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Urinary Incontinence and Sedentary Behaviour in Nursing-Home residents in Osona, Catalonia: protocol for the OsoNaH project, a multicentre observational study

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Abstract

Introduction. Several studies have shown that physical activity (PA) levels and sedentary behaviour (SB) are independent risk factors for many health-related issues. However, there is scarce evidence supporting the relationship between SB and urinary incontinence (UI) in community dwelling older adults, and no information on any possible association in institutionalized older adults. Stage 1 of this project has the main objective of determining the prevalence of UI and its associated factors in nursing home (NH) residents, as well as analysing the association between UI (and its types) and SB. Stage 2 aims to investigate the incidence and predictive factors of functional and continence decline, falls, hospitalizations, mortality and the impact of the COVID-19 pandemic among NH residents.

Methods and analysis. Stage 1 is an observational multicentre study that consists of a cross-sectional study with mixed methodology that aims to explore the current status of health-related outcomes in NH residents of the Osona country. The Prevalence Ratio will be used as an association measure and multivariate analysis will be undertaken using Poisson regression with robust variance. Stage 2 is a 2-year longitudinal study that aims to analyse functional and continence decline, incidence of falls, hospitalizations, mortality and the impact of the COVID-19 pandemic on these outcomes. A survival analysis using the actuarial method for functional decline and continence, evaluated every 6 months, and the Kaplan-Meier method for falls, hospitalizations and deaths and Cox regression for multivariate analysis will be undertaken.

Ethics and dissemination. The study was approved by the Ethics and Research Committee of the University of Vic – Central University of Catalonia (reference numbers: 92/2019 and 109/2020) and the Clinical Research Ethics Committee of the Osona Foundation for health research and education (FORES) (code 2020118/PR249). Study results will be disseminated at conferences, meetings and through peer-reviewed journals.

ClinicalTrials.gov ID: NCT04297904

Article Summary

Strengths and limitations of this study:

- The first study to focus on the association between UI and SB in the older institutionalized population and the largest study analysing SB patterns in the older institutionalized population with a gold standard measure (ActivPAL).
- Mixed methods study (quantitative and qualitative approach) considering a wide range of variables to assess health, based on the biopsychosocial model.
- An initial cohort firstly assessed before the pandemic (from January to March 2020) will be followed to analyse the impact of COVID-19 in NH residents.
- Limitations include: participation of NH residents or legal guardians in research-based studies, cognitive impairment that may affect information on some independent variables that require the participant response and the potential increase in SB during the COVID-19 pandemic.

Introduction

Low birth rates and an increased life expectancy are transforming the age pyramid of the European Union (EU); probably the most important change will be the marked transition towards an aged society, a characteristic that is already evident in several EU member states, in 2017, the 65+ population had an increase of 0.3% compared to the previous year, and an increase of 2.4% compared to the previous 10 years, in fact people aged over 80 years old are increasing at a faster rate than any other age segment of the EU population (1). This increase is linked to a growing demand for long-term care, which represents a significant overload on public health resources. One in four older adults will spend a period of their life in a nursing home (NH), and the need for such care will persist until their death (2). Older adults who live in a NH are the most frail of our society with high levels of functional limitations and physical dependence (3,4), and one third of them have cognitive impairment (5).

The prevalence of urinary incontinence (UI) in Spain is approximately 10% in women aged between 25 and 64 years old, and over 50% in those over 65 years old (6). In NH, this proportion is around 50% and is frequently associated with cognitive impairment, physical inactivity and immobility syndrome, among other factors (7). In this context, we can find a type of UI described as "functional" in that it is caused by an inability to move to the toilet independently, due to a physical, communicative or cognitive problem (e.g. dementia)(8). Most older adults mistakenly believe that incontinence is part of the normal aging process and/or is an irresolvable problem (9,10). However, UI is a geriatric syndrome that represents an indicator of frailty and quality of health care, as well as a risk factor for pressure ulcers, falls, fractures and even urinary sepsis or death (11–14).

NH residents are the least physically active of all older adults, and spend most of their awake time sedentary (15,16). Doing regular physical activity (PA) limits the development and progression of most prevalent chronic diseases (17). However, the time spent in sedentary behaviour (SB) by older adults has increased considerably in the last three decades (18) and SB increases with age (19). SB has been gaining recognition as a risk factor for specific health conditions and reduced mobility, sometimes independent of PA levels (20). A typical day for a resident will consist in a sequence of periods of SB, light intensity PA (LPA) and moderate to vigorous intensity PA (MVPA)(21,22). NH residents spend an average of 79% of their day sedentary, 20% in LPA and 1% in MVPA (23).

There is a consensus among researchers that low levels of PA and prolonged patterns of SB could be direct risk factors for UI in older adults (24–27). A recent observational study on the association between SB and urinary incontinence in community dwelling older women concluded that urgency urinary incontinence (UUI) was significantly associated with increased average duration of SB bouts. The importance of objective measurement of SB was highlighted and it was suggested that decreasing time in prolonged sitting may be a target intervention to reduce UUI (28). Researchers conclude that there is a lack of complementary studies of higher quality on the association between SB and UI (29–33)

Frailty is one of the most important concerns regarding our aging population as it is a leading contributor to functional decline and early mortality in older adults (5–7). Evidence grows that this state is linked to several relevant health outcomes, similarly prevalent in all countries. The last consensus defined frailty as "a clinical state in which there is an increase in an individual's vulnerability for developing an increased dependency and/or mortality when exposed to a stressor"(8).

