5,3; range n.a. - n.a.)
Analysed control group	48 subjects with mean age 68,3 (SD 4,95; range n.a. - n.a.)
Risk for	
Number of arms analysed / Total	2 / 2
Intervention	3D: tai chi
	Delivered by: Instructor
	Intensity level: Low
	Weekly minutes: 120
	Setting:
Control	Usual care
Compliance	n.a.
Outcomes and Results	Fear of falling (higher score indicate less fear) SMD 2,29 95% CI 1,70; 2,88
Follow-up (months)	24
Sensibility analyses	No

First author, year	Means 2005
Country	US
Participants	
Participants (% Females)	338 (57,1%)
Exp (n) / Control (n)	181 / 157
Lost at followup	100
Analysed exp. group	144 with mean age n.a. (SD n.a.; range n.a. - n.a.)
Analysed control group	94 subjects with mean age n.a. (SD n.a.; range n.a. - n.a.)
Risk for	previous falls
Number of arms analysed / Total	2 / 2
Intervention	Mixed exercises: Stretching, postural control, endurance walking, and repetitive muscle coordination exercises: exercise classes of 6/8 persons
	Delivered by: Physiotherapist
	Intensity level: Moderate
	Weekly minutes: 270
	Setting:
Control	Usual care/no intervention: Seminars no-health related
Compliance	12 never attended exercise
Outcomes and Results	Falls RR 0,41 95% CI 0,26; 0,63
	Fallers RR 0,4 95% CI 0,25; 0,64
Follow-up (months)	6
Sensibility analyses	No
First author, year	Park 2008
Country	South Korea

Participants	
Participants (% Females)	50 (100%)
Exp (n) / Control (n)	25 / 25
Lost at followup	5
Analysed exp. group	22 with mean age 68,4 (SD 3,4; range n.a. - n.a.)
Analysed control group	23 subjects with mean age 68,3 (SD 3,6; range n.a. - n.a.)
Risk for	
Number of arms analysed / Total	2 / 2
Intervention	Mixed exercises: Stretching (9min), strength (10 min), weight-bearing (23min) intensity 65%-70% of the maximal heart rate, balance and posture correction (18m)
	Delivered by: n.a.
	Intensity level: Moderate
	Weekly minutes: 180
	Setting:
Control	No intervention
Compliance	n.a.
Outcomes and Results	Fallers RR 1,04 95% CI 0,3; 3,65
Follow-up (months)	11
Sensibility analyses	No

First author, year	Reinsch 1992
Country	US
Participants	
Participants (% Females)	230 (80%)
Exp (n) / Control (n)	129 / 101
Lost at followup	0
Analysed exp. group	129 with mean age 73,9 (SD 6,7; range n.a. - n.a.)
Analysed control group	101 subjects with mean age 74,9 (SD 5,8; range n.a. - n.a.)
Risk for	
Number of arms analysed / Total	2 / 4
Intervention	Multicomponent interventions: Exercises "stand-up/step-up" procedures: low-intensity exercises program to improve strength and balance, stretching and movement to music + cognitive intervention
	Delivered by: n.a.
	Intensity level: Low
	Weekly minutes: 180
	Setting:
Control	Counselling: Cognitive intervention + discussion
Compliance	more than 70% of people were compliance with intervention
Outcomes and Results	Fallers RR 1,28 95% CI 0,9; 1,83
Follow-up (months)	12
Sensibility analyses	Yes
First author, year	Robertson 2001
Country	New Zealand

Participants	
Participants (% Females)	240 (67,5%)
Exp (n) / Control (n)	121 / 119
Lost at followup	29
Analysed exp. group	113 with mean age 80,8 (SD 3,8; range n.a. - n.a.)
Analysed control group	98 subjects with mean age n.a. (SD n.a.; range n.a. - n.a.)
Risk for	light impairment on mobility
Number of arms analysed / Total	2 / 2
Intervention	Mixed exercises: Muscle strenght, balance retraining exercise, walking
	Delivered by: Instructor
	Intensity level: Moderate
	Weekly minutes: 90
	Setting: Home
Control	Usual care
Compliance	113 (int) and 98 (ctrl) completed the trial
Outcomes and Results	Fallers RR 0,73 95% CI 0,53; 1,02
	Falls RR 0,54 95% CI 0,32; 0,9
	Persons sustaining a fracture for fall RR 0,28 95% CI 0,06; 1,32
Follow-up (months)	12
Sensibility analyses	Yes

First author, year	Steadman 2003
Country	UK
Participants	
Participants (% Females)	198 (17,68%)
Exp (n) / Control (n)	96 / 102
Lost at followup	0
Analysed exp. group	96 with mean age n.a. (SD n.a.; range n.a. - n.a.)
Analysed control group	102 subjects with mean age n.a. (SD n.a.; range n.a. - n.a.)
Risk for	
Number of arms analysed / Total	2 / 2
Intervention	Gait, balance, co-ordination and functional task ecxercises: functional and balance training
	Delivered by: Physiotherapist
	Intensity level: Moderate
	Weekly minutes: 90
	Setting: Clinical gym and other
Control	Mixed exercises: assisted walking within parallel bars, assessment for mobility aids, stair practice, general bed mobility skills, and transfers.
	Intensity level: Moderate
	Weekly minutes: 90
	Setting: Clinical gym and other
Compliance	not reported
Outcomes and Results	Falls RR 1 95% CI 0,64; 1,57

Follow-up (months)	6
Sensibility analyses	No

First author, year	Suzuki 2004
Country	Japan
Participants	
Participants (% Females)	52 (100%)
Exp (n) / Control (n)	28 / 24
Lost at followup	8
Analysed exp. group	22 with mean age 77,68 (SD 3,41; range n.a. - n.a.)
Analysed control group	22 subjects with mean age 78,45 (SD 4,42; range n.a. - n.a.)
Risk for	
Number of arms analysed / Total	2 / 2
Intervention	Mixed exercises: Group-based strength, balance and gait training plus home practice
	Delivered by: n.a.
	Intensity level: Low
	Weekly minutes: 180
	Setting: Multiple setting
Control	Advice, information: advice and information
Compliance	attendance ranged from 64 - 86%, with a mean of 75%.
Outcomes and Results	Falls RR 0,35 95% CI 0,14; 0,88
Follow-up (months)	20
Sensibility analyses	No

First author, year	Voukelatos 2007
Country	Australia
Participants	
Participants (% Females)	702 (84,05%)
Exp (n) / Control (n)	353 / 349
Lost at followup	18
Analysed exp. group	347 with mean age n.a. (SD n.a.; range n.a. - n.a.)
Analysed control group	337 subjects with mean age n.a. (SD n.a.; range n.a. - n.a.)
Risk for	previous falls
Number of arms analysed / Total	2 / 2
Intervention	3D: tai chi
	Delivered by: Instructor
	Intensity level: Low
	Weekly minutes: 60
	Setting: Gym, swimming pool and other
Control	Usual care
Compliance	6,76+12,81 dropout
Outcomes and Results	Falls RR 0,67 95% CI 0,46; 0,97
Follow-up (months)	6
Sensibility analyses	Yes

First author, year	Weerdesteyn 2006
Country	The Netherlands
Participants	
Participants (% Females)	113 (76,99%)
Exp (n) / Control (n)	79 / 28
Lost at followup	49
Analysed exp. group	30 with mean age 73,2 (SD 6,2; range n.a. - n.a.)
Analysed control group	28 subjects with mean age 74,9 (SD 6,5; range n.a. - n.a.)
Risk for	previous falls
Number of arms analysed / Total	2 / 2
Intervention	Gait, balance, co-ordination and functional task ecxercises: RCT observed 3 arms, but one is not randomised so we excluded it from this review (EX1 group). We included only EX2 group: Balance and gait exercises with obstacles avoidance with visual costraints
	Delivered by: n.a.
	Intensity level: Low
	Weekly minutes: 450
	Setting: Clinical gym and other
Control	Usual care
Compliance	87% exercise groups. 51% attended all sessions.
Outcomes and Results	Fallers RR 1,04 95% CI 0,52; 2,15
	Falls RR 0,53 95% CI 0,28; 1
Follow-up (months)	7
Sensibility analyses	No

First author, year	Wolf 1996
Country	US
Participants	
Participants (% Females)	200 (81%)
Exp (n) / Control (n)	136 / 64
Lost at followup	13
Analysed exp. group	72 subjects in Wolf 1996a and 64 subjects in Wolf 1996b with mean age 76,9 (SD 4,8), 76,3 (SD 5,1), respectively
Analysed control group	64 subjects with mean age 75,4 (SD 4,1)
Risk for	frails, previous falls
Number of arms analysed / Total	3 / 3
Intervention	
Wolf 1996a	3D: group-based tai chi
	Delivered by: Instructor
	Intensity level: Low
	Weekly minutes: 90
	Setting: Gym, swimming pool and other
Wolf 1996b	Gait, balance, co-ordination and functional task ecxercises: Individual, computerised balance training on force platform

	Delivered by: n.a.
	Intensity level: Low
	Weekly minutes: 45
	Setting: Home
Control	Education: education
Compliance	6/72 dropped out, 92% retention
Outcomes and Results	Falls Int.a vs. Ctrl RR 0,62 95% CI 0,39; 0,97; Int.b vs. Ctrl RR 0,99 95% CI 0,67; 1,47; Int.a vs. Int.b (Wolf 1996c) RR 0,63 95% CI 0,44; 0,9
Follow-up (months)	8
Sensibility analyses	No

First author, year	Woo 2007
Country	China
Participants	
Participants (% Females)	180 (50%)
Exp (n) / Control (n)	117 / 59 with mean age 69 (SD 2.6)
Lost at followup	59
Analysed exp. group	58 subjects in Woo 2007a, 59 subjects in Woo 2007b
Analysed control group	59 subjects
Risk for	
Number of arms analysed / Total	3 / 3
Intervention	
Woo 2007a	3D: tai chi yang style group-based
	Delivered by: n.a.
	Intensity level: Low
	Weekly minutes: not reported
	Setting: not reported
Woo 2007b	Strength and resistance: resistance training group: a theraband of medium strength for 30 times: arm lifting, hip abduction, heel raise, hip flexion, hip extension, squatting ankle dorsiflexion
	Delivered by: n.a.
	Intensity level: Low
	Weekly minutes: not reported
	Setting: not reported
Control	Usual care
Compliance	81%- 76%
Outcomes and Results	Fallers Int.a vs. Ctrl RR 0,49 95% CI 0,27; 0,9; Int.b vs. Ctrl RR 0,77 95% CI 0,47; 1,26; Int.a vs. Int.b (Woo 2007c) RR 0,63 95% CI 0,37; 1,06
Follow-up (months)	12
Sensibility analyses	No

First author, year	Wu 2010a
Country	US
Participants	
Participants (% Females)	64 (85,94%)
Exp (n) / Control (n)	44 / 20
Lost at followup	22
Analysed exp. group	22 with mean age 75,4 (SD 7; range n.a. - n.a.)
Analysed control group	20 subjects with mean age 75,9 (SD 6,3; range n.a. - n.a.)
Risk for	previous falls
Number of arms analysed / Total	3 / 3
Intervention	3D: tai chi delivered by videoconference (Tel-ex) yang style, home-based iuntercated by TV screen, supervision in real time
Woo 2007a	Delivered by: Instructor
	Intensity level: Low
	Weekly minutes: 180
	Setting: Home
Woo 2007b	3D: tai chi in live (Comm-ex): group-based yang style (classes)
	Intensity level: Low
	Weekly minutes: 180
	Setting: not reported
Control	3D: tai chi delivered by DVD (Home-ex) yang style
	Intensity level: Low
	Weekly minutes: 180
	Setting: Home
Compliance	total exercise time 30 ± 12 hours (69 ±27%)
Outcomes and Results	Falls Int.a vs. Int.b RR 1,36 95% CI 0,23; 8,11; Int.a vs. Ctrl RR 0,5 95% CI 0,12; 2,2
Follow-up (months)	15
Sensibility analyses	No

First author, year	Yoo 2010
Country	South Korea
Participants	
Participants (% Females)	21 (100%)
Exp (n) / Control (n)	11 / 19
Lost at followup	9
Analysed exp. group	11 with mean age 70,9 (SD 2,7; range n.a. - n.a.)
Analysed control group	10 subjects with mean age 71,1 (SD 2,7; range n.a. - n.a.)
Risk for	hypertensive, overweight
Number of arms analysed / Total	2 / 2
Intervention	Endurance: strenght/resistance walking exercise program
	Delivered by: Instructor
	Intensity level: Low

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	Weekly minutes: 180
	Setting: Gym, swimming pool and other
Control	Usual care
Compliance	n.a.
Outcomes and Results	Fear of falling (higher score indicate less fear) SMD 0,94 95% CI 0,02; 1,86
Follow-up (months)	3
Sensibility analyses	no

First author, year	Zhang 2006
Country	China
Participants	
Participants (% Females)	49 (46,94%)
Exp (n) / Control (n)	25 / 24
Lost at followup	2
Analysed exp. group	24 with mean age 70,2 (SD 3,6; range n.a. - n.a.)
Analysed control group	23 subjects with mean age 70,6 (SD 4,9; range n.a. - n.a.)
Risk for	previous falls
Number of arms analysed / Total	2 / 2
Intervention	3D: tai chi
	Delivered by: Instructor
	Intensity level: Low
	Weekly minutes: 420
	Setting: Outdoor spaces
Control	Usual care
Compliance	90%
Outcomes and Results	Fear of falling (higher score indicate less fear) SMD 0,59 95% CI 0; 1,18
Follow-up (months)	2
Sensibility analyses	No

Appendix B

Table B.1- Healthy people: meta-analysis by subgroups for fall
Meta-analysis was performed with a random effect using an estimate of Rate Ratio (RR) extracted from Cochrane SRs included (with their 95% CI).

	Comparisons	Estimate *	95% CI	I2 (%)	p-value
All types of exercises	**17**	**0.69**	**0.55; 0.86**	**67.9**	**0.000****
Mixed exercises					
Overall	7	0.80	0.64; 1.01	37.1	0.061
By follow-up					
Over 12-months	4	0.75	0.62; 0.92	0.0	0.006**
Until 12-months	3	0.96	0.51; 1.79	69.9	0.896
By weekly minutes					
<150	5	0.88	0.62; 1.25	47.8	0.480
>150	2	0.73	0.57; 0.93	0.0	0.010**
Strength and resistance					
Overall	4	0.6	0.37; 0.99	71.0	0.046**
By weekly minutes					
<150	3	0.82	0.65; 1.04	0.0	0.103
>150	1	0.28	0.15; 0.54		0.000**
Multicomponent					
Overall	2	0.54	0.16; 1.82	81.5	0.318
Flexibility					
Overall	1	0.75	0.26; 2.16		0.594
3D					
Overall	2	0.31	0.06; 1.52	93.2	0.148
GBCFT					
Overall	1	1.42	0.70; 2.88	-	0.33

* Rate Ratio; ** statistically significant.

Table B.2- Healthy people: meta-analysis by subgroups for people who fallen

Meta-analysis was performed with a random effect using an estimate of Risk Ratio (RR) extracted from Cochrane SRs included (with their 95% CI).

	Comparisons	Estimate	95% CI	I2 (%)	p-value
All types of exercises	**12**	**0.82**	**0.65; 1.03**	**41.5**	**0.065**
Mixed exercises					
Overall	8	0.74	0.58; 0.96	35.8	0.023**
By follow-up					
Over 12-months	4	0.69	0.53; 0.90	0.0	0.007**
Until 12-months	4	0.82	0.46; 1.46	65.7	0.499
By weekly minutes					
<150	5	0.85	0.63; 1.14	41.0	0.267
>150	3	0.51	0.34; 0.77	0.0	0.001**
Multicomponent					
Overall	2	1.21	0.89; 1.66	0.0	0.221
Flexibility					
Overall	1	0.57	0.2; 1.64	-	0.296
3D					
Overall	1	0.52	0.02; 12.87	-	0.690

* Risk Ratio; ** statistically significant.

Table B.3- Healthy people: meta-analysis by subgroups for persons sustaining a fracture for a fall

Meta-analysis was performed with a random effect using an estimate of Risk Ratio (RR) extracted from Cochrane SRs included (with their 95% CI).