Functional decline is one of the main health-related issues that affect older adults because it limits their autonomy and leads to dependency (34). In older adults, functional capacity can be defined as the ability to carry out basic activities of daily living (BADL)(10). The association between functional decline and urinary incontinence (UI) could be bidirectional, which can lead to a cycle where continence reduction results in functional decline, and functional decline leads to further decrease in continence (14,18).

Falls, though preventable, are common among older adults, and the resulting injuries can threaten their health, independence, and everyday routines. Aging is one of the main risk factors for falls, for this reason, older adults have a high risk of injuries, increased dependence, disabilities, and institutionalization. All these outcomes are also risk factors for frailty. (19,20). Several studies have shown that the transition from in-home to institutional care is related to substantially higher mortality rates, as well as reduced physical and cognitive function (21,29). It is well known that hospital admission can affect the process of usual aging due to adverse health outcomes after hospitalization, especially in terms of functional decline (35), mortality (21,22), frailty (23) and cognitive impairment (24).

Therefore, the aim of this study is to determine the prevalence of UI and its associated factors, specifically the association between UI types and SB patterns in older people living in NH in the Osona country

(Barcelona, Spain). Also, stage 1 of this project aims to analyse the current status of health-related outcomes, based on the biopsychosocial model of health, and to describe the current interventions to reduce SB and increase PA, and the control measures to manage UI by the NHs of the Osona country. In addition to this, it aims to understand the experience of having UI among residents and the experience of providing healthcare to these individuals among health professionals, using descriptive phenomenology.

On the other hand, the SARS-CoV-2, called coronavirus 2019 (COVID-19), has emerged as a worldwide pandemic (36). This virus has been shown to be particularly deadly for older adults and those with certain underlying medical conditions (37–40). In relation to deaths from COVID-19 in Spain, 87% of the reported deaths were 70 years or more and a 95% presented comorbidity (41). The population living in NH, generally with older age and multiple comorbidities, are the most vulnerable to COVID-19 (42). In Catalonian NHs 28,418 suspected cases, 11,560 confirmed positive cases and 3,055 deaths were reported until May 2020 (43–45). Due to the vulnerability of NH themselves to outbreaks of respiratory diseases (46,47) and the frailty of NH population, there is a need of analysing the impact of COVID-19 in NH residents in terms of mortality, hospitalisation, as well as other health, social and cognitive-related variables.

Stage 2 aims to follow-up the included cohort of stage 1 and analyse the incidence and predictive factors of functional decline, frailty, continence decline, falls, hospitalizations and mortality among older people living in NHs for a 2-year period. The cohort firstly assessed before the first diagnosis of COVID-19 in Catalonian NHs will be followed to identify the potential risk and protective factors for mortality due to COVID-19 and the impact of this disease on functioning and hospitalizations.

Methods and analysis

Study design

The present study follows the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines and consists of two stages:

1. Observational cross-sectional study on the prevalence of UI (and its types) and SB patterns and the possible association between both issues in the older population living in NH of the Osona country (Barcelona, Spain)
2. Observational 2-year longitudinal (cohort) study on functional and continence status, falls, hospitalizations and mortality (including COVID-19 data) among NH residents of the Osona country (Barcelona, Spain).

Stage 1. Prevalence of UI and its associated factors among NH residents in the Osona country (Barcelona, Spain)

Design

Cross-sectional study with mixed methodology.

Setting and location

The present study will be conducted in NHs of the Osona country (Barcelona, Spain). According to the Catalonia Government, there are 19 registered NH: 12 public (or private) and 7 for-profit. The first contact with the NHs will be by email and phone call, to explain the project, resolve any queries and send them the participation documents for the study if they are interested in taking part.

Patient and public involvement

There was no patient or public involvement in the design and conduct of the stage 1.

Sample size

The calculation of the study sample is based on the preliminary data from the pilot study. Calculating the sample from the difference between variables (presence of IU or not and the mean of the total time in hours of SB), an absolute precision of the 5% and a significance level of the 5%, the sample to estimate the association between IU and SB will be 120 subjects. Considering a 30% of possible non-response rate, the final sample corresponds to 145 subjects. A simple random sampling will be undertaken. The exclusion criteria will be given on a flow chart (48).

Eligibility criteria

All nursing home residents (male or female) aged 65 years or older who live in the institution permanently; residents with or without cognitive impairment will be included in the quantitative part of the study. Exclusion criteria are subjects in coma or palliative care (prognosis of short life), hospitalised and those who refuse to participate in the study. For the qualitative part of the study, inclusion criteria for older

people are: i) voluntary participation in the study, ii) diagnosed with UI for at least 6 months, iii) able to express themselves verbally. Inclusion criteria for NH professionals are: i) voluntary participation in the study and ii) caring older people with UI for at least 6 months.

Study procedures

In the beginning of the project, the research team will be trained, receive standardised operating procedures, and be calibrated to ensure the reliability of the data regarding anthropometry, handgrip test and Short Physical Performance Battery (SPPB) with its corresponding calculation of the interclass correlation coefficient (ICC). After the calibration, a pilot study will be conducted with a minimum of 20participants, with the aim to check if the evaluations and tests are reliable. Before starting data collection, every NH director must accept the participation in the project with a formal consent. After that, the list of residents will be obtained, and the individuals selected according to inclusion/exclusion criteria. Then, the residents or their legal guardians will be informed about the project and if willing to participate will sign the informed consent. The assessment procedure starts with the placement of the activPAL3^{TM} activity monitor (PAL Technologies Ltd., Glasgow, UK), a reliable and valid device considered as a gold standard to record and analyse the SB (49–51) The device will be worn on the anterior medial part of the right thigh, sealed with a flexible nitrile cover and adhered to the skin with a hypoallergenic adhesive dressing. The device will capture data continuously during both awake and sleeping time, for 7 consecutive days. Sociodemographic information will be obtained from the NH registers. Information on the continence status and other conditions will be checked with the residents' caregivers. Cognitive status will be assessed in all individuals and a more extended questionnaire on quality of life, incontinence, lower urinary tract symptoms, depressive and anxiety symptoms, social network and loneliness will be applied to residents with cognitive capacity. The approximate time of application of the physical tests and the questionnaire to the participant is 30-45 minutes. In case of fatigue, the participant will be offered the possibility of interrupting or stopping the assessment whenever he/she wishes.

Data collection

Section H of Minimum Data Set (MDS) version 3.0 (52) will be used to assess the presence of UI and other bladder and bowel conditions. Where a resident has preserved cognitive capacity to answer questionnaires, the continence status will be checked with the International Consultation on Incontinence Questionnaire Urinary Incontinence - Short Form (ICIQ-UI SF), validated to Spanish (53). According to the MDS and the ICIQ UI-SF, the type of UI will be determined: stress, urgency, mixed and functional. The number of absorbents (pads/diapers) used daily will also be taken into account. In addition, information on lower urinary tract symptoms will be collected using the International Prostate Symptoms Score (IPSS) (54). To evaluate SB, the variables of steps, duration in minutes of SB periods, total time in SB, SB bouts, total time in standing position and walking in hours and transitions from sitting to standing will be taken with the activPAL3^{TM} activity monitor, (PAL Technologies Ltd., Glasgow, UK) for 7 consecutive days. The

device placement is on the anterior and middle of the right thigh, or on the unaffected leg thigh in cases of stroke.

Sociodemographic variables such as age, gender, date of birth, date of institutionalization, number and type of deliveries (vaginal or caesarean), level of education, marital status, chronic conditions (high blood pressure, diabetes, cancer, lung disease, stroke, dementia, Parkinson's, osteoporosis, kidney failure, dyslipidaemia, cardiac disease and mental illness), history/current tobacco use and alcohol consumption urinary tract infection in the last 30 days, bone fracture in the last year, hospitalization in the last year, meds and normal routine blood analysis from NH records (biochemical data of vitamin D, albumin and pre-albumin, Protein C-Reactive) will be recorded. Regarding health-related variables, delirium, ulcers (any type), functional ability (modified Barthel Index)(55,56), cognitive status (Pfeiffer Scale)(57), faecal incontinence (according to MDS 3.0), lower tract urinary symptoms (through the International Prostate Symptoms Score), falls during the last year (number, places and consequences, from NH records), physical capacity using the Short Physical Performance Battery (SPPB)(58), mobility (Rivermead Mobility Index)(59), frailty (Clinical Frailty Scale)(60) and quality of life using the self-reported questionnaire EUROQOL-5D (EQ-5D)(61) will be assessed. To ensure we can compare with other studies on sarcopenia/frailty, we will also report any unintended weight loss in the last year (more than 4.5 kg or more than 5% of previous weight in the last year), and handgrip strength will be measured by JAMAR Plus Digital Hand dynamometer. The approximate consumption of water and drinks in millilitres and types of drinks will be collected over a 24-hour period and will be completed by the resident themselves, where their cognitive capacity is sufficiently preserved, or by health professionals in the NH. The total number of medications in daily use will be registered, as well as the types of medications, according to the international classification system *Anatomical Therapeutic Chemical* classification system and the Defined Daily Dose (ATC/DDD)(62). In addition, psychosocial factors will be considered: number of monthly visits from friends/family, according to the caregivers, as well as the Yesavage questionnaire (GDS-VE) (63) to assess depressive symptoms, the Hospital Anxiety and Depression Scale (HADS) for anxiety (64), social network through the Lubben social network scale (65) and loneliness through the 6-item Gierveld Scale (66,67) in all those subjects with sufficient cognitive capacity to answer questionnaires.

Anthropometric variables include weight (kg), height (m), body mass index (BMI), arm circumference (cm), waist circumference (cm), hip circumference (cm) and calf circumference (cm). These measurements will be obtained using a Seca 213 measuring device (Seca Medizinische Messsysteme und Waagen., Hamburg, Deutschland) and a measuring tape. Measures related to body composition will be reported as a percentage (%) of body fat, % of fat-free mass and % of body water, using a Tanita TBF-300 bioimpedance device (Tanita Institute., Tokyo, Japan). Finally, the nutritional status will be evaluated by the Mini Nutritional Assessment (MNA)(68), considered as a gold standard method for evaluating nutritional status.