	Comparisons	Estimate	95% CI	I2 (%)	p-value
All types of exercises	**7**	**0.65**	**0.43; 0.98**	**10.5**	**0.349**
Mixed exercises					
Overall	5	0.55	0.31; 1.00	33.7	0.051
By follow-up					
Over 12-months	2	0.62	0.27; 1.44	71.0	0.263
Until 12-months	3	0.31	0.09; 1.00	0.0	0.051
By weekly minutes					
<150	2	0.26	0.07; 1.02	0.0	0.053
>150	3	0.64	0.33; 1.22	44.0	0.176
Strength and resistance					
Overall	2	0.66	0.12; 3.46	0.0	0.619

* Risk Ratio

Figure B.4- Meta-analysis of bias: funnel plot for falls by types of exercises

Funnel plot by intervention types

Legend:
- ● 3D
- ▲ GBCFT ecxercises
- ■ Strength and resistance
- ◆ Flexibility
- + Mixed exercises
- × Multicomponent interventions
- − − − Lower CI
- − − − Upper CI
- ——— Pooled estimate
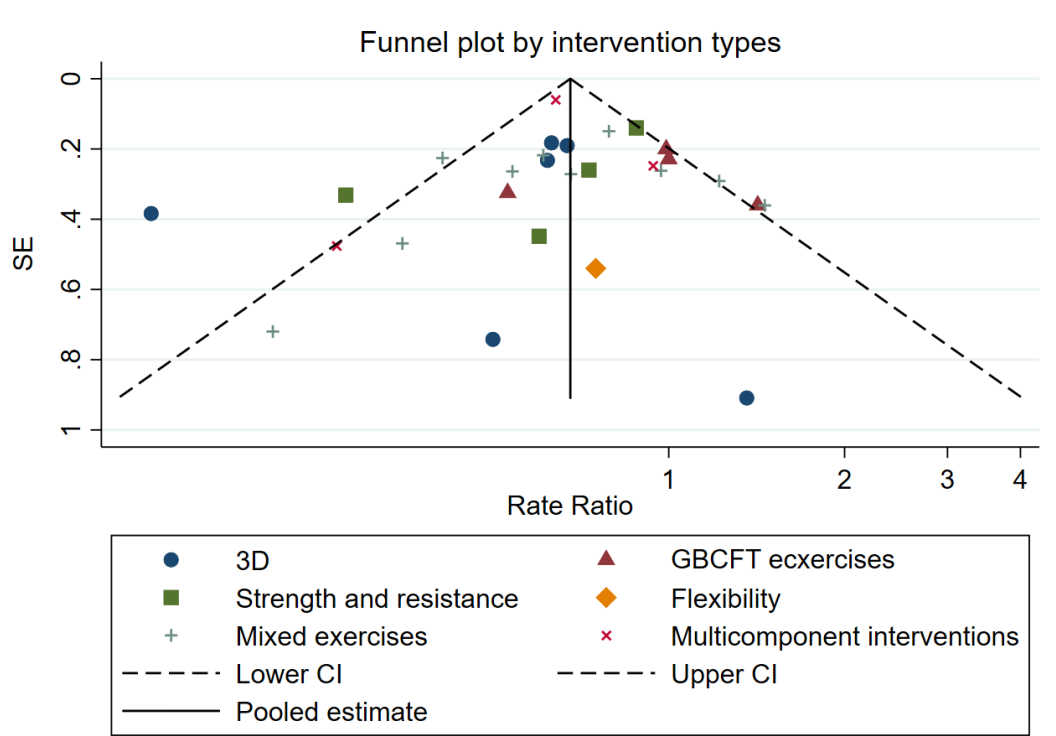
Figure B.5- Meta-analysis of bias: funnel plot for people who fallen by types of exercises

Funnel plot by intervention types

Legend:
- ● 3D
- ▲ GBCFT ecxercises
- ■ Strength and resistance
- ◆ Flexibility
- + Mixed exercises
- × Multicomponent interventions
- − − − Lower CI
- − − − Upper CI
- ——— Pooled estimate
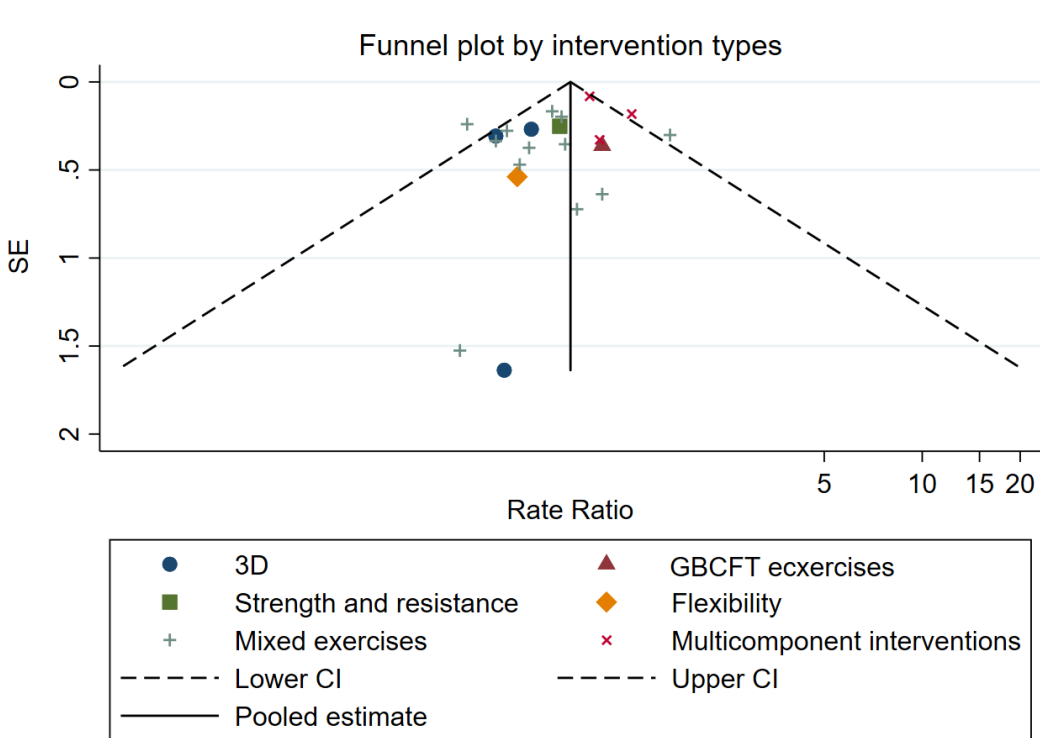
Figure B.6- Meta-analysis of bias: funnel plot for persons sustaining a fall-related fracture by types of exercises

Funnel plot by intervention types

● GBCFT exercises	▲ Strength and resistance
■ Mixed exercises	◆ Multicomponent interventions
− − − Lower CI	− − − Upper CI
──── Pooled estimate	
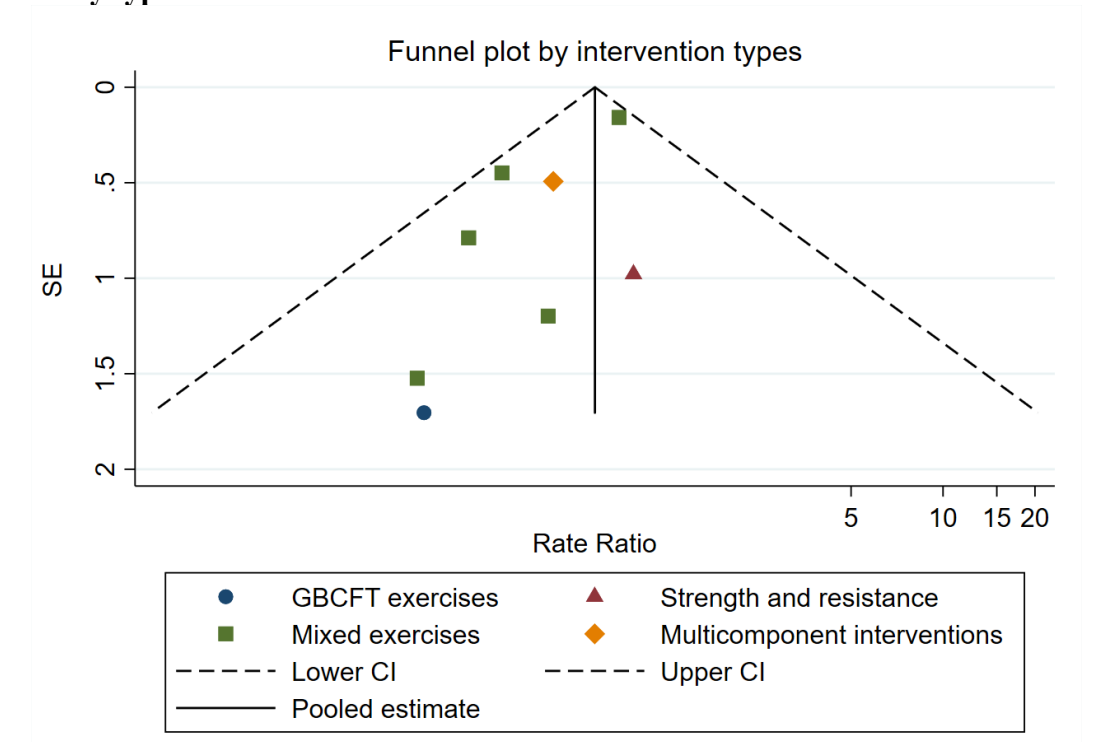
Figure B.7- Meta-analysis of bias: funnel plot for fear of falling by types of exercises

Funnel plot by intervention types

● 3D	▲ GBCFT exercises
■ Strength and resistance	◆ Endurance
+ Mixed exercises	− − − Lower CI
− − − Upper CI	──── Pooled estimate
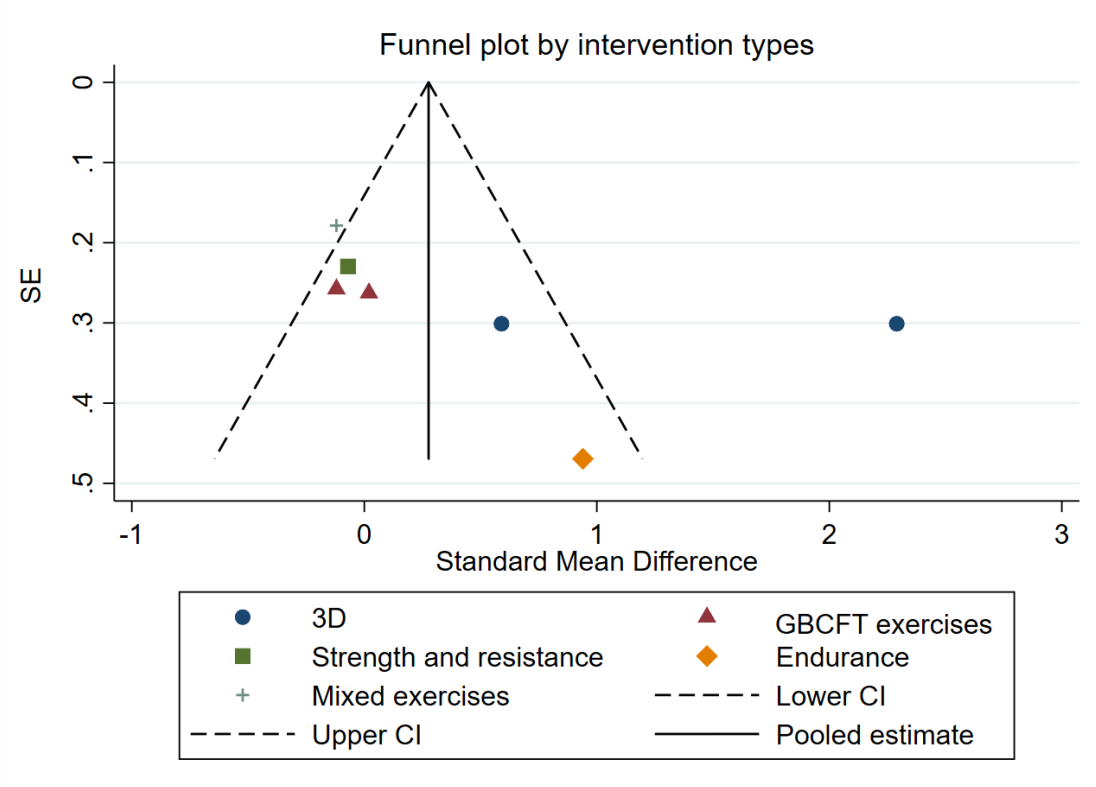
APPENDICES CHAPTER 8

APPENDIX 1 – Search strategy

Guidelines

Society	Website
Canadian Task Force on the Periodic Health Examination	https://canadiantaskforce.ca/guidelines/published-guidelines/
The Community Guide U.S.A. Preventive Task Force (CGPTF)	https://www.thecommunityguide.org/publications
U.S. Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.org/BrowseRec/Index
U.S. Agency for Healthcare Research and Quality (AHRQ)	https://www.ahrq.gov/research/publications/search.html
Scottish Intercollegiate Guideline Network (SIGN)	https://www.sign.ac.uk/our-guidelines.html
Centre for Evidence Based Medicine (CEBM) di Oxford	https://www.cebm.net/category/prevention/
The National Institute for Health and Care Excellence (NICE)	https://www.nice.org.uk/guidance/published?type=ap g,csg,cg,mpg,ph,sg,sc,dg,hst,ipg,mtg,qs,ta
Canadian Medical Association Infobase	https://joulecma.ca/cpg/homepage
New Zealand Guidelines Group	https://www.health.govt.nz/publications
Haute Autorité de Santé	https://www.has-sante.fr/jcms/fc_2875208/fr/rechercher-une-recommandation-un-avis?
Istituto Superiore di Sanità (ISS)	http://old.iss.it/publ/
U.S. Department of Health and Human Services (HHS)	https://www.hhs.gov/
Registered Nurses' Association of Ontario (RNAO)	https://rnao.ca/bpg/guidelines
World Health Organization (WHO)	https://www.who.int/ageing/publications/current/en/

PICO	#	Query	Results
POPULATION	1	("Aged"[Mesh]OR"Elderly"[Text word]OR"Aged, 80 and over"[Mesh]OR"Oldest Old"[Text word]OR"Nonagenarians"[Text word]OR"Nonagenarian"[Text word]OR"Octogenarian"[Text word]OR"Octogenarians"[Text word]OR"Centenarians"[Text word]OR"Centenarian"[Text word]OR"Frail Elderly"[Mesh]OR"Elderly, Frail"[Text word]OR"Frail Elders"[Text word]OR"Elder, Frail"[Text word]OR"Elders, Frail"[Text word]OR"Frail Elder"[Text word]OR"Functionally-Impaired Elderly"[Text word]OR"Elderly, Functionally-Impaired"[Text word]OR"Functionally Impaired Elderly"[Text word]OR"Frail Older Adults"[Text word]OR"Adult, Frail Older"[Text word]OR"Adults, Frail Older"[Text word]OR"Frail Older Adult"[Text word]OR"Older Adult, Frail"[Text word]OR"Older Adults, Frail"[Text word])	3029830
INTERVENTION	2	("Tai Ji"[Mesh]OR"Tai-ji"[Text word]OR"Tai Chi"[Text word]OR"Chi, Tai"[Text word]OR"Tai Ji Quan"[Text word]OR"Ji Quan, Tai"[Text word]OR"Quan, Tai Ji"[Text word]OR"Taiji"[Text word]OR"Taijiquan"[Text word]OR"T'ai Chi"[Text word]OR"Tai Chi Chuan"[Text word])	1774
	3	("Exercise Therapy"[Mesh]OR"Remedial Exercise"[Text word]OR"Exercise, Remedial"[Text word]OR"Exercises, Remedial"[Text word]OR"Remedial Exercises"[Text word]OR"Therapy, Exercise"[Text word]OR"Exercise Therapies"[Text word]OR"Therapies, Exercise"[Text word]OR"Rehabilitation Exercise"[Text word]OR"Exercise, Rehabilitation"[Text word]OR"Exercises, Rehabilitation"[Text word]OR"Rehabilitation Exercises"[Text word])	48107
	4	("Endurance Training"[Mesh]OR"Training, Endurance"[Text word]OR "Motion Therapy, Continous Passive"[Mesh]OR"Movement Therapy, Continuous Passive"[Text word]OR"Passive Movement Therapy, Continuous"[Text word]OR"Continuous Passive Motion Therapy"[Text word]OR"Passive Motion Therapy, Continuous"[Text word]OR"Continuous Passive Movement Therapy"[Text word]OR"CPM Therapy"[Text word]OR"CPM Therapies"[Text word]OR"Therapies, CPM"[Text word]OR"Therapy, CPM"[Text word]OR"Muscle Stretching Exercises"[Mesh]OR"Exercise, Muscle Stretching"[Text word]OR"Exercises, Muscle Stretching"[Text word]OR"Muscle Stretching Exercise"[Text word]OR"Static Stretching"[Text word]OR	13802

| | | "Stretching, Static"[Text word]OR"Passive Stretching"[Text word]OR "Stretching, Passive"[Text word]OR"Relaxed Stretching"[Text word]OR "Stretching, Relaxed"[Text word]OR"Static-Passive Stretching"[Text word]OR"Static Passive Stretching"[Text word]OR"Stretching, Static-Passive"[Text word]OR"Isometric Stretching"[Text word]OR"Stretching, Isometric"[Text word]OR"Active Stretching"[Text word]OR"Stretching, Active"[Text word]OR"Static-Active Stretching"[Text word]OR"Static Active Stretching"[Text word]OR"Stretching, Static-Active"[Text word]OR"Ballistic Stretching"[Text word]OR"Stretching, Ballistic"[Text word]OR"Dynamic Stretching"[Text word]OR"Stretching, Dynamic"[Text word]OR"Proprioceptive Neuromuscular Facilitation (PNF) Stretching"[Text word]OR"Plyometric Exercise"[Mesh]OR"Exercise, Plyometric"[Text word]OR"Exercises, Plyometric"[Text word]OR"Plyometric Exercises"[Text word]OR"Plyometric Drill"[Text word]OR"Drill, Plyometric"[Text word]OR"Drills, Plyometric"[Text word]OR"Plyometric Drills"[Text word]OR"Plyometric Training"[Text word]OR"Plyometric Trainings"[Text word]OR"Training, Plyometric"[Text word]OR"Trainings, Plyometric"[Text word]OR"Stretch-Shortening Exercise"[Text word]OR"Exercise, Stretch-Shortening"[Text word]OR"Exercises, Stretch-Shortening"[Text word]OR"Stretch Shortening Exercise"[Text word]OR"Stretch-Shortening Exercises"[Text word]OR"Stretch-Shortening Cycle Exercise"[Text word]OR"Cycle Exercise, Stretch-Shortening"[Text word]OR"Cycle Exercises, Stretch-Shortening"[Text word]OR"Exercise, Stretch-Shortening Cycle"[Text word]OR"Exercises, Stretch-Shortening Cycle"[Text word]OR"Stretch Shortening Cycle Exercise"[Text word]OR"Stretch-Shortening Cycle Exercises"[Text word]OR"Stretch-Shortening Drill"[Text word]OR"Drill, Stretch-Shortening"[Text word]OR"Drills, Stretch-Shortening"[Text word]OR"Stretch Shortening Drill"[Text word]OR"Stretch-Shortening Drills"[Text word]OR"Resistance Training"[Mesh]OR"Training, Resistance"[Text word]OR"Strength Training"[Text word]OR"Training, Strength"[Text word]OR"Weight-Lifting Strengthening Program"[Text word]OR"Strengthening Program, Weight-Lifting"[Text word]OR"Strengthening Programs, Weight-Lifting"[Text word]OR"Weight Lifting Strengthening Program"[Text word]OR"Weight-Lifting Strengthening Programs"[Text word]OR"Weight-Lifting Exercise Program"[Text word]OR"Exercise Program, Weight-Lifting"[Text word]OR"Exercise Programs, Weight-Lifting"[Text word]OR"Weight Lifting Exercise Program"[Text | |