In the qualitative part of the study, descriptive phenomenology will be used as it is one of the leading methodologies used in social sciences and healthcare research in order to understand the lived

experiences of individuals (69). Therefore, for being able to understand the experience of having UI among residents and explore health professionals' experience of providing health services to residents with UI, descriptive phenomenology will be considered as the methodological approach of the qualitative part. We aim for the participants to be heterogeneous in terms of their descriptive characteristics (e.g. age, gender, duration and level of incontinence among residents; gender and years of experience with residents with UI among health professionals).

Two semi-structured interview guides will be used, one with residents and one with health professionals. The guides were created by the researchers with two general research questions in mind: (a) What is your experience of having UI and what effects does it have on everyday life? (b) How is the experience of providing healthcare to residents with UI and what are the difficulties experienced in this aspect? Individual interviews will be conducted with residents due to the delicate character of the experienced problem, meanwhile, with health professionals, a focus group will be conducted as it is a method which facilitates remembering the forgotten experiences. In both interviews, the data collection process will be terminated after data saturation is reached, in other words, when no new topic arises during the interviews (70). As recommended by Sandelowski (1995) (71) the sample size will be large enough to allow the unfolding of a new and richly textured understanding of the studied phenomenon, but small enough to be able to do a deep and case-oriented analysis of the qualitative data. In the qualitative analysis of the obtained data, Colaizzi's phenomenological data analysis method will be considered. This method was largely influenced by Husserl's descriptive phenomenological approach and it will allow the researchers to discover the fundamental structures of the phenomena which is being investigated (72).

Statistical Analysis

Firstly, descriptive analysis will be undertaken indicating absolute and relative frequencies for categorical variables and mean and standard deviation for quantitative variables. Before doing the bivariate analysis, a sub-analysis of the minimum number of days with the ActivPAL that are necessary to have a reliable data record on SB will be performed, following the PA procedure performed by Nicolai et al. (2010) (73)Subsequently, the bivariate analysis will be applied through the Chi-square test (or Fisher's test) and the linear Chi-square test in case of dichotomous or ordinal variables, as well as the Student t-test for quantitative variables. As an association measure, the Prevalence Ratio will be used, with a confidence level of 95%. The multivariate analysis will be undertaken through the Poisson regression with robust variance.

Stage II. Incidence and predictor factors of functional and continence decline, falls, hospitalisations, mortality among older people in NH. A two-year cohort study.

Design

Longitudinal prospective 2-year study.

Setting

NHs and residents participating in stage 1 will be followed up over the next two years. Every 6 months through interviews with the professionals of the institutions will be asked for information on functional decline, frailty, continence status, hospitalizations, mortality, diagnosis and suspected cases of COVID-19 and changes in the medication of their residents. Data related to falls will be collected through a continuous prospective register in every institution.

Patient and public involvement

There was no patient or public involvement in the design and conduct of the stage 2.

Sample size

According to a 2-year longitudinal study conducted by Jerez-Roig *et al.* (2017)(4) in institutionalised older people, an initial sample of 280 people is powered to detect prognostic factors of functional decline.

Eligibility criteria

All nursing home residents (male or female) aged 65 years or older who live in the institution permanently. Subjects in coma or palliative care (prognosis of short life) will be excluded. For the study of functional decline, residents with limitations in all basic activities of daily living will be excluded from the study. For the study of continence decline, the participants who have a urinary catheter fitted, or ostomy, as well as those with total UI defined by Section H of Minimum Data Set (MDS) version 3.0 (52) at baseline will be excluded. For analysing the incidence of falls, those subjects who do not walk independently (with or without aids) will be excluded.

Study procedures

After baseline (stage I), the Stage 2 of the OsoNaH. The variables are mortality and causes, hospitalizations and causes, falls, functional capacity evaluated by means of the Barthel scale, frailty evaluated by the Clinical Frailty Scale, COVID-19 diagnostic by test (PCR or serological), suspected case of COVID-19 and modifications in the medication in the last 6 months.

Data collection

Functional status will be assessed by the modified (5-point Likert scale) Barthel's index. Continence status will be assessed using the section H of Minimum Data Set (MDS) 3.0. Falls will be registered continuously taking into account the date, location and consequences of falls. Dates and causes of hospitalizations and mortality (dates and causes) will be also registered retrospectively during the 6-month assessments. For the COVID-19-related variables the following information will be collected: date and results of diagnosis tests of COVID-19 (PCR or serological antibody test), suspected case (symptoms of cough, fever and/or breathing difficulties during the previous 6 months). The levels of frailty of the resident will be assessed with the Clinical Frailty Scale (60). Finally, any change in the regular medication in the last 6 months (include the name of the med, dose and the duration of treatment) will be registered.

Statistical Analysis

The actuarial method will be utilized to analyse functional and continence decline throughout the 5-wave cohort. The Kaplan-Meier method will be used for falls, hospitalizations and deaths. Log-rank test will be applied for bivariate analysis. Those variables with $p<0.25$ and variables "age" and "sex" will be considered susceptible for testing in the multiple model. Multivariate analysis will be performed using Cox regression. Forward selection will be utilized to introduce covariables in the model, firstly introducing those variables with higher hazard ratio (HR) values and observing the behaviour and adjustment of the model (stepwise forward). Risk measurements will be presented for HR, with the respective confidence intervals (CI) and p values. Finally, the proportionality test will be carried out for the final model, followed by Schoenfeld residual analysis to verify validity of Cox's semiparametric model. The ROC curve will be analysed to determine the predictive ability of the created functionality decline index. The inferential statistical analysis will be performed at a 95% confidence level.

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	11
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 11

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	n/a

Objectives	#7	Specific objectives or hypotheses	4
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4,5
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6, 10
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6,10
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7,11
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	n/a

		change in response to harms, participant request, or improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7, 11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7,11
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6, 10
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6, 10

Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a

Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7, 11
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	7, 11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	n/a
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9, 11

Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	9, 11
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	9, 11
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a

Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	2
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	n/a
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	n/a
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	11

Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	11
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	n/a
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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Urinary Incontinence and Sedentary Behaviour in Nursing-Home residents in Osona, Catalonia: protocol for the OsoNaH project, a multicentre observational study

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Urinary Incontinence and Sedentary Behaviour in Nursing-Home residents in Osona, Catalonia: protocol for the OsoNaH project, a multicentre observational study

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Abstract

Introduction. Several studies have shown that physical activity (PA) levels and sedentary behaviour (SB) are independent risk factors for many health-related issues. However, there is scarce evidence supporting the relationship between SB and urinary incontinence (UI) in community dwelling older adults, and no information on any possible association in institutionalized older adults. Stage I of this project has the main objective of determining the prevalence of UI and its associated factors in nursing home (NHs) residents, as well as analysing the association between UI (and its types) and SB. Stage II aims to investigate the incidence and predictive factors of functional and continence decline, falls, hospitalizations, mortality and the impact of the COVID-19 pandemic among NHs residents.

Methods and analysis. Stage I is an observational, multicentre, cross-sectional study with mixed methodology that aims to explore the current status of several health-related outcomes in NHs residents of Osona (Barcelona, Spain). The Prevalence Ratio will be used as an association measure and multivariate analysis will be undertaken using Poisson regression with robust variance. Stage II is a 2-year longitudinal study that aims to analyse functional and continence decline, incidence of falls, hospitalizations, mortality and the impact of the COVID-19 pandemic on these outcomes. A survival analysis using the actuarial method for functional decline and continence, evaluated every 6 months, and the Kaplan-Meier method for falls, hospitalizations and deaths and Cox regression for multivariate analysis will be undertaken.

Ethics and dissemination. The study received the following approvals: University of Vic - Central University of Catalonia Ethics and Research Committee (92/2019 and 109/2020), Clinical Research Ethics Committee of the Osona Foundation for Health Research and Education (FORES) (code 2020118/PR249). Study results will be disseminated at conferences, meetings and through peer-reviewed journals.
ClinicalTrials.gov ID: NCT04297904

Article Summary

Strengths and limitations of this study:

- The first study to focus on the association between UI and SB in the older institutionalized population and the largest study analysing SB patterns in the older institutionalized population with a gold standard measure (ActivPAL).
- Mixed methods study (quantitative and qualitative approach) considering a wide range of variables to assess health, based on the biopsychosocial model.
- An initial cohort firstly assessed before the pandemic (from January to March 2020) will be followed to analyse the impact of COVID-19 in NHs residents.

- Limitations include: participation of NHs residents or legal guardians in research-based studies, cognitive impairment that may affect information on some independent variables that require the participant response and the potential increase in SB during the COVID-19 pandemic.

Introduction

Low birth rates and an increased life expectancy are transforming the age pyramid of the European Union (EU); probably the most important change will be the marked transition towards an aged society, a characteristic that is already evident in several EU member states, in 2017, the 65+ population had an increase of 0.3% compared to the previous year, and an increase of 2.4% compared to the previous 10 years, in fact people aged over 80 years old are increasing at a faster rate than any other age segment of the EU population (1). This increase is linked to a growing demand for long-term care, which represents a significant overload on public health resources. One in four older adults will spend a period of their life in a nursing home (NHs), and the need for such care will persist until their death (2). Older adults who live in a NHs are the most frail of our society with high levels of functional limitations and physical dependence (3,4), and one third of them have cognitive impairment (5).

The prevalence of urinary incontinence (UI) in Spain is approximately 10% in women aged between 25 and 64 years old, and over 50% in those over 65 years old (6). In NHs, this proportion is around 50% and is frequently associated with cognitive impairment, physical inactivity and immobility syndrome, among other factors (7). In this context, we can find a type of UI described as "functional" in that it is caused by an inability to move to the toilet independently, due to a physical, communicative or cognitive problem (e.g. dementia)(8). Most older adults mistakenly believe that incontinence is part of the normal aging process and/or is an irresolvable problem (9,10). However, UI is a geriatric syndrome that represents an indicator of frailty and quality of health care, as well as a risk factor for pressure ulcers, falls, fractures and even urinary sepsis or death (11–14).

NHs residents are the least physically active of all older adults, and spend most of their awake time sedentary (15,16). Doing regular physical activity (PA) limits the development and progression of most prevalent chronic diseases (17). However, the time spent in sedentary behaviour (SB) by older adults has increased considerably in the last three decades (18) and SB increases with age (19). SB has been gaining recognition as a risk factor for specific health conditions and reduced mobility, sometimes independent of PA levels (20). A typical day for a resident will consist in a sequence of periods of SB, light intensity PA (LPA) and moderate to vigorous intensity PA (MVPA)(21,22). NHs residents spend an average of 79% of their day sedentary, 20% in LPA and 1% in MVPA (23).