		word]OR"Weight-Lifting Exercise Programs"[Text word]OR"Weight-Bearing Strengthening Program"[Text word]OR"Strengthening Program, Weight-Bearing"[Text word]OR"Strengthening Programs, Weight-Bearing"[Text word]OR"Weight Bearing Strengthening Program"[Text word]OR"Weight-Bearing Strengthening Programs"[Text word]OR"Weight-Bearing Exercise Program"[Text word]OR"Exercise Program, Weight-Bearing"[Text word]OR"Exercise Programs, Weight-Bearing"[Text word]OR"Weight Bearing Exercise Program"[Text word]OR"Weight-Bearing Exercise Programs"[Text word])	
	5	2 OR 3 OR 4 OR	53410
OUTCOME	6	("Accidental Falls"[Mesh]OR"Accidental Fall"[Text word]OR"Falls"[Text word]OR"Fall"[Text word]OR"Falling"[Text word]OR"Falls, Accidental"[Text word]OR"Fall Accidental"[Text word]OR"Slip and Fall"[Text word]OR"Fall and Slip"[Text word]OR"Slips and Falls"[Text word]OR"Falls and slips"[Text word]OR"Slips"[Text word]OR"Slip"[Text word])	175566
	7	("Fractures, Bone"[Mesh]OR"Broken Bones"[Text word]OR"Bone, Broken"[Text word]OR"Bones, Broken"[Text word]OR"Broken Bone"[Text word]OR"Bone Fractures"[Text word]OR"Bone Fracture"[Text word]OR"Fracture, Bone"[Text word]OR"Spiral Fractures"[Text word]OR"Fracture, Spiral"[Text word]OR"Fractures, Spiral"[Text word]OR"Spiral Fracture"[Text word]OR"Torsion Fractures"[Text word]OR"Fracture, Torsion"[Text word]OR"Fractures, Torsion"[Text word]OR"Torsion Fracture"[Text word])	181750
	8	("Fear"[Mesh]OR"Fear of Fall"[Text word]OR"Fear of Falls"[Text word]OR"Fear of Falling"[Text word]OR"Prevention"[Mesh]OR"Fall Prevention"[Text word]OR"Falls Prevention"[Text word]OR"Prevention of Falls"[Text word]OR"Prevention of Fall"[Text word]OR"Prevention of Falling"[Text word])	35755
	9	6 OR 7 OR 8	378882
	13	1 AND 5 AND 10	1721
	14	Filters "Humans"	2181
	15	Publication date from 08/02/2018	131

PubMed – RCT 23/07/2019

PICO	#	Query	Results
POPULATION	1	("Aged"[Mesh]OR"Elderly"[Text word]OR"Aged, 80 and over"[Mesh]OR"Oldest Old"[Text word]OR"Nonagenarians"[Text word]OR"Nonagenarian"[Text word]OR"Octogenarian"[Text word]OR"Octogenarians"[Text word]OR"Centenarians"[Text word]OR"Centenarian"[Text word]OR"Frail Elderly"[Mesh]OR"Elderly, Frail"[Text word]OR"Frail Elders"[Text word]OR"Elder, Frail"[Text word]OR"Elders, Frail"[Text word]OR"Frail Elder"[Text word]OR"Functionally-Imapaired Elderly"[Text word]OR"Elderly, Functionally-Impaired"[Text word]OR"Functionally Impaired Elderly"[Text word]OR"Frail Older Adults"[Text word]OR"Adult, Frail Older"[Text word]OR"Adults, Frail Older"[Text word]OR"Frail Older Adult"[Text word]OR"Older Adult, Frail"[Text word]OR"Older Adults, Frail"[Text word])	3012205
INTERVENTION	2	("Tai Ji"[Mesh]OR"Tai-ji"[Text word]OR"Tai Chi"[Text word]OR"Chi, Tai"[Text word]OR"Tai Ji Quan"[Text word]OR"Ji Quan, Tai"[Text word]OR"Quan, Tai Ji"[Text word]OR"Taiji"[Text word]OR"Taijiquan"[Text word]OR"T'ai Chi"[Text word]OR"Tai Chi Chuan"[Text word])	1743
	3	("Exercise Therapy"[Mesh]OR"Remedial Exercise"[Text word]OR"Exercise, Remedial"[Text word]OR"Exercises, Remedial"[Text word]OR"Remedial Exercises"[Text word]OR"Therapy, Exercise"[Text word]OR"Exercise Therapies"[Text word]OR"Therapies, Exercise"[Text word]OR"Rehabilitation Exercise"[Text word]OR"Exercise, Rehabulitation"[Text word]OR"Exercises, Rehabilitation"[Text word]OR"Rehabilitation Exercises"[Text word])	47289
	4	("Endurance Training"[Mesh]OR"Training, Endurance"[Text word]OR "Motion Therapy, Continous Passive"[Mesh]OR"Movement Therapy, Continuous Passive"[Text word]OR"Passive Movement Therapy, Continuous"[Text word]OR"Continuous Passive Motion Therapy"[Text word]OR"Passive Motion Therapy, Continuous"[Text word]OR"Continuous Passive Movement Therapy"[Text word]OR"CPM Therapy"[Text word]OR"CPM Therapies"[Text word]OR"Therapies, CPM"[Text word]OR"Therapy, CPM"[Text word]OR"Muscle Stretching Exercises"[Mesh]OR"Exercise, Muscle Stretching"[Text word]OR"Exercises, Muscle Stretching"[Text word]OR "Muscle Stretching Exercise"[Text word]OR"Static Stretching"[Text word]OR	13609

203

| | | “Stretching, Static”[Text word]OR“Passive Stretching”[Text word]OR “Stretching, Passive”[Text word]OR“Relaxed Stretching”[Text word]OR “Stretching, Relaxed”[Text word]OR“Static-Passive Stretching”[Text word]OR “Static Passive Stretching”[Text word]OR“Stretching, Static-Passive”[Text word]OR “Isometric Stretching”[Text word]OR “Stretching, Isometric”[Text word]OR “Active Stretching”[Text word]OR “Stretching, Active”[Text word]OR “Static-Active Stretching”[Text word]OR “Static Active Stretching”[Text word]OR“Stretching, Static-Active”[Text word]OR“Ballistic Stretching”[Text word]OR“Stretching, Ballistic”[Text word]OR“Dynamic Stretching”[Text word]OR“Stretching, Dynamic”[Text word]OR“Proprioceptive Neuromuscular Facilitation (PNF) Stretching”[Text word]OR“Plyometric Exercise”[Mesh]OR“Exercise, Plyometric”[Text word]OR“Exercises, Plyometric”[Text word]OR“Plyometric Exercises”[Text word]OR“Plyometric Drill”[Text word]OR“Drill, Plyometric”[Text word]OR“Drills, Plyometric”[Text word]OR“Plyometric Drills”[Text word]OR“Plyometric Training”[Text word]OR“Plyometric Trainings”[Text word]OR“Training, Plyometric”[Text word]OR“Trainings, Plyometric”[Text word]OR“Stretch-Shortening Exercise”[Text word]OR“Exercise, Stretch-Shortening”[Text word]OR“Exercises, Stretch-Shortening”[Text word]OR“Stretch Shortening Exercise”[Text word]OR“Stretch-Shortening Exercises”[Text word]OR“Stretch-Shortening Cycle Exercise”[Text word]OR“Cycle Exercise, Stretch-Shortening”[Text word]OR“Cycle Exercises, Stretch-Shortening”[Text word]OR“Exercise, Stretch-Shortening Cycle”[Text word]OR“Exercises, Stretch-Shortening Cycle”[Text word]OR“Stretch Shortening Cycle Exercise”[Text word]OR“Stretch-Shortening Cycle Exercises”[Text word]OR“Stretch-Shortening Drill”[Text word]OR“Drill, Stretch-Shortening”[Text word]OR“Drills, Stretch-Shortening”[Text word]OR“Stretch Shortening Drill”[Text word]OR“Stretch-Shortening Drills”[Text word]OR“Resistance Training”[Mesh]OR“Training, Resistance”[Text word]OR“Strength Training”[Text word]OR“Training, Strength”[Text word]OR“Weight-Lifting Strengthening Program”[Text word]OR“Strengthening Program, Weight-Lifting”[Text word]OR“Strengthening Programs, Weight-Lifting”[Text word]OR“Weight Lifting Strengthening Program”[Text word]OR“Weight-Lifting Strengthening Programs”[Text word]OR“Weight-Lifting Exercise Program”[Text word]OR“Exercise Program, Weight-Lifting”[Text | |

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	5	2 OR 3 OR 4 OR	52532
OUTCOME	6	("Accidental Falls"[Mesh]OR"Falls"[Text word]OR"Falling"[Text word]OR"Falls, Accidental"[Text word]OR"Accidental Fall"[Text word]OR"Slip and Fall"[Text word]OR"Fall and Slip"[Text word]OR "Falls"[Text word]OR"Slips and Falls"[Text word]OR"Falls and slips"[Text word]OR"Accidental falls"[Text word]OR"Slips")	75783
	7	("Postural Balance"[Mesh]OR"Balance, Postural"[Text word]OR"Musculoskeletal Equilibrium"[Text word]OR"Equilibrium Musculoskeletal"[Text word]OR"Postural Equilibrium"[Text word]OR"Equilibrium, Postural"[Text word])	21549
	8	("Fractures, Bone"[Mesh]OR"Broken Bones"[Text word]OR"Bone, Broken"[Text word]OR"Bones, Broken"[Text word]OR"Broken Bone"[Text word]OR"Bone Fractures"[Text word]OR"Bone Fracture"[Text word]OR"Fracture, Bone"[Text word]OR"Spiral Fractures"[Text word]OR"Fracture, Spiral"[Text word]OR"Fractures, Spiral"[Text word]OR"Spiral Fracture"[Text word]OR"Torsion Fractures"[Text word]OR"Fracture, Torsion"[Text word]OR"Fractures, Torsion"[Text word]OR"Torsion Fracture"[Text word])	180976
	9	("Fear of Fall"[Text word]OR"Fear of Falls"[Text word]OR"Fear of falling"[Text word]OR"Fall Prevention"[Text word]OR"Falls Prevention"[Text word])	4618
	10	6 OR 7 OR 8 OR 9	267537
	13	1 AND 5 AND 10	2204
	14	Fiters "Humans"	2181
	15	Publication date from 02/05/2018	106

Cochrane Library - Review 23/07/2019

PICO	#	Query	Results
POPULATION	#1	MeSH descriptor: [Aged] explode all trees	1236
	#2	("Aged"):ti,ab,kw OR ("Elderly"):ti,ab,kw OR ("Frail Elder*"):ti,ab,kw OR ("Functionally-Impaired Elderly"):ti,ab,kw OR ("Aged, 80 and over"):ti,ab,kw	490791
	#3	#1 OR #2	490791
INTERVENTION	#4	MeSH descriptor: [Exercise Therapy] explode all trees	12092
	#5	MeSH descriptor: [Exercise Movement Techniques] explode all trees	1870
	#6	MeSH descriptor: [Sports] explode all trees	14553
	#7	("Exercise Therapy"):ti,ab,kw OR ("Exercise Movement Techniques"):ti,ab,kw OR ("Tai Chi"):ti,ab,kw OR ("Gymnastic"):ti,ab,kw OR ("Resistance Training"):ti,ab,kw	18107
	#8	#4 OR #5 OR #6 OR #7	30413
OUTCOME	#9	MeSH descriptor: [Accidental Falls] explode all trees	1334
	#10	("Accidental Fall*"):ti,ab,kw OR ("Falling"):ti,ab,kw OR ("Slip*"):ti,ab,kw OR ("Fall*"):ti,ab,kw OR ("Slip* and Fall*"):ti,ab,kw	14433
	#11	MeSH descriptor: [Fractures, Bone] explode all trees	5423
	#12	MeSH descriptor: [Fear] explode all trees	1395
	#13	("Fear of falling"):ti,ab,kw OR ("Fear of Fall*"):ti,ab,kw OR ("Fear of Falling"):ti,ab,kw OR ("Prevention of Fall*"):ti,ab,kw OR ("Prevention of Falling"):ti,ab,kw	605
	#14	MeSH descriptor: [Accident Prevention] explode all trees	3790
	#15	#9 OR #10 OR #11 OR #12 OR #13 OR #14	24865
	#16	#3 AND #10 AND #15 with Cochrane Library publication date from Feb 2018 to present, in Cochrane Reviews (Word variations have been searched)	2

Cochrane Library – RCT 23/07/2019

PICO	#	Query	Results
POPULATION	#1	MeSH descriptor: [Aged] explode all trees	1236
	#2	("Aged"):ti,ab,kw OR ("Elderly"):ti,ab,kw OR ("Frail Elder*"):ti,ab,kw OR ("Functionally-Impaired Elderly"):ti,ab,kw OR ("Aged, 80 and over"):ti,ab,kw	490791
	#3	#1 OR #2	490791
INTERVENTION	#4	MeSH descriptor: [Exercise Therapy] explode all trees	12092
	#5	MeSH descriptor: [Exercise Movement Techniques] explode all trees	1870
	#6	MeSH descriptor: [Sports] explode all trees	14553
	#7	("Exercise Therapy"):ti,ab,kw OR ("Exercise Movement Techniques"):ti,ab,kw OR ("Tai Chi"):ti,ab,kw OR ("Gymnastic"):ti,ab,kw OR ("Resistance Training"):ti,ab,kw	18107
	#8	#4 OR #5 OR #6 OR #7	30413
OUTCOME	#9	MeSH descriptor: [Accidental Falls] explode all trees	1334
	#10	("Accidental Fall*"):ti,ab,kw OR ("Falling"):ti,ab,kw OR ("Slip*"):ti,ab,kw OR ("Fall*"):ti,ab,kw OR ("Slip* and Fall*"):ti,ab,kw	14433
	#11	MeSH descriptor: [Fractures, Bone] explode all trees	5423
	#12	MeSH descriptor: [Fear] explode all trees	1395
	#13	("Fear of falling"):ti,ab,kw OR ("Fear of Fall*"):ti,ab,kw OR ("Fear of Falling"):ti,ab,kw OR ("Prevention of Fall*"):ti,ab,kw OR ("Prevention of Falling"):ti,ab,kw	605
	#14	MeSH descriptor: [Accident Prevention] explode all trees	3790
	#15	#9 OR #10 OR #11 OR #12 OR #13 OR #14	24865
	#16	#3 AND #10 AND #15 with Publication Year from 2018 to present, with Cochrane Library publication date from May 2018 to present, in Trials (Word variations have been searched)	81

Embase - Review 23/07/2019

PICO	#	Query	Results
POPULATION	#1	('aged'/exp OR 'aged':ti,ab OR 'aged patient':ti,ab OR 'aged people':ti,ab OR 'aged person':ti,ab OR 'aged subject':ti,ab OR 'elderly':ti,ab OR 'elderly patient':ti,ab OR 'elderly people':ti,ab OR 'elderly person':ti,ab OR 'elderly subject':ti,ab OR 'senior citizen':ti,ab OR 'senium':ti,ab OR 'very elderly'/exp OR 'aged, 80 and over':ti,ab OR 'centenarian':ti,ab OR 'centenarians':ti,ab OR 'nonagenarian':ti,ab OR 'nonagenarians':ti,ab OR 'octogenarian':ti,ab OR 'octogenarians':ti,ab OR 'very elderly':ti,ab OR 'very old':ti,ab OR 'frail elderly'/exp OR 'frail elderly':ti,ab OR 'older adults'/exp OR 'frail older adults':ti,ab)	
INTERVENTION	#2	('tai chi'/exp OR 'tai chi':ti,ab OR 'tai chi chuan':ti,ab OR 'tai ji':ti,ab OR 'taiji quan':ti,ab OR 'taijiquan':ti,ab OR 'kinesiotherapy'/exp OR 'exercise movement techniques':ti,ab OR 'exercise therapy':ti,ab OR 'exercise treatment':ti,ab OR 'kinesiotherapy':ti,ab OR 'kinesitherapy':ti,ab OR 'therapeutic exercise':ti,ab OR 'therapy, exercise':ti,ab OR 'treatment, exercise':ti,ab OR 'remedial exercise':ti,ab OR 'rehabilitation exercise':ti,ab OR 'exercise rehabilitation':ti,ab OR 'endurance training'/exp OR 'endurance exercise':ti,ab OR 'endurance exercise training':ti,ab OR 'endurance training':ti,ab OR 'movement therapy'/exp OR 'motion therapy':ti,ab OR 'motion therapy, continuous passive':ti,ab OR 'movement therapy':ti,ab OR 'motion therap*':ti,ab OR 'passive movement therapy':ti,ab OR 'cpm therap*':ti,ab OR 'therap* cpm':ti,ab OR 'stretching exercise'/exp OR 'muscle stretching exercises':ti,ab OR 'stretching exercise':ti,ab OR 'stretching exercises':ti,ab OR 'static stretching'/exp OR 'stretching static':ti,ab OR 'passive stretching':ti,ab OR 'stretching passive':ti,ab OR 'muscle stretching'/exp OR 'muscle stretch' OR 'muscle stretching' OR 'muscular stretch' OR 'muscular stretching' OR 'stretch, muscle' OR 'stretching, muscle' OR 'myotasis' OR 'stretching'/exp OR 'stretching':ti,ab OR 'proprioceptive neuromuscular facilitation'/exp OR 'plyometrics'/exp OR 'plyometric exercise':ti,ab OR 'plyometric training':ti,ab OR 'plyometrics':ti,ab OR 'stretch shortening':ti,ab	