There is a consensus among researchers that low levels of PA and prolonged patterns of SB could be direct risk factors for UI in older adults (24–27). A recent observational study on the association between SB and urinary incontinence in community dwelling older women concluded that urgency urinary incontinence (UUI) was associated with significantly increased average duration of SB bouts. The importance of

objective measurement of SB was highlighted and it was suggested that decreasing time in prolonged sitting may be a target intervention to reduce UUI (28). Researchers conclude that there is a lack of complementary studies of higher quality on the association between SB and UI (29–33)

Frailty is one of the most important concerns regarding our aging population as it is a leading contributor to functional decline and early mortality in older adults (5–7). Evidence grows that this state is linked to several relevant health outcomes, similarly prevalent in all countries. The last consensus defined frailty as "a clinical state in which there is an increase in an individual's vulnerability for developing an increased dependency and/or mortality when exposed to a stressor"(8).

Functional decline is one of the main health-related issues that affect older adults because it limits their autonomy and leads to dependency (34). In older adults, functional capacity can be defined as the ability to carry out basic activities of daily living (BADL) (10). The association between functional decline and urinary incontinence (UI) could be bidirectional, which can lead to a cycle where continence reduction results in functional decline, and functional decline leads to further decrease in continence (14,18).

Falls, though preventable, are common among older adults, and the resulting injuries can threaten their health, independence, and everyday routines. Aging is one of the main risk factors for falls, for this reason, older adults have a high risk of injuries, increased dependence, disabilities, and institutionalization. All these outcomes are also risk factors for frailty (19,20). Several studies have shown that the transition from in-home to institutional care is related to substantially higher mortality rates, as well as reduced physical and cognitive function (21,29). It is well known that hospital admission can affect the process of usual aging due to adverse health outcomes after hospitalization, especially in terms of functional decline (35), mortality (21,22), frailty (23) and cognitive impairment (24).

Therefore, the aim of this study is to determine the prevalence of UI and its associated factors, specifically the association between UI types and SB patterns in older people living in NHs in Osona, a region of Catalonia, Spain. Also, Stage I of this project aims to analyse the current status of health-related outcomes, based on the biopsychosocial model of health, and to describe the current interventions to reduce SB and increase PA, and the control measures to manage UI by the NHs of Osona. In addition to this, it aims to understand the experience of having UI among residents and the experience of providing healthcare to these individuals among health professionals, using descriptive phenomenology.

On the other hand, the SARS-CoV-2, called coronavirus 2019 (COVID-19), has emerged as a worldwide pandemic (36). This virus has been shown to be particularly deadly for older adults and those with certain underlying medical conditions (37–40). In relation to deaths from COVID-19 in Spain, 87% of the reported

deaths were 70 years or more and 95% presented comorbidity (41). The population living in NHs, generally with older age and multiple comorbidities, are the most vulnerable to COVID-19 (42). In Catalonian NHs from 28,418 suspected cases, 11,560 confirmed positive cases and 3,055 deaths were reported until May 2020 (43–45). Due to the vulnerability of NHs themselves to outbreaks of respiratory diseases (46,47) and the frailty of NHs populations, there is a need to analyse the impact of COVID-19 on NHs residents in terms of mortality, hospitalisation, as well as other health, social and cognitive-related variables.

Stage II aims to follow-up the included cohort of Stage I and analyse the incidence and predictive factors for functional decline, frailty, continence decline, falls, hospitalizations and mortality among older people living in NHs for a 2-year period. The cohort firstly assessed before the first diagnosis of COVID-19 in NHs will be followed to identify the potential risk and protective factors for mortality due to COVID-19 and the impact of this disease on functioning and hospitalizations.

Methods and analysis

Study design

The present study follows the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines and consists of two stages (48):

- Stage I. Observational cross-sectional study on the prevalence of UI (and its types) and SB patterns and the possible association between both issues in the older population living in NHs.
- Stage II. Observational 2-year longitudinal (cohort) study on functional and continence status, falls, hospitalizations and mortality (including COVID-19 data) among NHs residents.

Stage I. Prevalence of UI and its associated factors among NHs residents in Osona (Barcelona, Spain)

Design

Cross-sectional study with mixed methodology. The starting month was September 2019, main data collection was conducted between January and March 2020 and, after data analysis, the study is planned to be finalised in May 2021.

Setting and location

The present study was conducted in NHs of Osona. According to the Catalonia Government, there are 19 registered NHs: 12 public (or private) and 7 for-profit. The first contact with the NHs was done by email and phone call, to explain the project, resolve any queries and send them the participation documents for the study if they are interested in taking part.

Patient and public involvement

There was no patient or public involvement in the design and conduct of the Stage I.

Sample size

The calculation of the study sample was based on the preliminary data from the pilot study. Calculating the sample from the difference between variables (presence of IU or not and the mean of the total time in hours of SB), an absolute precision of the 5% and a significance level of the 5%, the sample to estimate the association between IU and SB was 120 subjects. Considering a 30% possible non-response rate, the final sample corresponds to 145 subjects. A simple random sampling was undertaken. The exclusion criteria will be given in a flow chart (49).

Eligibility criteria

All NHs residents (male or female) aged 65 years or older who lived in the institution permanently, with or without cognitive impairment were included in the quantitative part of the study. Exclusion criteria were subjects in a coma or palliative care (prognosis of short life), hospitalised and those who refused to participate in the study. For the qualitative part of the study, inclusion criteria for older people were: i)

voluntary participation in the study, ii) diagnosed with UI for at least 6 months, iii) able to express themselves verbally. Inclusion criteria for NHs professionals were: i) voluntary participation in the study and ii) caring older people with UI for at least 6 months.