		OR 'resistance training'/exp OR 'resistance exercise':ti,ab OR 'resistance exercise training':ti,ab OR 'resistance training':ti,ab OR 'strength training':ti,ab OR 'weight bearing exercise':ti,ab OR 'weight lifting'/exp OR 'lifting, weight':ti,ab OR 'weight lifting':ti,ab OR 'weight bearing'/exp OR 'load carrying':ti,ab OR 'weight bearing':ti,ab OR 'weight-bearing':ti,ab)	
OUTCOME	#3	('falling'/exp OR 'fall':ti,ab OR 'falling':ti,ab OR 'accidental falls':ti,ab OR 'falls'/exp OR 'falls accidental':ti,ab OR 'slip and fall*':ti,ab OR 'balance postural':ti,ab OR 'body equilibrium'/exp OR 'body equilibrium':ti,ab OR 'body sway':ti,ab OR 'equilibrium, body':ti,ab OR 'musculoskeletal equilibrium':ti,ab OR 'postural balance':ti,ab OR 'postural equilibrium':ti,ab OR 'fracture'/exp OR 'bone cement fracture':ti,ab OR 'bone fracture':ti,ab OR 'closed fracture':ti,ab OR 'fracture':ti,ab OR 'fractures':ti,ab OR 'fractures, bone':ti,ab OR 'fractures, closed':ti,ab OR 'skeleton fracture':ti,ab OR 'unstable fracture':ti,ab OR 'fear of falling'/exp OR 'basophobia':ti,ab OR 'fear of falling':ti,ab OR 'fear of walking':ti,ab)	
	#4	#1 AND #2 AND #3	5842
	#5	#4 AND (2018:py OR 2019py) AND 'human'de	489

Embase – RCT 23/07/2019

PICO	#	Query	Results
POPULATION	#1	('aged'/exp OR 'aged':ti,ab OR 'aged patient':ti,ab OR 'aged people':ti,ab OR 'aged person':ti,ab OR 'aged subject':ti,ab OR 'elderly':ti,ab OR 'elderly patient':ti,ab OR 'elderly people':ti,ab OR 'elderly person':ti,ab OR 'elderly subject':ti,ab OR 'senior citizen':ti,ab OR 'senium':ti,ab OR 'very elderly'/exp OR 'aged, 80 and over':ti,ab OR 'centenarian':ti,ab OR 'centenarians':ti,ab OR 'nonagenarian':ti,ab OR 'nonagenarians':ti,ab OR 'octogenarian':ti,ab OR 'octogenarians':ti,ab OR 'very elderly':ti,ab OR 'very old':ti,ab OR 'frail elderly'/exp OR 'frail elderly':ti,ab OR 'older adults'/exp OR 'frail older adults':ti,ab)	
INTERVENTION	#2	('tai chi'/exp OR 'tai chi':ti,ab OR 'tai chi chuan':ti,ab OR 'tai ji':ti,ab OR 'taiji quan':ti,ab OR 'taijiquan':ti,ab OR 'kinesiotherapy'/exp OR 'exercise movement techniques':ti,ab OR 'exercise therapy':ti,ab OR 'exercise treatment':ti,ab OR 'kinesiotherapy':ti,ab OR 'kinesitherapy':ti,ab OR 'therapeutic exercise':ti,ab OR 'therapy, exercise':ti,ab OR 'treatment, exercise':ti,ab OR 'remedial exercise':ti,ab OR 'rehabilitation exercise':ti,ab OR 'exercise rehabilitation':ti,ab OR 'endurance training'/exp OR 'endurance exercise':ti,ab OR 'endurance exercise training':ti,ab OR 'endurance training':ti,ab OR 'movement therapy'/exp OR 'motion therapy':ti,ab OR 'motion therapy, continuous passive':ti,ab OR 'movement therapy':ti,ab OR 'motion therap*':ti,ab OR 'passive movement therapy':ti,ab OR 'cpm therap*':ti,ab OR 'therap* cpm':ti,ab OR 'stretching exercise'/exp OR 'muscle stretching exercises':ti,ab OR 'stretching exercise':ti,ab OR 'stretching exercises':ti,ab OR 'static stretching'/exp OR 'stretching static':ti,ab OR 'passive stretching':ti,ab OR 'stretching passive':ti,ab OR 'muscle stretching'/exp OR 'muscle stretch' OR 'muscle stretching' OR 'muscular stretch' OR 'muscular stretching' OR 'stretch, muscle' OR 'stretching, muscle' OR 'myotasis' OR 'stretching'/exp OR 'stretching':ti,ab OR 'proprioceptive neuromuscular facilitation'/exp OR 'plyometrics'/exp OR 'plyometric exercise':ti,ab OR 'plyometric training':ti,ab OR 'plyometrics':ti,ab OR 'stretch shortening':ti,ab	

		OR 'resistance training'/exp OR 'resistance exercise':ti,ab OR 'resistance exercise training':ti,ab OR 'resistance training':ti,ab OR 'strength training':ti,ab OR 'weight bearing exercise':ti,ab OR 'weight lifting'/exp OR 'lifting, weight':ti,ab OR 'weight lifting':ti,ab OR 'weight bearing'/exp OR 'load carrying':ti,ab OR 'weight bearing':ti,ab OR 'weight-bearing':ti,ab)	
OUTCOME	#3	('falling'/exp OR 'fall':ti,ab OR 'falling':ti,ab OR 'accidental falls':ti,ab OR 'falls'/exp OR 'falls accidental':ti,ab OR 'slip and fall*':ti,ab OR 'balance postural':ti,ab OR 'body equilibrium'/exp OR 'body equilibrium':ti,ab OR 'body sway':ti,ab OR 'equilibrium, body':ti,ab OR 'musculoskeletal equilibrium':ti,ab OR 'postural balance':ti,ab OR 'postural equilibrium':ti,ab OR 'fracture'/exp OR 'bone cement fracture':ti,ab OR 'bone fracture':ti,ab OR 'closed fracture':ti,ab OR 'fracture':ti,ab OR 'fractures':ti,ab OR 'fractures, bone':ti,ab OR 'fractures, closed':ti,ab OR 'skeleton fracture':ti,ab OR 'unstable fracture':ti,ab OR 'fear of falling'/exp OR 'basophobia':ti,ab OR 'fear of falling':ti,ab OR 'fear of walking':ti,ab)	
	#4	#1 AND #2 AND #3	5842
	#5	#4 AND (2018:py OR 2019py) AND 'human'de	404

PEDro - Review 23/07/2019

PICO	#	Query	Results
POPULATION	# 1	Subdiscipline ("Gerontology")	
INTERVENTI ON	# 2	Therapy ("stretching, mobilisation, manipulation, massage" OR "strength training" OR "skill training" OR "fitness training")	
OUTCOM E	# 3	Abstract & Title ("Accidental fall*" OR "Fall* prevention" OR "Fall*" OR "Slip*" OR "Fear*" OR "Fear of falling" OR "Fracture*")	
	# 4	Published since ("2018")	
	# 5	#1 AND #2 AND #3 AND #4	167

PEDro – RCT 23/07/2019

PICO	#	Query	Results
POPULATION	# 1	Subdiscipline ("Gerontology")	
INTERVENTI ON	# 2	Therapy ("stretching, mobilisation, manipulation, massage" OR "strength training" OR "skill training" OR "fitness training")	
OUTCOM E	# 3	Abstract & Title ("Accidental fall*" OR "Fall* prevention" OR "Fall*" OR "Slip*" OR "Fear*" OR "Fear of falling" OR "Fracture*")	
	# 4	Published since ("2018")	
	# 5	#1 AND #2 AND #3 AND #4	167

CINAHL – Review 23/07/2019

PICO	#	Query	Limits / Expanders	Results
POPULATIOM	S1	((MH "Aged+") OR "aged" OR (MH "Aged, 80 and Over+"))	Expanders - Apply related words Search modes - Boolean/Phrase	826239
	S2	((MH "Frail Elderly") OR "elderly")	Expanders - Apply related words Search modes - Boolean/Phrase	85949
	S3	(S1 OR S2)	Search modes - Boolean/Phrase	843521
INTERVENTION	S4	((MH "Exercise Therapy: Muscle Control (Iowa NIC)") OR (MH "Exercise Therapy: Joint Mobility (Iowa NIC)") OR (MH "Exercise Therapy: Balance (Iowa NIC)") OR (MH "Exercise Therapy: Ambulation (Iowa NIC)") OR (MH "Therapeutic Exercise+") OR "Exercise therapy" OR (MH "Resistance Training") OR (MH "Motion Therapy, Continuous Passive") OR (MH "Open Kinetic Chain Exercises") OR (MH "Core Exercises") OR (MH "Group Exercise") OR (MH "Aquatic Exercises") OR (MH "Exercise Positions+") OR (MH "Lower Extremity Exercises") OR (MH "Isometric Exercises") OR (MH "Isokinetic Exercises") OR (MH "Arm Exercises") OR (MH "Anaerobic Exercises") OR (MH "Exercise+"))	Expanders - Apply related words Search modes - Boolean/Phrase	120724

	S5	((MH "Therapeutic Exercise+") OR "Exercise movement techniques")	Expanders - Apply related words Search modes - Boolean/Phrase	49025
	S6	((MH "Gymnastics") OR "gymnastic")	Expanders - Apply related words Search modes - Boolean/Phrase	847
	S7	((MH "Tai Chi") OR "tai chi" OR (MH "Qigong") OR (MH "Martial Arts") OR "martial art")	Expanders - Apply related words Search modes - Boolean/Phrase	3646
	S8	(MH "Sports+") OR "sports" OR (MH "Aquatic Sports+")	Expanders - Apply related words Search modes - Boolean/Phrase	93889
	S9	(S4 OR S5 OR S6 OR S7 OR S8)	Search modes - Boolean/Phrase	192435
OUTCOME	S10	((MH "Accidental Falls") OR (MH "Fall Prevention (Iowa NIC)") OR "accidental fall")	Expanders - Apply related words Search modes - Boolean/Phrase	19798
	S11	("slip*") OR ("fall*")	Expanders - Apply related words Search modes - Boolean/Phrase	56504
	S12	((MH "Fear (Saba CCC)") OR (MH "Fear Control (Iowa NOC)") OR (MH "Fear+") OR "fear of falling")	Expanders - Apply related words Search modes - Boolean/Phrase	12797
	S13	((MH "Fractures+") OR "fracture*")	Expanders - Apply related words Search modes - Boolean/Phrase	73669
	S14	(S10 OR S11 OR S12 OR S13)	Search modes - Boolean/Phrase	136227
	S15	(S3 AND S9 AND S14)	Limiters - Published Date: 20180201-; English Language; Peer Reviewed; Exclude MEDLINE records; Human; Language: English; Age Groups: Aged:	164

			65+ years Search modes - Boolean/Phrase	
	S16	(S3 AND S9 AND S14)	Limiters - Published Date: 20180201-; English Language; Peer Reviewed; Exclude MEDLINE records; Human; Language: English; Age Groups: Aged, 80 and over Search modes - Boolean/Phrase	75
	S17	(S15 OR S16)	Search modes - Boolean/Phrase	171

PICO	#	Query	Limits / Expanders	Results
POPULATION	S1	((MH "Aged+") OR "aged" OR (MH "Aged, 80 and Over+"))	Expanders - Apply related words Search modes - Boolean/Phrase	826239
	S2	((MH "Frail Elderly") OR "elderly")	Expanders - Apply related words Search modes - Boolean/Phrase	85949
	S3	(S1 OR S2)	Search modes - Boolean/Phrase	843521
INTERVION	S4	((MH "Exercise Therapy: Muscle Control (Iowa NIC)") OR (MH "Exercise Therapy: Joint Mobility (Iowa NIC)") OR (MH "Exercise Therapy: Balance (Iowa NIC)") OR (MH "Exercise Therapy: Ambulation (Iowa NIC)") OR (MH "Therapeutic Exercise+") OR "Exercise therapy" OR (MH "Resistance Training") OR (MH "Motion Therapy, Continuous Passive") OR (MH "Open Kinetic Chain Exercises") OR (MH "Core Exercises") OR (MH "Group Exercise") OR (MH "Aquatic Exercises") OR (MH "Exercise Positions+") OR (MH "Lower Extremity Exercises") OR (MH "Isometric Exercises") OR (MH "Isokinetic Exercises") OR (MH "Arm Exercises") OR (MH "Anaerobic Exercises") OR (MH "Exercise+"))	Expanders - Apply related words Search modes - Boolean/Phrase	120724

	S5	((MH "Therapeutic Exercise+") OR "Exercise movement techniques")	Expanders - Apply related words Search modes - Boolean/Phrase	49025
	S6	((MH "Gymnastics") OR "gymnastic")	Expanders - Apply related words Search modes - Boolean/Phrase	847
	S7	((MH "Tai Chi") OR "tai chi" OR (MH "Qigong") OR (MH "Martial Arts") OR "martial art")	Expanders - Apply related words Search modes - Boolean/Phrase	3646
	S8	(MH "Sports+") OR "sports" OR (MH "Aquatic Sports+")	Expanders - Apply related words Search modes - Boolean/Phrase	93889
	S9	(S4 OR S5 OR S6 OR S7 OR S8)	Search modes - Boolean/Phrase	192435
OUTCOME	S10	((MH "Accidental Falls") OR (MH "Fall Prevention (Iowa NIC)") OR "accidental fall")	Expanders - Apply related words Search modes - Boolean/Phrase	19798
	S11	("slip*") OR ("fall*")	Expanders - Apply related words Search modes - Boolean/Phrase	56504
	S12	((MH "Fear (Saba CCC)") OR (MH "Fear Control (Iowa NOC)") OR (MH "Fear+") OR "fear of falling")	Expanders - Apply related words Search modes - Boolean/Phrase	12797
	S13	((MH "Fractures+") OR "fracture*")	Expanders - Apply related words Search modes - Boolean/Phrase	73669
	S14	(S10 OR S11 OR S12 OR S13)	Search modes - Boolean/Phrase	136227
	S15	(S3 AND S9 AND S14)	Limiters - Published Date: 20180501-; English Language; Peer Reviewed; Exclude MEDLINE records; Human; Language: English; Age Groups: Aged: 65+ years	141

			Search modes - Boolean/Phrase	
S16		(S3 AND S9 AND S14)	Limiters - Published Date: 20180502-; English Language; Peer Reviewed; Exclude MEDLINE records; Human; Language: English; Age Groups: Aged, 80 and over Search modes - Boolean/Phrase	67
	S17	(S15 OR S16)	Search modes - Boolean/Phrase	148

Scopus - Review 23/07/2019

PICO	#	Query	Results
POPULATION	1	(TITLE-ABS-KEY ("Elderly") OR TITLE-ABS-KEY ("Frail Elderly"))	
INTERVENTION	2	(TITLE-ABS-KEY ("Exercise Therapy: Muscle Control") OR TITLE-ABS-KEY ("Exercise Therapy: Joint Mobility") OR TITLE-ABS-KEY ("Exercise Therapy: Balance") OR TITLE-ABS-KEY ("Exercise Therapy: Ambulation") OR TITLE-ABS-KEY ("Therapeutic Exercise+") OR TITLE-ABS-KEY ("Motion Therapy, Continuous Passive") OR TITLE-ABS-KEY ("Open Kinetic Chain Exercises") OR TITLE-ABS-KEY ("Core Exercises") OR TITLE-ABS-KEY ("Group Exercise") OR TITLE-ABS-KEY ("Aquatic Exercises ") OR TITLE-ABS-KEY ("Exercise Positions+") OR TITLE-ABS-KEY ("Lower Extremity Exercises") OR TITLE-ABS-KEY ("Isometric Exercises") OR TITLE-ABS-KEY ("Isokinetic Exercises") OR TITLE-ABS-KEY ("Anaerobic Exercises") OR TITLE-ABS-KEY ("Exercise+") OR TITLE-ABS-KEY ("Therapeutic Exercise+") OR TITLE-ABS-KEY ("Exercise Therapy*") OR TITLE-ABS-KEY ("Exercise Movement Technique*") OR TITLE-ABS-KEY ("Sport*") OR TITLE-ABS-KEY ("Tai Chi") OR TITLE-ABS-KEY ("Gymnastic*") OR TITLE-ABS-KEY ("Resistance Training") OR TITLE-ABS-KEY ("Qigong") OR TITLE-ABS-KEY ("Martial Arts")	
OUTCOME	3	(TITLE-ABS-KEY ("accidental fall*") OR TITLE-ABS-KEY ("Falling") OR TITLE-ABS-KEY ("Fall*") OR TITLE-ABS-KEY ("Slip*") OR TITLE-ABS-KEY ("Fracture*") OR TITLE-ABS-KEY ("Fear") OR TITLE-ABS-KEY ("Fear of falling") OR TITLE-ABS-KEY ("Fear of fall*") OR TITLE-ABS-KEY ("Prevention of fallling") OR TITLE-ABS-KEY ("Prevention of fall*"))	
	4	1 AND 2 AND 3	
	14	(LIMIT-TO (SRCTYPE , "j")) AND (LIMIT-TO (PUBSTAGE , "final")) AND (LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018)) AND (LIMIT-TO (LANGUAGE , "English")) AND (LIMIT-TO (EXACTKEYWORD , "Human") OR LIMIT-TO (EXACTKEYWORD , "Aged") OR LIMIT-TO (EXACTKEYWORD , "Humans"))	341