Study procedures

In the beginning of the project (October-November 2019), the research team was trained, received standardised operating procedures, and was calibrated to ensure the reliability of the data regarding anthropometry, handgrip test and Short Physical Performance Battery (SPPB) with its corresponding calculation of the interclass correlation coefficient (ICC). After the calibration, a pilot study was conducted with a minimum of 20 participants in January 2020, with the aim to check if the evaluations and tests were reliable. Before starting data collection, every NHs director accepted the participation in the project with a formal consent. After that, the list of residents was obtained, and the individuals selected according to inclusion/exclusion criteria. Then, the residents or their legal guardians were informed about the project and those who accepted to participate, signed the informed consent. The assessment procedure started with the placement of the activPAL^{3TM} activity monitor (PAL Technologies Ltd., Glasgow, UK), a reliable and valid device considered as a gold standard to record and analyse the SB (50–52).

The device was worn on the anterior medial part of the right thigh, sealed with a flexible nitrile cover and adhered to the skin with a hypoallergenic adhesive dressing. The device captured data continuously during both awake and sleeping time, for 7 consecutive days. Sociodemographic information was obtained from the NHs registers. Information on the continence status and other conditions were checked with the residents' caregivers. Cognitive status was assessed in all individuals and a more extended questionnaire on quality of life, incontinence, lower urinary tract symptoms, depressive and anxiety symptoms, social network and loneliness was applied to residents with cognitive capacity (53). The approximate time of application of the physical tests and the questionnaire to the participant was 30-45 minutes. In case of fatigue, the participant was offered the possibility of interrupting or stopping the assessment whenever he/she wished.

Data collection

Section H of Minimum Data Set (MDS) version 3.0 (54) was used to assess the presence of UI and other bladder and bowel conditions. When a resident had preserved cognitive capacity to answer questionnaires, the continence status was checked with the International Consultation on Incontinence Questionnaire Urinary Incontinence - Short Form (ICIQ-UI SF), validated to Spanish (55). According to the MDS and the ICIQ UI-SF, the type of UI was determined: stress, urgency, mixed and functional. The number of absorbents (pads/diapers) used daily were also considered. In addition, information on lower urinary tract symptoms was collected using the International Prostate Symptoms Score (IPSS) (56). To evaluate SB, the variables of steps, duration in minutes of SB periods, total time in SB, SB bouts, total time in standing position and walking in hours and transitions from sitting to standing were taken with the

activPAL3™ activity monitor, (PAL Technologies Ltd., Glasgow, UK) for 7 consecutive days. The device placement was on the anterior and middle of the right thigh, or on the unaffected leg thigh in cases of stroke.

Sociodemographic variables such as age, gender, date of birth, date of institutionalization, number and type of deliveries (vaginal or caesarean), level of education, marital status, chronic conditions (high blood pressure, diabetes, cancer, lung disease, stroke, dementia, Parkinson's, osteoporosis, kidney failure, dyslipidemia, cardiac disease and mental illness), history/current tobacco use and alcohol consumption urinary tract infection in the last 30 days, bone fracture in the last year, hospitalization in the last year, medication and normal routine blood analysis from NHs records (biochemical data for Vitamin D, Albumin, Pre-Albumin and Protein C-Reactive) were recorded. Regarding health-related variables, delirium, ulcers (any type), functional ability (modified Barthel Index)(57,58), cognitive status (Pfeiffer Scale)(59), faecal incontinence (according to MDS 3.0), lower tract urinary symptoms (through the International Prostate Symptoms Score), falls during the last year (number, places and consequences, from NHs records), physical capacity using the Short Physical Performance Battery (SPPB)(60), mobility (Rivermead Mobility Index)(61), frailty (Clinical Frailty Scale)(62) and quality of life using the self-reported questionnaire EUROQOL-5D (EQ-5D)(63) were assessed. To ensure a possible comparison with other studies on sarcopenia/frailty, the handgrip strength measured by JAMAR Plus Digital Hand dynamometer (64) and any unintended weight loss in the last year (more than 4.5 kg or more than 5% of previous weight in the last year), were recorded. The approximate consumption liquids (water and drinks in millilitres and types of drinks) were collected over a 24-hour period, completed by the residents themselves if their cognitive capacity was sufficiently preserved, or by health professionals of the NHs. The total number of daily use medications were registered, as well as the types of medications, according to the international *Anatomical Therapeutic Chemical* classification system (ATC)(65). In addition, psychosocial factors were considered in all residents with sufficient cognitive capacity to answer questionnaires: number of monthly visits from friends/family, according to the caregivers, as well as the Yesavage geriatric depression scale (5-GDS) (66) to assess depressive symptoms, the Hospital Anxiety and Depression Scale (HADS) for anxiety (67), social networks through the Lubben social network scale (68) and loneliness through the 6-item De Jong- Gierveld Loneliness Scale (69,70).