Scopus – RCT 23/07/2019

PICO	#	Query	Results
POPULATION	1	(TITLE-ABS-KEY ("Elderly") OR TITLE-ABS-KEY ("Frail Elderly"))	
INTERVENTION	2	(TITLE-ABS-KEY ("Exercise Therapy: Muscle Control") OR TITLE-ABS-KEY ("Exercise Therapy: Joint Mobility") OR TITLE-ABS-KEY ("Exercise Therapy: Balance") OR TITLE-ABS-KEY ("Exercise Therapy: Ambulation") OR TITLE-ABS-KEY ("Therapeutic Exercise+") OR TITLE-ABS-KEY ("Motion Therapy, Continuous Passive") OR TITLE-ABS-KEY ("Open Kinetic Chain Exercises") OR TITLE-ABS-KEY ("Core Exercises") OR TITLE-ABS-KEY ("Group Exercise") OR TITLE-ABS-KEY ("Aquatic Exercises ") OR TITLE-ABS-KEY ("Exercise Positions+") OR TITLE-ABS-KEY ("Lower Extremity Exercises") OR TITLE-ABS-KEY ("Isometric Exercises") OR TITLE-ABS-KEY ("Isokinetic Exercises") OR TITLE-ABS-KEY ("Anaerobic Exercises") OR TITLE-ABS-KEY ("Exercise+") OR TITLE-ABS-KEY ("Therapeutic Exercise+") OR TITLE-ABS-KEY ("Exercise Therapy*") OR TITLE-ABS-KEY ("Exercise Movement Technique*") OR TITLE-ABS-KEY ("Sport*") OR TITLE-ABS-KEY ("Tai Chi") OR TITLE-ABS-KEY ("Gymnastic*") OR TITLE-ABS-KEY ("Resistance Training") OR TITLE-ABS-KEY ("Qigong") OR TITLE-ABS-KEY ("Martial Arts")	
OUTCOME	3	(TITLE-ABS-KEY ("accidental fall*") OR TITLE-ABS-KEY ("Falling") OR TITLE-ABS-KEY ("Fall*") OR TITLE-ABS-KEY ("Slip*") OR TITLE-ABS-KEY ("Fracture*") OR TITLE-ABS-KEY ("Fear") OR TITLE-ABS-KEY ("Fear of falling") OR TITLE-ABS-KEY ("Fear of fall*") OR TITLE-ABS-KEY ("Prevention of fallling") OR TITLE-ABS-KEY ("Prevention of fall*"))	
	4	1 AND 2 AND 3	
	14	(LIMIT-TO (SRCTYPE , "j")) AND (LIMIT-TO (PUBSTAGE , "final")) AND (LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018)) AND (LIMIT-TO (LANGUAGE , "English")) AND (LIMIT-TO (EXACTKEYWORD , "Human") OR LIMIT-TO (EXACTKEYWORD , "Aged") OR LIMIT-TO (EXACTKEYWORD , "Humans"))	268

APPENDIX 2 – Quality assessment tools

Guideline - AGREE II (Brouwers et al., 2012)

Domains	Item	Score (1-7)	Final score for domain
1 Scope and purpose	1		
	2		
	3		
2 Stakeholder involvement	4		
	5		
	6		
3 Rigour of development	7		
	8		
	9		
	10		
	11		
	12		
	13		
	14		
4 Clarity of presentation	15		
	16		
	17		
5 Applicability	18		
	19		
	20		
	21		
6 Editorial independence	22		
	23		
Overall guideline assessment	1. rate the overall quality of this guideline		
	2. I would recommend this guideline for use		

User's manual:
- **Score for domain from 1 to 7:** 7-point scale: from "strongly disagree" (1) to "strongly agree" (7);
- **Final score for domain:** domain scores are calculated by summing up all the scores of the individual items in a domain and by scaling the total as a percentage of the maximum possible score for that domain:

$$\frac{(\text{obtained score} - \text{minimum possible score})}{(\text{maximum possible score} - \text{minimum possible score})}.$$

- minimum possible score = 1(strongly disagree) x number of appraisers x number of items
- maximum possible score = 7(strongly agree) x number of appraisers x number of items

Reviews – AMSTAR (Shea et al., 2007) + **PRISMA** (Moher et al, 2009) + **criteria for the evidence's strength** (Faggiano et al., 2018)

Items PRISMA	Score PRISMA	Items AMSTAR	Score AMSTAR	Final PRISMA+AMSTAR score
1				
2				
3				
4				
5		1		
6		4		
7		3		
8				
9		2		
10				
11				
12		7		*(if also 19/7 is evaluated with "3")*
13				
14				
15				
16				
17		5		
18		6		
19		7		
20				
21		9		*(if also 23/9 is evaluated with "3")*
22		10		
23		9		
24				
25		8		
26				
27		11		
	Tot.			
Reporting bias		If total PRISMA score is between 54 to 81		
Review of RCT				
Review of non-RCT				
Bias in the primary studies				
Bias in the review				
Results' inconsistency				
Indirect or subjective outcome				

User's manual:

- **Score PRISMA and AMSTAR from 1 to 3:**
    - (1) if there isn't the information or it is declared how not to do or it's methodological incorrect,
    - (2) if there is the information but it is insufficient to evaluate the methodological rigour,
    - (3) if there is the information and it is correct to evaluate the methodological rigour.
- **Final PRISMA+AMSTAR score:** +1 if PRISMA and AMSTAR are (3), otherwise 0.
- **Reporting bias:** +1 if the total PRISMA score is between 54 and 81.
- **Evidence's strength:**

    +1 if it's a RCT's review; otherwise 0.

    -1 if a non-RCT review, if there is bias in the primary studies or in the review, if there is inconsistency results or there is indirect/subjective outcome; otherwise 0.
- **Final score:**

    [Final AMSTAR+PRISMA score + 1 or 0 or -1 (evidence's strength)] x 100

    13

RCT – Cochrane Risk of Bias Tool (Jüni et al., 2001)

Domain	Score
Selection bias (random sequence generation)	
Selection bias (allocation concealment)	
Performance bias	
Detection bias	
Attrition bias	
Reporting bias	

User's manual:

- **Score for domain:**
  - o <u>Low risk</u>: if bias is controlled;
  - o <u>Unclear</u>: if there is insufficient information;
  - o <u>Hight risk</u>: if bias is uncontrolled.
- **Final score** is calculated comparing the total of bias assessed at low risk out of the total of bias evaluated.

APPENDIX 3 – Quality assessment

Guidelines

Domains	Final score for domains (*100)				
	HHS[1]	ISS[5]	RNAO[3]	USPSTF[2]	WHO[4]
1 Scope and purpose	77%	68%	87%	60%	82%
2 Stakeholder involvement	64%	71%	90%	17%	71%
3 Rigour of development	73%	73%	87%	45%	95%
2 Clarity of presentation	76%	83%	97%	46%	96%
5 Applicability	10%	51%	81%	3%	78%
6 Editorial independence	33%	5%	68%	85%	100%
Overall score	**56%**	**59%**	**85%**	**43%**	**87%**
Graphic representation	++	++	+++	+	+++

Reviews

Items AMSTAR (considering PRISMA)	Agreed by reviews - score							
	Dipietro et al., 2019	Elliott & Leland, 2018	Finnegan, Seers, & Bruce, 2019	Hamed, Bohm, Mersmann, & Arampatzis, 2018	Lopez et al., 2018	Sherrington et al., 2019	Vetrovsky, Steffl, Stastny, & Tufano, 2019	Weber et al., 2018
1	1	0	1	0	0	1	1	0
2	0	1	0	0	1	1	1	1
3	0	1	1	1	1	1	1	1
4	0	0	0	0	0	0	0	0
5	0	0	0	0	0	1	0	0
6	0	1	1	1	1	1	1	1
7	0	1	1	1	1	1	0	0
8	1	1	1	1	1	1	1	1
9	0	0	1	0	0	1	0	0
10	0	0	0	0	0	1	0	0
11	0	0	0	0	0	0	0	0
Reporting bias	1	1	1	1	1	1	1	1
Review of RCT	1	1	1	1	1	1	1	1
Review of non-RCT	0	0	0	0	0	0	0	0
Bias in the primary studies	0	0	0	0	0	0	0	0
Bias in the review	0	0	0	0	0	0	0	0

Results' inconsistency	0	0	0	0	0	0	0	0
Indirect or subjective outcome	0	0	0	0	0	0	0	0
Overall score	**4/13= 31%**	**7/13= 54%**	**8/13= 62%**	**6/13= 46%**	**7/13= 54%**	**11/13= 85%**	**7/13= 54%**	**6/13= 46%**
Graphic representation	+	++	++	+	++	+++	++	+

Randomized controlled trials

Domains	Agreed by reviews - score				
	Aibar-Almazán et al., 2019	Jiménez-García et al., 2019	Li et al., 2018	Li et al., 2019	Liu–Ambrose et al., 2019
Selection bias (random sequence generation)	Low risk	Low risk	Low risk	Low risk	Low risk
Selection bias (allocation concealment)	Low risk	Low risk	Low risk	Low risk	Low risk
Performance bias	High risk	High risk	High risk	High risk	High risk
Detection bias	Unclear risk	Unclear risk	Low risk	Low risk	Low risk
Attrition bias	High risk	Unclear risk	Low risk	Unclear risk	Unclear risk
Reporting bias	Low risk	Low risk	Low risk	Low risk	Low risk
Overall score	**3/6 = 50%**	**3/6 = 50%**	**5/6 = 83%**	**4/6 = 67%**	**4/6 = 67%**
Graphic representation	+	+	+++	++	++

APPENDIX 4 – Data extraction

Guidelines

Scientific society and publication year	Recommendation	Evidence's Strength	Reference
RNAO, 2017	Exercises and physical training are recommended for adults at risk of falling, to improve strength and balance. An individualized, multi-component activity program that matches the person's current capacities and abilities should be encouraged.	1a	El-Khoury, Cassou, Charles, & Dargent-Molina, 2015; Gillespie et al., 2012; National Institute for Health and Care Excellence, 2013; Stubbs, Brefka, & Denkinger, 2015; Moyer & U.S. Preventive Services Task Force, 2012.
WHO, 2017	Multi-component exercises (balance, strength, flexibility and functional training) should be recommended for older people with declining physical capacity and/or at risk of falling.	Strong	Gillespie et al., 2012.

Review

Author and publication year	Typology and number of studies included	Aim and target	Outcome and effects (IC 95%)
Sherrington, 2019	59 RCT	Evaluate the effect of exercise to prevent falls of older people living in the community.	EXERCISES (IN GENERAL) <u>Number of falls:</u> Exercises vs no routine intervention/care: RR 0.77 (95% CI 0.71; 0.83) - subgroup not selected for high risk of falling (N = 29): RR 0.74 (95% CI 0.65; 0.84) - subgroup selected for high risk of falling (N = 30): RR 0.80 (95% CI 0.72; 0.88) - subgroup by age of participants <75 yy (N = 46): RR 0.75 (95% CI 0.69; 0.82) - subgroup by age of participants = or > 75 yy (N = 13):> RR 0.83 (95% CI 0.72; 0.97) - subgroup for intervention provided by healthcare personnel (N = 25): RR 0.69 (95% CI 0.61; 0.79) - subgroup for intervention provided by non-healthcare personnel (N = 34): RR 0.82 (95% CI 0.75; 0.90) - subgroup for exercises delivered in groups (N = 40): RR 0.76 (95% CI 0.69; 0.85) - subgroup for individually delivered exercises (N = 21): RR 0.79 (95% CI 0.71; 0.88)
	63 RCT		<u>Falling people</u> Exercises vs no routine intervention/care: RR 0.85 (95% CI 0.81; 0.89) - subgroup not selected for high risk of falling (N = 28): RR 0.82 (95% CI 0.73; 0.92)

	- subgroup selected for high risk of falling (N = 35): RR 0.87 (95% CI 0.83; 0.91)
	- subgroup by age of participants <75 yy (N = 50): RR 0.85 (95% CI 0.79; 0.91)
	- subgroup by age of participants = or > 75 yy (N = 13): RR 0.86 (95% CI 0.80; 0.92)
	- subgroup for intervention provided by healthcare personnel (N = 26): RR 0.82 (95% CI 0.74; 0.91)
	- subgroup for intervention provided by non-healthcare personnel (N = 36): RR 0.86 (95% CI 0.81; 0.92)
	- subgroup for exercises delivered in groups (N = 48): RR 0.83 (95% CI 0.78; 0.90)
10 RCT	- subgroup for exercises delivered individually (N = 16): RR 0.88 (95% CI 0.83; 0.93)
	<u>Number of people who developed 1 or more fall-related fractures</u> Exercises vs no routine intervention/care: RR 0.73 (95% CI 0:56; 0.95)
5 RCT	- subgroup not selected for high risk of falling (N = 5): RR 0.48 (95% CI 0:26; 0.91)
	- subgroup by age of participants <75 yy (N = 7): RR 0.53 (95% CI 0:29; 0.96)
	<u>People who had 1 or more falls who required a medical examination</u> Exercises VS no routine intervention/care: RR 0.61 (95% CI 0:47; 0.79)

39 RCT		
		- subgroup by activity program followed by long follow-up (N = 2): RR 0.54 (95% CI 0:37; 0.78)
		BALANCE AND FUNCTIONAL EXERCISES <u>Number of falls:</u> Balance and functional exercises vs no routine intervention/treatment: RR 0.76 (95% CI 0.70; 0.81)
		- subgroup not selected for high risk of falling (N = 18): RR 0.80 (95% CI 0.72; 0.90) - subgroup for high risk of falling (N = 21): RR 0.72 (95% CI 0.65; 0.80)
37 RCT		- subgroup for intervention provided by healthcare personnel (N = 20): RR 0.67 (95% CI 0:58; 0.76) - subgroup for intervention provided by non-healthcare personnel (N = 19): RR 0.82 (95% CI 0.76; 0.88)
		- subgroup for exercises delivered in groups (N = 20): RR 0.73 (95% CI 0.65; 0.82) - subgroup for exercises delivered individually (N = 20): RR 0.77 (95% CI 0.70; 0.85)
		<u>Number of people falling:</u> Balance and functional exercises vs no routine intervention/treatment: RR 0.87 (95% CI 0.82; 0.91)
		- subgroup not selected for high risk of falling (N = 15): RR 0.88 (95% CI 0.80; 0.97) - subgroup for high risk of falling (N = 22):

	RR 0.86 (95% CI 0.81; 0.91)
7 RCT	- subgroup for intervention provided by non-healthcare personnel (N = 19): RR 0.82 (95% CI 0.75; 0.90) - subgroup for intervention provided by non-healthcare personnel (N = 18): RR 0.89 (95% CI 0.84; 0.94)
7 RCT	- subgroup for exercises delivered in groups (N = 22): RR 0.87 (95% CI 0.80; 0.95) - subgroup for exercises delivered individually (N = 16): RR 0.87 (95% CI 0.82; 0.92)
8 RCT	- subgroup by activity program followed by long follow-up (N = 2): RR 0.86 (95% CI 0.78; 0.94)
1 RCT	Number of people who developed 1 or more fall-related fractures Balance and functional exercises vs no routine intervention/treatment: RR 0.44 (95% CI 0:25; 0.76)
11 RCT	TAI CHI EXERCISES Number of falls: Thai Chi exercises vs no routine intervention/care: RR 0.81 (95% CI 0.67; 0.99) Number of people falling: Thai Chi exercises vs no routine intervention/care: RR 0.80 (95% CI 0.70; 0.91) People who had 1 or more falls who required a medical examination Thai Chi exercises vs no routine intervention/care: RR 0.35 (95% CI 0:13; 0.93)

	MIXED EXERCISES Number of falls: Exercises vs no routine intervention/care: RR 0.66 (95% CI 0:50; 0.88)
17 RCT	
	- subgroup not selected for high risk of falling (N = 6): RR 0.54 (95% CI 0:29; 0.99) - subgroup for high risk of falling (N = 5): RR 0.77 (95% CI 0.63; 0.94)
2 RCT	
	- subgroup for intervention provided by healthcare personnel (N = 3): RR 0.65 (95% CI 0:43; 0.99) - subgroup for intervention provided by non-healthcare personnel (N = 8): RR 0.66 (95% CI 0:44; 0.99)
	- subgroup for exercises delivered in groups (N = 10): RR 0.64 (95% CI 0:46; 0.89)
	Number of people falling: Exercises vs no routine intervention/care: RR 0.78 (95% CI 0.64; 0.96)
	People who had 1 or more falls that required a medical examination Exercises vs no routine intervention/care: RR 0.44 (95% CI 0:29; 0.66)

Randomized controlled trial

Author and publication year	Typology of studies included	Aim and target	Outcome and effects (IC 95%)
Li, 2018	RCT	Evaluate the effectiveness of Tai ji quan compared to mixed exercises or stretching exercises to reduce falls in the elderly at high risk of falling.	Number of falls: Group 1 (Tai ji quan) VS group 3 (stretching) at 6 months: IRR 0.42 (95% CI 0.31; 0:56) Group 2 (mixed exercises) VS group 3 (stretching) at 6 months: IRR 0.60 (95% CI 0.45; 0.80) Group 1 (Tai ji quan) VS group 2 (mixed exercises) to 6 months: IRR 0.69 (95% CI 0.52; 0.94)

APPENDIX 5- Full text manual

IPEST Physical Exercise Manual

1. **Target audience**

The target population of the intervention for the implementation of an exercise program is older people aged 65 or older and residing at home. The recommendations discussed in this appendix have been tested in studies that include a mixed and heterogeneous older population (Registered Nurses' Association of Ontario, 2017), which often excludes people with severe cognitive impairments (Mini Mental State Examination <20 on a scale of 0 to 30) or to whom physical activity has been advised against for particular medical reasons (Li et al., 2018).

2. **What do we mean by "exercise"?**

According to the World Health Organization (WHO) definition, physical activity means any body movement produced by skeletal muscles that involves energy expenditure, including working, playing, doing household chores, traveling, and engaging in recreational and social activities (WHO, 2010, 2018).

The term "physical activity" should not be confused with the term "exercise". The latter is a subset of the former characterized by being planned, structured, and repetitive and is aimed at improving or maintaining one or more aspects of physical fitness.

The European network for the prevention of falls has developed a taxonomy (ProFaNE) (Lamb et al., 2005, 2011) that classifies exercise into the following types:

- 3D exercise, that is, any exercise involving constant movement in a controlled, fluid, and repetitive way in three dimensions (such as tai chi, qi gong, or dance);
- balance, coordination, and functional exercises (such as heel lifting, toe lifting, toe walking, heel walking, walking backward, forward, and sideways, turning around, bending over, doing one step, specific exercises involving changes in rhythm and intensity level, obstacle courses, ball exercises, walking in line, games that stimulate reactivity, and dynamic and static balance);
- muscle strength and endurance exercises (such as weight lifting, using fixed resistance equipment and resistance bands, jumping, Pilates resistance exercises, and machine exercises);
- endurance activities, such as aerobic activities for cardiovascular training (e.g., fast walking, ergometer cycling, running on a treadmill, rowing, and running);
- generic exercises, that is, any movement produced by skeletal-muscle contraction with increasing energy expenditure (such as low-intensity walking, swimming, cycling, and team sports);
- flexibility exercises, such as exercises that involve any form of stretching practiced in a progressive way (e.g., dynamic and static stretching and yoga);
- mixed exercises, that is, activities characterized by a combination of exercises belonging to more than one category;
- multicomponent interventions when physical exercise is accompanied by other interventions (environmental interventions, counseling, education, and diet);

- other exercises not classifiable in the above categories.

Physical exercises are also classified according to the intensity with which they are practiced (WHO, 2014). Intensity refers to the speed with which the activity is performed or the amount of effort required to perform it. It is related to how hard a person performing an activity works in terms of energy expenditure. Intensity is often expressed in metabolic equivalents (METs), which express the relationship between the metabolic rate during work and that at rest. The energy expenditure of sitting idly is 1 MET, equivalent to 1 kcal/hour. It is estimated that calorie consumption is three to six times higher (3-6 MET) when a person is moderately active compared to sitting idly and more than six times higher (> 6 MET) when vigorously active. A physical activity of moderate intensity (3-6 METs) requires moderate effort and a noticeably accelerated heartbeat. Some examples are fast walking, dancing, gardening, doing housework, hunting and gathering (agriculture), active games and sports activities, walking a dog, restoration and construction activities, and moving weights <20kg. Physical activity of vigorous intensity (> 6 MET) requires considerable effort and entails an increase in respiratory and cardiac activity. Examples are running, walking uphill, cycling (racing), aerobic activities, fast swimming, sports and competitive games, hoeing and digging, moving weights > 20 kg. The cardiovascular effort related to the intensity with which physical exercise is practiced varies according to individual characteristics such as habits, weight, age, and health condition.

3. Effectiveness of exercise in reducing the number of falls, the number of people falling, and the fear of falling

The available literature was evaluated according to the criteria introduced by the framework for the Interventions for fall Prevention that are Effective, Sustainable, and Transferable (IPEST) (Faggiano et al., 2018). Two guidelines (RNAO, 2017; WHO, 2017), a systematic review (Sherrington et al., 2019), and a randomized controlled trial (Li et al., 2018) not included in the previously found reviews and meta-analyses were included at the end of the selection process.

Th types of exercises that most impact a person's abilities are those including multiple types of exercise (such as strength, endurance, and balance training) or three-dimensional ones (such as tai chi, dancing, and qui gong) (Sherrington et al., 2019). It has been shown that such programs reduce functional decline and the fear of falling and increase social relationships, self-esteem, quality of life, and psycho-physical health. Research shows that long-term participation and adherence is better if the exercises are performed in a group (RNAO, 2017) or with the regular participation of the caregiver or the family network (WHO, 2017).

The Registered Nurses' Association of Ontario (RNAO) 2017 guideline (**Table 1**) argues that exercise greatly reduces the risk of falling and the number of falls, especially those with severe outcomes, such as fractures. Such interventions show a high efficacy, especially in those people with a history of falls or with balance/gait deficits. They have also been shown to be effective for people with Parkinson's disease, multiple sclerosis, and osteoarthritis of the knee and in particularly frail older people. Efficacy increases when physical exercise is accompanied by other interventions aimed at reducing the risk, such as multifactorial assessments, health education, environmental changes, correction of visual deficits, and pharmacological revision/reconciliation – in other words, with multicomponent interventions.

The same guideline emphasizes the importance of developing an activity program aligned with the person's preferences and abilities, and culturally acceptable. Effective interventions include the following:

- exercises that include tai chi or gait training, strength, flexibility, and endurance exercises;
- exercises for strengthening the muscles of the lower limbs;
- dynamic balance exercises with external perturbation;
- gait training exercises;
- tai chi (which has been proven more effective than other 3D exercise for older people who are not frail and have a lower risk of falling).

The WHO 2017 guideline (**Table 1**) emphasizes that exercise programs, which must be tailored to the individual's characteristics, compensate for the loss of mass and muscle strength typical of the elderly, which increases the risk of falling. The shown data hold up, as activities that include balance, strength, flexibility, and functional training are effective in preventing falls. Finally, the guideline shows that exercise is overall safe. Studies on which the recommendations are based have shown few adverse events, the occurrence of which is difficult to correlate with the exercise program.

Table 1- Evidence of effectiveness in the guidelines

Company and year	Recommendation	Strength of evidence	References	LG quality
RNAO, 2017	Exercises and physical training are recommended for adults at risk of falling, to improve strength and balance. An individualized, multi-component activity program that matches the person's current capacities and abilities should be encouraged.	1a[*]	El-Khoury, Cassou, Charles, & Dargent-Molina, 2015; Gillespie et al., 2012; National Institute for Health and Care Excellence, 2013; Stubbs, Brefka, & Denkinger, 2015; Moyer & U.S. Preventive Services Task Force, 2012.	+++
WHO, 2017	Multi-component exercises (balance, strength, flexibility and functional training) should be recommended for older people with declining physical capacity and/or at risk of falling.	Strong	Gillespie et al., 2012.	+++

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[*] Evidence obtained from metanalysis or systematic reviews of randomized controlled trials, and/or synthesis of multiple studies mainly of quantitative research.

A meta-analysis by Sherrington et al. 2019 (**Table 2**) shows that physical exercise reduces, in the long term, the number of falls and the number of people who fall, regardless of the stratification of risk and the population's age.

The types of exercises identified as effective in reducing falls are balance and functional exercises and tai chi. However, it is particularly difficult to identify a specific activity plan supported by the literature, as the various programs differ in both duration and frequency of the interventions. In conclusion, exercise is an extremely safe tool: overall, it does not increase the risk of falling in the treated population compared to the general population.

Table 2- Evidence of effectiveness in systematic reviews and meta-analyses

Author and year	Type of studies and number	Aim and target	Outcome and effect (95% CI)	Quality of the study
Sherrington et al., 2019	59 RCT	Evaluate the effect of exercise to prevent falls of older people living in the community.	EXERCISES (IN GENERAL) <u>Number of falls:</u> Exercises vs no routine intervention/care: RR 0.77 (95% CI 0.71; 0.83) - subgroup not selected for high risk of falling (N = 29): RR 0.74 (95% CI 0.65; 0.84) - subgroup selected for high risk of falling (N = 30): RR 0.80 (95% CI 0.72; 0.88) - subgroup by age of participants <75 yy (N = 46): RR 0.75 (95% CI 0.69; 0.82) - subgroup by age of participants = or > 75 yy (N = 13):> RR 0.83 (95% CI 0.72; 0.97) - subgroup for intervention provided by healthcare personnel (N = 25): RR 0.69 (95% CI 0.61; 0.79)	+++

63 RCT	- subgroup for intervention provided by non-healthcare personnel (N = 34): RR 0.82 (95% CI 0.75; 0.90) - subgroup for exercises delivered in groups (N = 40): RR 0.76 (95% CI 0.69; 0.85) - subgroup for individually delivered exercises (N = 21): RR 0.79 (95% CI 0.71; 0.88)
10 RCT	Falling people Exercises vs no routine intervention/care: RR 0.85 (95% CI 0.81; 0.89) - subgroup not selected for high risk of falling (N = 28): RR 0.82 (95% CI 0.73; 0.92) - subgroup selected for high risk of falling (N = 35): RR 0.87 (95% CI 0.83; 0.91) - subgroup by age of participants <75 yy (N = 50): RR 0.85 (95% CI 0.79; 0.91) - subgroup by age of participants = or > 75 yy (N = 13): RR 0.86 (95% CI 0.80; 0.92) - subgroup for intervention provided by healthcare personnel (N = 26): RR 0.82 (95% CI 0.74; 0.91)

	- subgroup for intervention provided by non-healthcare personnel (N = 36): RR 0.86 (95% CI 0.81; 0.92)
5 RCT	- subgroup for exercises delivered in groups (N = 48): RR 0.83 (95% CI 0.78; 0.90) - subgroup for exercises delivered individually (N = 16): RR 0.88 (95% CI 0.83; 0.93)
39 RCT	<u>Number of people who developed 1 or more fall-related fractures</u> Exercises vs no routine intervention/care: RR 0.73 (95% CI 0:56; 0.95) - subgroup not selected for high risk of falling (N = 5): RR 0.48 (95% CI 0:26; 0.91) - subgroup by age of participants <75 yy (N = 7): RR 0.53 (95% CI 0:29; 0.96)
37 RCT	<u>People who had 1 or more falls who required a medical examination</u> Exercises VS no routine intervention/care: RR 0.61 (95% CI 0:47; 0.79) - subgroup by activity program followed by long follow-up (N = 2): RR 0.54 (95% CI 0:37; 0.78)

	BALANCE AND FUNCTIONAL EXERCISES
	<u>Number of falls:</u>
	Balance and functional exercises vs no routine intervention/treatment:
	RR 0.76 (95% CI 0.70; 0.81)
	- subgroup not selected for high risk of falling (N = 18):
	RR 0.80 (95% CI 0.72; 0.90)
	- subgroup for high risk of falling (N = 21):
	RR 0.72 (95% CI 0.65; 0.80)
	- subgroup for intervention provided by healthcare personnel (N = 20):
	RR 0.67 (95% CI 0:58; 0.76)
	- subgroup for intervention provided by non-healthcare personnel (N = 19):
	RR 0.82 (95% CI 0.76; 0.88)
	- subgroup for exercises delivered in groups (N = 20):
7 RCT	RR 0.73 (95% CI 0.65; 0.82)
	- subgroup for exercises delivered individually (N = 20):
	RR 0.77 (95% CI 0.70; 0.85)
7 RCT	<u>Number of people falling:</u>
	Balance and functional exercises vs no routine intervention/treatment:
	RR 0.87 (95% CI 0.82;
8 RCT	0.91)

1 RCT	- subgroup not selected for high risk of falling (N = 15): RR 0.88 (95% CI 0.80; 0.97) - subgroup for high risk of falling (N = 22): RR 0.86 (95% CI 0.81; 0.91)
11 RCT	- subgroup for intervention provided by non-healthcare personnel (N = 19): RR 0.82 (95% CI 0.75; 0.90) - subgroup for intervention provided by non-healthcare personnel (N = 18): RR 0.89 (95% CI 0.84; 0.94)
	- subgroup for exercises delivered in groups (N = 22): RR 0.87 (95% CI 0.80; 0.95) - subgroup for exercises delivered individually (N = 16): RR 0.87 (95% CI 0.82; 0.92)
17 RCT	- subgroup by activity program followed by long follow-up (N = 2): RR 0.86 (95% CI 0.78; 0.94) Number of people who developed 1 or more fall-related fractures
2 RCT	Balance and functional exercises vs no routine intervention/treatment: RR 0.44 (95% CI 0:25; 0.76) TAI CHI EXERCISES Number of falls:

Thai Chi exercises vs no routine intervention/care: RR 0.81 (95% CI 0.67; 0.99)

Number of people falling:
Thai Chi exercises vs no routine intervention/care: RR 0.80 (95% CI 0.70; 0.91)

People who had 1 or more falls who required a medical examination
Thai Chi exercises vs no routine intervention/care: RR 0.35 (95% CI 0:13; 0.93)

MIXED EXERCISES
Number of falls:
Exercises vs no routine intervention/care: RR 0.66 (95% CI 0:50; 0.88)

- subgroup not selected for high risk of falling (N = 6): RR 0.54 (95% CI 0:29; 0.99)
- subgroup for high risk of falling (N = 5): RR 0.77 (95% CI 0.63; 0.94)

- subgroup for intervention provided by healthcare personnel (N = 3): RR 0.65 (95% CI 0:43; 0.99)
- subgroup for intervention provided by non-healthcare personnel (N = 8): RR 0.66 (95% CI 0:44; 0.99)

- subgroup for exercises delivered in groups (N = 10):

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			RR 0.64 (95% CI 0:46; 0.89)	
			Number of people falling: Exercises vs no routine intervention/care: RR 0.78 (95% CI 0.64; 0.96)	
			People who had 1 or more falls that required a medical examination Exercises vs no routine intervention/care: RR 0.44 (95% CI 0:29; 0.66)	

Li et al. 2018 (**Table 3**) show that tai chi is more effective in reducing the risk of falling than flexibility exercises alone, such as stretching. They also argue that exercise is a safe and effective method of reducing falls, although it is often difficult to choose the most appropriate type for the various characteristics of the patients.

Table 3- Evidence of efficacy in primary studies

Author and year	Type of trial	Aim and target	Outcome and effect (95% CI)	Quality of the study
Li et al., 2018	RCT	Evaluate the effectiveness of Tai ji quan compared to mixed exercises or stretching exercises to reduce falls in the elderly at high risk of falling.	Number of falls: Group 1 (Tai ji quan) VS group 3 (stretching) at 6 months: IRR 0.42 (95% CI 0.31; 0:56) Group 2 (mixed exercises) VS group 3 (stretching) at 6 months: IRR 0.60 (95% CI 0.45; 0.80) Group 1 (Tai ji quan) VS group 2 (mixed exercises) to 6 months: IRR 0.69 (95% CI 0.52; 0.94)	+++

Warnings for particular cases

The literature shows that identifying the risk of falling for people over 65 is a fundamental step before initiating an intervention (RNAO, 2017; WHO, 2017). This assessment must be performed by integrating the professional's clinical judgment with the collection of information related to the history of falls and evaluation of balance, posture, and motor difficulties to identify the right program for the person's characteristics (RNAO, 2017). This warning is particularly important for the high-risk population, for which interventions should be individualized and managed by an expert (RNAO, 2017; WHO, 2017), as inappropriate exercise programs could further increase the risk of falling (Sherrington et al., 2019). For people with dementia or cognitive impairments or people who present signs of incontinence or stroke, the literature has yet to reach a consensus (RNAO, 2017).

4.   **Transferability of interventions to local contexts**

In Italy, there are already physical exercise programs for the elderly at the local level, at home or in groups, that take advantage of the social congregation structures of an area. The purpose of these programs, however, is not so much the implementation of scientifically validated interventions to reduce falls as the prevention of social isolation. In fact, the promoters of these activities are mostly voluntary organizations employed in the area for projects of a social nature (Centro Sportivo Italiano & Unione Italiana Sport per Tutti, n.d.; Riccadonna, 2019; UNIVR MAGAZINE, 2010).

The literature examined shows that it is possible to implement structured and effective programs thanks to the training and awareness of the staff assigned to primary care, the involvement of the caregivers (RNAO, 2017), and the creation of a network between the promoters of the initiative, regional bodies, and health professionals (such as general practitioners and regional specialists, nurses, social workers, and pharmacists) in contact with citizens (Li et al., 2018). Li et al. posit that it is possible to use congregation places already present in an area (such as churches, gyms, and premises of nonprofit organizations) to set up exercise groups (Li et al., 2018). In fact, the establishment of groups along with promoting long-term adherence to exercise programs is particularly useful in preventing or mitigating social isolation (RNAO, 2017). Studies have demonstrated the effectiveness of involving existing associations and resources in an area to more easily integrate the activity program in the social context (RNAO, 2017; Sherrington et al., 2019).

5.   **Sustainability of physical exercise programs**

In Canada, a health-care system expenditure of approximately 8.7 billion USD is estimated due to falls of the elderly annually (Scott et al., 2010). In fact, falls cause an average hospital stay of 22 days (Public Health Agency of Canada, 2014). In addition to more or less severe injuries, they often result in a reduction in individuals' autonomy, negatively affecting their quality of life (Local Health Integration Network Collaborative, 2011).

The literature suggests that structured and effective exercise programs aimed at the elderly are practically and economically feasible (Davis et al., 2010). The effectiveness of an intervention, however, depends on the individual's continuous participation. Support and training of caregivers and family members contribute to reducing the total costs of the intervention and raising awareness of the problem, which correlates with long-term sustainability (WHO, 2017).

Furthermore, for people with a medium-low risk of falling, group activities managed by volunteers (also identified among the participants themselves) with the purposes of reducing costs, increasing acceptability and participation, promoting long-term adherence, and reducing gender inequalities can be initiated. For example, a group activity for medium-low risk individuals stimulates participation, as it can be performed with friends and thus perceived as an opportunity for socialization, is often accessible at low cost, and, when outdoors, offers a sense of security. In fact, some people need to be motivated by the presence of people important to them (Giles-Corti & Donovan, 2002) to be willing to make the effort to participate in a group activity. In these cases, the physical and social benefits of participation tend to outweigh the costs of moving (Sherwood & Jeffery, 2000). This is especially the case for female participants: females tend to participate in group physical activities more than males, especially in activities performed on the street, for the additional reason of a perceived sense of security. For young women, the feeling of being able to walk alone and a sense of security in the neighborhood in which they live are important factors (Wiltshire, 2014). In contrast, overweight and obese people tend to prefer sports practiced at home, out of other people's sight (Sherwood & Jeffery, 2000).

Sport is also less practiced by women due to gender inequalities in the management of domestic life: it is less practiced by women who have to look after family members (grandchildren, older parents, or children and/or spouses who are not self-sufficient) (Sherwood & Jeffery, 2000). A lack of time and the economic cost of going to private gyms, swimming pools and golf courses, can be obstacles to regular physical activity, especially among the lower social classes (Sherwood & Jeffery, 2000).

In light of this, activity programs for the elderly should be planned in collaboration with local authorities and voluntary organizations to promote the participation of the most underprivileged people, such as women preoccupied with care work and those who are economically disadvantaged, by offering subsidized participation and women with reduced mobility by providing, for example, transportation to and from the activity places.

6. The manual

The following manual details how to set up structured exercise programs for older people living at home.

Steps for creating and implementing a structured exercise program	- Identify a local health structure and a person responsible for promoting the initiative; - involve all entities and organizations willing to collaborate (e.g., municipal and provincial administration, voluntary associations, and nonprofit organizations); - organize the initiative and identify the people to whom the intervention should target (for example, in terms of fall risk categories and regional demographic distribution); - involve the social bodies present in the area (such as social services or departments for social policies) and devise strategies aimed at increasing citizens' participation, without increasing social and gender inequalities (e.g., transportation to and from the activity places and disbursement of subsidies according to income);

- inform regional figures who are in contact with citizens and have a liaison role (such as general practitioners, family and community nurses, and outpatient specialists);
- organize the promotion of the initiative (e.g., informational sessions, informal meetings, brochures, posters, and access to meeting places);
- recruit participants by spontaneous registration or sending invitations by regional health professionals;
- identify and train the professionals (such as family and community nurses, general practitioners, geriatricians, and physiatrists) who will be responsible for evaluating individuals' risk of falling and enrolling them in the most appropriate exercise programs with respect to residual functional abilities;
- identify and train the intervention providers (family and community nurses, physiotherapists, graduates in physical sciences, occupational therapists, volunteers of associations, or peers identified within the exercise group) on how to encourage and maintain the participation of individuals not accustomed to sports;
- train volunteers and peers in group management techniques, the most suitable movements, the risks associated with sports practiced by the elderly and the unfamiliar, safety measures to be adopted, especially in public settings, and first aid techniques;
- establish an intervention timetable.
Recommendations:
- for the recruitment of participants, rely on general practitioners' and family and community nurses' knowledge of their clients;
- for the assessment of the risk of falling, professionals should combine their clinical judgment with the collection of information on previous falls and evaluation of balance, posture, and motor difficulties. If the professional deems it appropriate, a validated risk stratification tool identified with respect to the individual's characteristics can be used;
- for people at a medium-low risk of falling,
    - rely on trained employees and volunteer staff, also identified among the program participants;
    - deliver group interventions in communal places in the area;
    - provide information on reducing risks related to the home environment;
    - involve the caregivers;
    - involve health personnel and provide occasional training when necessary;
- for people at a high risk of falling,
    - rely on trained health personnel;
    - deliver interventions at individuals' homes for a period adequate for them to learn the exercises;
    - analyze the home environment and reduce the related risk factors;
    - educate the caregivers and family members;
    - at the end of the activity program, continue with a long-term telephone follow-ups and/or refer individuals to exercise groups.

Indicators to evaluate the effectiveness of the intervention	- **NUMBER OF PARTICIPANTS AND PARTICIPATION FREQUENCY;** - **NUMBER OF PEOPLE LEAVING THE PROGRAM;** - **NUMBER OF FALLS REPORTED TO THE GENERAL PRACTITIONER;** - **NUMBER OF REFERRALS TO THE EMERGENCY ROOM DUE TO FALLS;** - **AVERAGE HOSPITAL STAY DUE TO A FALL;** - **NUMBER OF FALLS WITH SEVERE OUTCOMES;** - **NUMBER OF VISITS TO NURSING HOMES AFTER FALLS.**
Material and infrastructural resources	The target population is advised to wear comfortable clothing and to always bring and consume liquids during the activity. A few material resources are necessary: mats, gym sticks and weights in sufficient quantity for all participants. Regarding infrastructures for group interventions, it is possible to use premises existing in the area, such as halls of nonprofit organizations, churches, private gyms, public school gyms, or other places large enough and safe for group exercises. For home interventions, a vehicle is needed for the professional's transportation. Necessary information materials should be distributed to the general population, the participants, and their caregivers.
Human capital	It is necessary to involve: - communication experts to organize the information campaign; - volunteers from associations or individuals identified within the exercise group who are continuously trained to conduct of activities with groups of people at a medium-low risk of falling; - trained family nurses, physiotherapists, and occupational therapists who can provide interventions at high-risk people's home during their work hours.
Stakeholders to be involved	It is useful to involve local sports associations, nonprofit organizations (e.g., voluntary work organizations or mountain communities), places for older people to socialize (such as bowling clubs, churches, or mutual aid societies), public bodies (such as districts, municipal, and provincial authorities or social welfare consortia), associations of companies and individuals, pharmacies, regional specialists, families, caregivers, and other community members. In some cases, involving the neighborhood or community in which the elderly person lives may be helpful.
Frequency, duration, and intensity of the intervention	Biweekly 60-minute sessions are recommended. The exercises performed can be tai chi or mixed, that is, training for strength, balance, resistance, and gait. The intensity of the interventions should be modulated according to the participants' characteristics.
Information material	Professionals will be able to use paper/digital information material to increase the effectiveness and adherence to the intervention, especially in the long term. Examples of material currently available: Guide to promoting physical activity in the elderly population – EpiCentro (Istituto Superiore di Sanità, 2005) www.epicentro.iss.it/attivita_fisica/pdf/Guidaall'attivit%C3%A0fisica.pdf Guidelines on physical activity for different age groups and with reference to physiological and pathophysiological situations and specific population subgroups – Italian Health Ministry (Ministero della Salute, 2017)

	www.salute.gov.it/imgs/C_17_pubblicazioni_2828_allegato.pdf Physical activity in the elderly - fundamental aspects – B. Johnston (Johnston, 2018) www.msdmanuals.com/it-it/casa/aspetti-fondamentali/attività-e-forma-fisica/attività-fisica-negli-anziani Sports for the elderly: benefits and exercises to stay healthy (Pariset, 2019) www.melarossa.it/fitness/workout/sport-anziani-benefici-esercizi-per-salute/ Home physical exercises for the elderly - Galliera Genoa Hospital (Ente Ospedaliero Galliera di Genova, 2014) – Ente Ospedaliero Galliera Genova (Ente Ospedaliero Galliera di Genova, 2014) https://www.galliera.it/20/58/strutture-sanitarie/179/brochure/esercizi-domiciliari-di-attivita-fisica-per-lanziano-1 How to promote a walking group in the city – DoRS (DoRS Regione Piemonte, n.d.-b) www.dors.it
Models to promote exercise	In order to promote participation, it is particularly useful to inform and educate both people and their caregiver/family, with a view to empowerment related to the knowledge of the risks of falling and the importance of regular physical exercise.
Similar projects in Italy	"Home Gymnastics" Project - Piedmont and Lombardy: - http://www.uisp.it/varese/pagina/ginnastica-a-domicilio (Unione Italiana Sport per tutti, 2010) - http://www.uisp.it/alessandria/pagina/la-ginnastica-a-domicilio (Unione Italiana Sport per tutti, 2016) Database Pro.Sa. by DoRS – Piedmont Region - https://www.retepromozionesalute.it/bd2_riclib.php (DoRS Regione Piemonte, n.d.-a)

7. Conclusions

Exercise has been proven to be highly effective in reducing falls among elderly home residents. Structured exercise programs reduce social isolation, retard psycho-physical decline, and improve self-efficacy and quality of life. The cost incurred by the implementation of operational programs is compensated by the reduction of costs related to falls and their outcomes. To propose programs tailored to individuals' needs, it is important to evaluate their risk of falling. Such assessments must be performed by trained professionals according to their clinical judgment and, if deemed appropriate, with the help of validated tools. The involvement of families and caregivers positively correlates with long-term adherence. The recruitment of trained voluntary staff is necessary for reducing costs and ensuring the participation of people at a medium-low risk of falling. Family and community nurses, where available and with the support of physiotherapists and experts in motor sciences, seem to be adequate for the implementation of interventions for high risk people at home, where they can also offer counseling for the reduction of other modifiable risk factors, such as changes in the home environment.

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APPENDICES CHAPTER 9

APPENDIX 1 – Search strategy

Guidelines – 01/02/2019

Society	Website
Canadian Task Force on the Periodic Health Examination	https://canadiantaskforce.ca/guidelines/published-guidelines/
The Community Guide U.S.A. Preventive Task Force (CGPTF)	https://www.thecommunityguide.org/publications
U.S. Preventive Services Task Force (USPSTF)	https://www.uspreventiveservicestaskforce.org/BrowseRec/Index
U.S. Agency for Healthcare Research and Quality (AHRQ)	https://www.ahrq.gov/research/publications/search.html
Scottish Intercollegiate Guideline Network (SIGN)	https://www.sign.ac.uk/our-guidelines.html
Centre for Evidence Based Medicine (CEBM) di Oxford	https://www.cebm.net/category/prevention/
The National Institute for Health and Care Excellence (NICE)	https://www.nice.org.uk/guidance/published?type=ap g,csg,cg,mpg,ph,sg,sc,dg,hst,ipg,mtg,qs,ta
Canadian Medical Association Infobase	https://joulecma.ca/cpg/homepage
New Zealand Guidelines Group	https://www.health.govt.nz/publications
Haute Autorité de Santé	https://www.has-sante.fr/jcms/fc_2875208/fr/rechercher-une-recommandation-un-avis?
Istituto Superiore di Sanità (ISS)	http://old.iss.it/publ/
U.S. Department of Health and Human Services (HHS)	https://www.hhs.gov/
Registered Nurses' Association of Ontario (RNAO)	https://rnao.ca/bpg/guidelines
World Health Organization (WHO)	https://www.who.int/ageing/publications/current/en/

CINAHL – Reviews and RCTs 23/07/2019

PICO	#	Query	Limits / Expanders	Results
POPULATIOM	S1	((MH "Aged+") OR (MH "Aged, 80 and Over+"))	Search modes - Boolean/Phrase	726589
	S2	(MH "Frail Elderly")	Search modes - Boolean/Phrase	6618
	S3	(S1 OR S2)	Search modes - Boolean/Phrase	726589
INTERVENTION	S4	(MH "Accidents, Home")	Search modes - Boolean/Phrase	1017
	S5	((MH "Home Modification") OR (MH "Home Safety") OR (MH "Home Environment"))	Search modes - Boolean/Phrase	10278
	S6	(S4 OR S5)	Search modes - Boolean/Phrase	11144
OUTCOME	S7	((MH "Accidental Falls") OR (MH "Fall Prevention (Iowa NIC)") OR (MH "Fall Risk (Saba CCC)") OR (MH "Safety Status: Falls Occurrence (Iowa NOC)") OR (MH "Safety Behavior: Fall Prevention (Iowa NOC)"))	Expanders - Apply related words Search modes - Boolean/Phrase	19716
	S8	(S3 AND S6 AND S7)	Limiters - Published Date: 20150101-; Search modes - Boolean/Phrase	105

Embase – Reviews and RCTs 23/07/2019

PICO	#	Query	Results
POPULATION	#1	('aged'/exp OR 'aged patient':ti,ab OR 'aged person':ti,ab OR 'aged subject':ti,ab OR 'elderly':ti,ab OR 'elderly patient':ti,ab OR 'elderly people':ti,ab OR 'elderly person':ti,ab OR 'elderly subject':ti,ab OR 'senior citizen':ti,ab OR 'senium':ti,ab OR 'aged':ti,ab OR 'aged people':ti,ab OR 'very elderly'/exp OR 'aged, 80 and over':ti,ab OR 'centenarian':ti,ab OR 'centenarians':ti,ab OR 'nonagenarian':ti,ab OR 'nonagenarians':ti,ab OR 'octogenarian':ti,ab OR 'octogenarians':ti,ab OR 'very elderly':ti,ab OR 'very old':ti,ab OR 'frail elderly'/exp OR 'frail elderly':ti,ab OR 'older adults'/exp OR 'frail older':ti,ab)	
INTERVENTION	#2	('home accident'/exp OR 'accident, domestic':ti,ab OR 'accident, home':ti,ab OR 'accidents, home':ti,ab OR 'domestic accident':ti,ab OR 'home accident':ti,ab OR 'safety home':ti,ab OR 'environmental planning'/exp OR 'environment design':ti,ab OR 'environmental planning':ti,ab OR 'planning, environmental':ti,ab OR 'home modification':ti,ab OR 'home adjusted':ti,ab OR 'home hazard':ti,ab OR 'environmental hazard'/exp OR 'environmental factor'/exp OR 'environmental factor':ti,ab OR 'factor, environmental':ti,ab OR 'home intervention':ti,ab OR 'home interventions':ti,ab)	
OUTCOME	#3	('falling'/exp OR 'accidental falls':ti,ab OR 'fall':ti,ab OR 'falling':ti,ab OR 'falls'/exp OR 'fall risk'/exp OR 'fall risk':ti,ab OR 'fall risk assessment'/exp OR 'fall risk assessment':ti,ab OR 'fall risk assessment tool':ti,ab OR 'preventing fall':ti,ab OR 'falls prevention':ti,ab OR 'falls risk':ti,ab OR 'falls risk assessment':ti,ab OR 'preventing falls':ti,ab OR 'fall prevention':ti,ab)	
	#4	#1 AND #2 AND #3	794
	#5	#4 AND (2015:py OR 2016:py OR 2017:py OR 2018:py OR 2019:py)	157

PubMed – Reviews and RCTs 23/07/2019

PICO	#	Query	Results
POPULATION	1	("Aged" [Mesh] OR "Aged, 80 and over" [Mesh] OR "Frail Elderly" [Mesh] OR "aged" [Title/Abstract] OR "elderly" [Title/Abstract] OR "senium" [Title/Abstract] OR "senior" [Title/Abstract] OR "centenarian*" [Title/Abstract] OR "octogenarian*" [Title/Abstract] OR "nonagenarian*" [Title/Abstract])	3403081
INTERVENTION	2	("Accidents, Home" [Mesh] OR "Accident Prevention" [Mesh] OR "home accident" [Title/Abstract] OR "home accidents" [Title/Abstract] OR "domestic accident" [Title/Abstract] OR "domestic accidents"[Title/Abstract])	86423
	3	("home safety" [Title/Abstract] OR "environmental planning" [Title/Abstract] OR "home modification" [Title/Abstract] OR "home modifications" [Title/Abstract] OR "home modified" [Title/Abstract] OR "home adjustment" [Title/Abstract] OR "home adjustments" [Title/Abstract] OR "home hazard" [Title/Abstract] OR "home hazards" [Title/Abstract] OR "environmental hazard" [Title/Abstract] OR "environmental hazards" [Title/Abstract] OR "environmental factor" [Title/Abstract] OR "environmental factors"[Title/Abstract] OR "home intervention" [Title/Abstract] OR "home interventions" [Title/Abstract])	66871
	4	2 OR 3	152602
OUTCOME	5	("Accidental Falls" [Mesh] OR "accidental fall" [Title/Abstract] OR "accidental falling" [Title/Abstract] OR "accidental falls" [Title/Abstract] OR "falling" [Title/Abstract] OR "falls" [Title/Abstract] OR "fall risk" [Title/Abstract] OR "falls risk" [Title/Abstract] OR "fall" [Title/Abstract])	166428
	6	1 AND 4 AND 5	1818
	7	Publication date from 01/01/2015	329

APPENDIX 2 – Quality assessment

Guidelines

Domains	Final score for domains (*100)	
	RNAO, 2017	**WHO, 2017**
1 Scope and purpose	87%	82%
2 Stakeholder involvement	90%	71%
3 Rigour of development	87%	95%
2 Clarity of presentation	97%	96%
5 Applicability	81%	78%
6 Editorial independence	68%	100%
Overall score	**85%**	**87%**
Graphic representation	+++	+++

Randomized controlled trials

Domains	Agreed by reviews - score
	Pey June Tan, 2018
Selection bias (random sequence generation)	Low risk
Selection bias (allocation concealment)	Low risk
Performance bias	Unclear
Detection bias	Unclear
Attrition bias	Low risk
Reporting bias	Low risk
Overall score	**66,7%**
Graphic representation	++

APPENDIX 3 – Data extraction

Guidelines

Scientific society and publication year	Recommendation	Evidence's Strength	Reference
RNAO, 2017	Interventions tailored to the health-care setting are recommended to prevent falls or fall injuries in the community. Identifying and modifying factors in the physical/structural environment is necessary to reduce risk for falls and falls injuries.	1a 1a	Goodwin et al., 2014; Turner et al., 2011; Gillespie et al., 2012; Stubbs, Brefka, & Denkinger, 2015; Moyer & U.S. Preventive Services Task Force, 2012. Choi, Lawler, Boenecke, Ponatoski, & Zimring, 2011; National Institute for Health and Care Excellence, 2013; Ambrose, Paul, & Hausdorff, 2013; Boelens, Hekman, & Verkerke, 2013; Ambrose, Cruz, & Paul, 2015.
WHO, 2017	Following a specialist's assessment, home modifications to remove environmental hazards that could cause falls should be recommended for older people.	Quality of the evidence: moderate – Strength of the recommendation: strong	Gillespie et al., 2012.

APPENDIX 4 - Full text manual

IPEST home modification manual

1. Target population

The target of the intervention to modify the home environment is the elderly population aged 65 years and over, resident at home, and without serious cognitive impairment (MMSE <20 on a scale from 0 to 30) (Registered Nurses' Association of Ontario, 2017).

2. The domestic environment modification intervention

By environmental modification intervention, we mean an activity aimed at reducing the risk of a person falling in their home environment. This intervention is based on an assessment of the specific risks of each individual and their home environment.

From the analysis of the literature, we can deduce that the main sources of risk are represented by 1) inappropriate flooring (e.g. the presence of shiny, slippery surfaces such as parquet, the application of floor wax, or the presence of movable carpets); 2) an inadequate lighting system (i.e., one that does not provide good visibility or is difficult to activate because there are insufficient switches that may be difficult to reach); 3) inappropriate furnishings (e.g., the presence of beds and chairs that are too high or too low, the absence of armrests for chairs or rails for beds, and the absence of handrails in hallways/stairs and bathrooms; and 4) an unsuitable domestic layout (i.e. narrow hallways, steep or shallow stairs, and the absence of a stair lift where necessary) (Registered Nurses' Association of Ontario, 2017).

3. The effectiveness of environmental intervention to reduce the number of falls; the number of people falling and the fear of falling

The literature has been analyzed and evaluated according to the criteria introduced by the IPEST method (Effective Sustainable and Transferable Prevention Interventions) (Faggiano et al., 2018). Only two 2017 guidelines were included at the end of the selection process (Registered Nurses' Association of Ontario, 2017; World Health Organization, 2017).

Environmental modification interventions, besides being effective and functional for the individual at risk, act indiscriminately on anyone else who occupies or passes through the redesigned house (Registered Nurses' Association of Ontario, 2017). Scientific evidence, shows that long-term effectiveness is closely related to the awareness and involvement of the person and his/her caregiver (World Health Organization, 2017).

The Registered Nurses' Association of Ontario guideline, 2017 (**Table 1**) state environmental change measures reduce the risk of falling and the number of falls. The literature shows that interventions are more effective when preceded by an individual risk assessment of the patient and the home environment. This implies the need to include the environmental intervention in a multifactorial educational and operational plan, which allows the creation of individualized interventions to which both the caregiver and the patient agree. In other words, it is essential to promote changes that are line with the habits, culture, and perceptions of the patient, as well as with those of family members living together. A non-exhaustive list of factors to be considered

with respect to the physical/structural environment includes adequate flooring, lighting, and furnishings; the use of safe and functional equipment; adequate space; supports such as handles and handrails; and the arrangement of space and the environment to accommodate a patient with dementia.

The World Health Organization guideline, 2017 (**Table 1**) highlights that environmental change is effective only if it is individualized according to the characteristics of the person, and if a broad agreement exists among family/caregivers to promote its acceptability. The involvement of professionals trained in both assessing patients and their environment and in the principles of good communication is recommended.

Table 1- Evidence of effectiveness in the guidelines

Company and year	Recommendation	Strenght of evidence	References	LG Quality
RNAO, 2017	Interventions in the living environment are recommended to prevent falls and their consequences. Identifying and modifying physical and structural environmental factors is necessary to reduce falls and their consequences.	$1a^2$	V.A. Goodwin et al., 2014 (Goodwin et al., 2014); Turner et al., 2011 (Turner et al., 2011); Gillespie et al., 2012 (Gillespie et al., 2012); Stubbs, Brefka, & Denkinger, 2015 (Stubbs, Brefka, & Denkinger, 2015); U.S. Preventive Service Task Force, 2012 (Moyer & U.S. Preventive Services Task Force, 2012). Choi et al., 2011 (Choi, Lawler, Boenecke, Ponatoski, & Zimring, 2011); National Institute for Health and Care Excellence, 2013 (National Institute for Health and Care Excellence, 2013); Ambrose et al., 2013 (Ambrose, Paul, & Hausdorff, 2013); Boelens et al., 2013 (Boelens, Hekman, & Verkerke, 2013);	+++

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[2] Evidence obtained from metanalysis or systematic reviews of randomized controlled trials, and/or synthesis of multiple studies mainly of quantitative research.

			Ambrose et al., 2015 (Ambrose, Cruz, & Paul, 2015).	
WHO, 2017	The assessment of the home environment by a specialist, with the removal of factors that could cause falls, decreases both the risk of falling in the elderly population and the number of falls.	Quality of evidence: moderate- Strength of recommendation: strong[3].	Gillespie et al., 2012 (Gillespie et al., 2012).	+++

The first step: Assessment

In the literature, the first step is to identify the risk of falling in elderly individuals (Registered Nurses' Association of Ontario, 2017; World Health Organization, 2017). This assessment is conducted by a practitioner who forms their clinical judgement by gathering information relating to the history of the patient's falls and by assessing the patient's balance, posture, and motor difficulties. The practitioner establishes an individualized program tailored to the person's overall situation, taking into account any pathologies or physical and cognitive health conditions (Registered Nurses' Association of Ontario, 2017). Due to the many combinations of interventions that can be implemented in relation to different domestic environments, the evidence regarding the net effectiveness and adherence over time of each individual intervention is limited (World Health Organization, 2017). In the population at high risk of falling, interventions are more effective if they are managed not only by experienced professionals but by multidisciplinary teams (Registered Nurses' Association of Ontario, 2017; World Health Organization, 2017).

4. The transferability of the intervention in local contexts

Currently, in Italy, several organizations have brochures and information guides to educate their clients about the risk of falling in an inadequate home environment; however, there are no local, structured programs run by professionals.

The literature reviewed provides a detailed set of interventions and shows how effective programs can be implemented through training and raising the awareness of primary care staff and increasing caregiver involvement.

The creation of a network between the promoters of the intervention and the territorial professionals (such as general practitioners and territorial specialists, nurses, social workers, and pharmacists) is a fundamental requirement to structure and manage the intervention program over time, guaranteeing the dissemination and durability of the initiative (Registered Nurses' Association of Ontario, 2017). Moreover, the literature shows that interventions are

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[3] Evidence strongly consistent between different studies and populations, obtained from sufficient but limited evidence to determine the effects on preventive service.

generally carried out by professionals such as occupational therapists (World Health Organization, 2017).

5. The sustainability of the home modification program

In Canada, falls by the elderly result in average hospitalizations of 22 days (Public Health Agency of Canada, 2014) and cost the healthcare system about US$ 8.7 billion per year the elderly (Scott, Wagar, & Elliott, 2010).

In addition to more and less severe outcomes, falls often lead to a reduction in the person's autonomy, negatively affecting the quality of life (Local Health Integration Network Collaborative, 2011).

Effective, structured programs are easy to implement and cost effective, especially if developed by multidisciplinary teams with multi-component activities. The effectiveness of the preventive intervention is closely linked to adherence to the environmental changes agreed on and implemented, so the sharing of the care plan with family members, caregivers, and the person assisted is of fundamental importance, not only for long-term sustainability but also for effectiveness in the short term. Economic sustainability is closely related to the type of intervention itself. In fact, some interventions are largely sustainable by the patient (e.g., the removal of carpets or the installation of handles, etc.); others may be difficult to access (such as redesigning the home). For these reasons, it is appropriate to carefully assess individual risk and containment measures. Public subsidies would be appropriate for the implementation of individual environmental changes, even if they are not sustainable on a large scale (Registered Nurses' Association of Ontario, 2017).

6. The manual

Below is the manual that explains the environmental risk identification and modification program for the elderly population living at home.

| Activities and steps | The steps to be taken to create and implement a structured program to identify environmental risk and modify the home environment are the following:
 • identify the local health facility and a responsible person to promote the initiative;
 • involve all bodies and organizations willing to collaborate (municipal and provincial administrations, voluntary associations, non-profit organizations);
 • organize the initiative and identify the people to whom the intervention should be addressed (fall risk classes, territorial demographic distribution, etc.);
 • interest the social bodies present in the territory (social services, social policy department, etc.) and activate strategies to increase citizens' participation, without increasing social and gender inequalities (implement guidance desks; create facilitated routes for people with difficulties; provide bonuses linked to citizens' economic situation, etc.); |

- inform the territorial figures who are in contact with the person to be assisted who will act as intermediaries (general practitioners, family and community nurses, outpatient specialists, etc.);
- present the initiative (information evenings, informal meetings, advertising brochures, posters, etc.);
- recruit participants, either by spontaneous registration or by asking for referrals from local healthcare professionals;
- identify and train the professionals who will assess patients' risk of falling and include them in the most appropriate environmental change program with respect to the assessments carried out and the agreed upon objectives (family and community nurses, general practitioners, geriatricians, etc.);
- identify and train the providers of the intervention (family and community nurses, general practitioners, occupational therapists, territorial specialists);
- establish a timetable of interventions, in relation to the clinical priorities of the patients.

The following are recommended:
- for the recruitment of participants, use the knowledge that general practitioners and family and community nurses have of their patients;
- for the assessment of fall risk, the practitioner should base their clinical judgement on information relating to the patients' previous history of falls and on an assessment of the patient's balance, posture and motor difficulties; if the practitioner considers it appropriate, the assessment may be supported by a validated risk stratification tool, to be identified with respect to the characteristics of the person;
- analyze the home environment; assess which individual risk management strategies are most appropriate, taking into account the principle of equity and the limited resources available; agree on shared activity plans with the person assisted, the family members, and the caregiver;
- for the delivery of interventions, use trained healthcare personnel who, within multi-professional teams, can provide multi-component interventions;
- continue with a long-term follow-up.

Implementation indicators	Useful indicators to assess the effectiveness of the intervention may be: - Number of memberships in the program at zero time and after follow-up; - Number of falls reported by people to their general practitioner; - Number of emergency room accesses for accidental falls; - Average hospital stay following an accidental fall; - Number of falls with severe outcomes; - Number of accesses to nursing homes following falls.
Material and infrastructural resources	Informational materials for the person assisted and their caregiver are needed first. In some cases, professionals (general practitioner, family and community nurses, occupational therapist, social worker) will be able to provide informational materials as well as municipal and non-municipal organizations (social policy department, non-profit organizations, etc.). The resources provided should be directly related to the individual program of

	modification of the environment. For home interventions, a vehicle is required for the professional.
Human capital	It is necessary to involve: • Communication experts to organize an information campaign; • Trained family and community nurses/occupational therapists who can provide interventions during their work at people's homes; • Professional specialist staff to respond to the individual needs of patients.
Stakeholders to be involved	It is useful to involve in the project non-profit organizations (e.g., voluntary organizations, mountain communities, etc.), associations of companies and individuals, public bodies (e.g., districts, municipalities, provinces, social welfare consortia, etc.), pharmacies, territorial specialists, families, caregivers, and other cohabitants. In some situations, the involvement of the neighborhood or community in which the elderly person lives could be useful.
Frequency, duration and intensity of the intervention	Operational interventions can be provided in parallel with educational interventions, or at times and in ways related to the individual evaluations of professionals. However, it is appropriate to agree on long-term, shared, and supported business plans. Follow-up is useful, even by phone.
Information material	Professionals will be able to use paper-based information material to increase the effectiveness of the educational intervention. Examples of material currently available: "Casa sicura" Project– regione Abruzzo (Regione Abruzzo, 2010) https://sanita.regione.abruzzo.it/sites/default/files/prevenzione/piano_preven zione/pprev_8.pdf Falls prevention at home – regione Friuli-Venezia-Giulia (Regione Friuli-Venezia-Giulia, 2015) https://www.burlo.trieste.it/sites/default/files/documenti-basicpage/Prevenire_le_cadute_nella_vita_quotiadina-_ADULTO.pdf Falls at home. Knowing the risk to avoid them – Istituto Superiore di Sanità (Istituto Superiore di Sanità, 2008) http://www.gestionerischio.asl3.liguria.it/pdf/cadute_anziani_versione_per_i_cittadini.pdf
Models to promote exercise	To produce effective and sustainable interventions in the long term, it is necessary to promote the active participation of both family members and caregivers. Empowerment in relation to knowledge of risks and their perception is strategic, especially when related to self-efficacy.
Similar projects in Italy	"Passi d'argento" project – Regione Emilia-Romagna (Istituto Superiore di Sanità, n.d.) https://www.epicentro.iss.it/passi-argento/

7. Conclusion

Structured programs to change the home environment improve the quality of life and reduce the risk of falls in the elderly population living at home. The cost that could result from the implementation of education programs and modifications of the home environment is related to the type of modifications carried out. It is appropriate to assess each case individually to identify risk factors and treatment alternatives. Adherence to the program is strongly conditioned by the involvement of the family and the caregiver as well as the person assisted. The sharing of activity plans is a prerequisite for an effective intervention. The family nurse seems to be an appropriate professional to implement the intervention, and the nurse can also perform other activities to provide multi-component interventions in relation to the characteristics of the person being assisted.

With respect to applicability of interventions, the evidence of environmental change reported in the literature is mostly studied in hospital and long-term care settings, but general precautions can also be adapted and successfully applied in the home setting.

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APPENDICES CHAPTER 10

Protocollo 1024/CE
Studio n. CE 246/21

PARERE DEL COMITATO ETICO

A. IDENTIFICAZIONE DELLO STUDIO - STUDIO OSSERVAZIONALE	
1.Titolo completo del protocollo	*La prevenzione delle cadute negli anziani a domicilio attraverso il sistema di monitoraggio TED*
2.Promotore	Università Piemonte Orientale
3.Codice, versione e data del Protocollo	Studio TED, ver_1, 01-09-2021
4.N. RSO:	N/A

B. IDENTIFICAZIONE DEL COMITATO ETICO (costituito ai sensi del DM 8 febbraio 2013)	
1.Denominazione del CE	Comitato Etico Interaziendale AOU "Maggiore della Carità" di Novara, ASL BI, ASL NO, ASL VCO
2.Nome e cognome del Presidente	Prof. Mario Pirisi
3.Indirizzo del CE	C.so Mazzini n.18 - 28100 Novara
4.Numero di telefono	0321.3733081
5.Numero di fax	0321.3733080
6.E-mail	segreteria.scientifica@comitatoeticonovara.it

C. IDENTIFICAZIONE DEL MEDICO RICHIEDENTE	
1.Nome Cognome	Dirigente Medico Luca Magistrelli
2.Centro Clinico	A.O.U. Maggiore della Carità(NO)
3.Indirizzo del centro clinico	Corso Mazzini n. 18-28100-Novara-NO
4.Reparto	-

D. SEDUTA DEL COMITATO ETICO	
1.Data della seduta	07-10-2021
2.Numero del registro dei pareri del CE	CE 246/21
3.Componenti del CE presenti e qualifiche	

* FRANCESCO BARONE ADESI *biostatistico*
* REMIGIO BELCREDI *esperto in materie giuridiche*
* FABRIZIO CONDORELLI *farmacologo*
* LUISA DE SANCTIS *pediatra*
* MASSIMILIANO GARZARO *clinico di area chirurgica*
* GERMANO GIORDANO *medico legale*
* GIUSEPPE GUZZARDI *Esperto clinico nuove procedure*
* DANIELA KOZEL *Direttore Sanitario AOU Novara*
* MARCO KRENGLI *Clinico di Area medica Specialistica*
* ROBERTO MARI *rappresentante del volontariato*
* MARIO PIRISI *Clinico di area medica internistica*
* ALESSIA PISTERNA *esperto in dispositivi medici*
* GIULIA PLATINI *ingegnere clinico*
* ANTONIO RIMEDIO *esperto in bioetica*

E. DOCUMENTAZIONE ESAMINATA	

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Protocollo 1024/CE
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4.Reparto	-

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- ALESSIA PISTERNA *esperto in dispositivi medici*
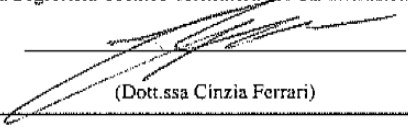- GIULIA PLATINI *ingegnere clinico*
- ANTONIO RIMEDIO *esperto in bioetica*

E. DOCUMENTAZIONE ESAMINATA	

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- Lettera D'Intenti
- CV PI
- Assenza di Conflitto di interesse
- Dichiarazione sede dello studio
- Lettera UPO Biobank
- Scheda Riassuntiva Dichiarativa
- Scheda DOMANDA
- PARERE DIREZIONE SANITARIA
- Protocollo
- Sinossi
- CRF Arruolamento
- CRF Follow up
- Informativa + Consensi
- Lettera Copertura costi

La Segreteria Tecnico-scientifica del CE interaziendale

(Dott.ssa Cinzia Ferrari)

F. DECISIONE DEL COMITATO ETICO	
1.Parere	Parere favorevole Il Prof. Dal Molin non partecipa alla valutazione del protocollo né alla votazione in quanto indirettamente coinvolto.
2.Sperimentazione da condurre presso	A.O.U. "Maggiore della Carità" di Novara
3.Numero dei pazienti previsti	26
4.Data	07-10-2021

G. FIRMA DEL PRESIDENTE DEL COMITATO ETICO	
1.Il Comitato Etico ha espresso il parere/sospensione della decisione: • verificata la sussistenza del numero legale, essendo presenti membri n.14 su n.18	
2.Nome e Cognome	Prof. Mario Pirisi
3.Data	07-10-2021
4.Firma	

NOTE
• Si raccomanda, come da vigente normativa, la diffusione e la pubblicazione dei risultati