Anthropometric variables included weight (kg), height (m), body mass index (BMI), arm circumference (cm), waist circumference (cm), hip circumference (cm) and calf circumference (cm). These measurements were obtained using a Seca 213 measuring device (Seca Medizinische Messsysteme und Waagen, Hamburg, Deutschland) and a measuring tape. Measures related to body composition were reported as a percentage (%) of body fat, % of fat-free mass and % of body water, using a Tanita TBF-300 bioimpedance device (Tanita Institute., Tokyo, Japan) (71) Finally, the nutritional status was evaluated by the Mini Nutritional Assessment Test (MNA)(72), considered as a gold standard method for evaluating nutritional status in old people.

In the qualitative part of the study, descriptive phenomenology will be used, as it is one of the leading methodologies used in social sciences and healthcare research, in order to understand the lived experiences of individuals (73). Therefore, to understand the experience of having UI among residents and explore health professionals' experience of providing health services to residents with UI, descriptive phenomenology is planned to be considered as the methodological approach of the qualitative part. We aimed for the participants to be heterogeneous in terms of their descriptive characteristics (e.g. age, gender, duration and level of incontinence among residents; gender and years of experience with residents with UI among health professionals).

During the initial plan, two semi-structured interview guides will be used, one with residents and one with health professionals. The guides were created by the researchers with two general research questions in mind: (a) What is your experience of having UI and what effects does it have on everyday life? (b) How is the experience of providing healthcare to residents with UI and what are the difficulties experienced in this aspect? Individual interviews were considered as the data collection method to use with residents due to the delicate character of the experienced problem, meanwhile, with health professionals, a focus group was considered as an ideal data collection method and facilitates remembering forgotten experiences. In both interviews, the data collection process will be terminated after data saturation is reached, in other words, when no new topic arises during the interviews (74). As recommended by Sandelowski (1995) (75) the sample size must be large enough to allow the unfolding of a new and richly textured understanding of the studied phenomenon, but small enough to be able to do a deep and case-oriented analysis of the qualitative data. In the qualitative analysis of the obtained data, Colaizzi's phenomenological data analysis method will be considered. This method was largely influenced by Husserl's descriptive phenomenological approach and will allow the researchers to discover the fundamental structures of the phenomena which is being investigated (76).

The feasibility of the qualitative dimension was adversely affected by the physical restrictions applied in NHs due to the COVID-19 pandemic as face-to-face interviews with residents, and focus groups with health professionals were considered unsafe for both participant groups due to increased risk of transmission. For this reason, online video conferencing was planned to be used during the collection of the qualitative data. However, it is foreseen that conducting individual interviews via video conferencing with residents will decrease both the applicability of the interview and the quality of the data obtained due to their unfamiliarity with this virtual method and the possible auditory and/or visual limitations that they may have. Thus, it was decided to exclude the dimension of UI experiences among residents and only have individual interviews with healthcare professionals via video conferencing instead of creating online focus groups, which will be relatively challenging to manage virtually.

Statistical Analysis

Firstly, descriptive analysis will be undertaken indicating absolute and relative frequencies for categorical variables and mean and standard deviation for quantitative variables. Before doing the bivariate analysis, a sub-analysis of the minimum number of days with the ActivPAL that are necessary to have a reliable data record on SB will be performed, following the PA procedure performed by Reid et al. (2013) (77) Subsequently, the bivariate analysis will be applied through the Chi-square test (or Fisher's test) and the linear Chi-square test in case of dichotomous or ordinal variables, as well as the Student t-test for quantitative variables. As an association measure, the Prevalence Ratio will be used, with a confidence level of 95%. The multivariate analysis will be undertaken through the Poisson regression with robust variance.

Stage II. Incidence and predictor factors of functional and continence decline, falls, hospitalisations, mortality among older people in NHs. A two-year cohort study.

Design

Stage II of the OsoNaH project is a longitudinal prospective 2-year study and follows the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines (48). The starting month was January 2020 and, following the data analysis, the study is planned to be finalized in December 2022. Data will be collected every 6 months over 2 years focussing on functional decline, frailty, continence status, hospitalizations, mortality, diagnosis and suspected cases of COVID-19 and changes in the medication of their residents in the NHs, already assessed at the baseline from January to March 2020. The information is provided by the NHs staff and the NHs records according to the COVID-19 health measures, by phone call or email avoiding direct contact with the NHs staff.

Setting

NHs and residents participating in Stage I will be followed up over the next two years. Every 6 months through interviews with the professionals of the institutions will be asked for information on functional decline, frailty, continence status, hospitalizations, mortality, diagnosis and suspected cases of COVID-19, COVID-19 containment measures within NHs and changes in the medication of their residents. Data related to falls will be collected through a continuous prospective register in every institution.

Patient and public involvement

There was no patient or public involvement in the design and conduct of the Stage II.

Sample size

According to a 2-year longitudinal study conducted by Jerez-Roig *et al.* (2017)(4) in institutionalised older people, an initial sample of 280 people is powered to detect prognostic factors of functional decline.

Eligibility criteria

NHs residents (male or female) aged 65 years or older who live in the institution permanently will be included. Subjects in coma or palliative care (prognosis of short life) will be excluded. For the study of functional decline, residents with limitations in all basic activities of daily living will be excluded from the study. For the study of continence decline, the participants who have a urinary catheter fitted, or ostomy, as well as those with total UI defined by Section H of Minimum Data Set (MDS) version 3.0 (54) at baseline will be excluded. For analysing the incidence of falls, those subjects who do not walk independently (with or without aids) will be excluded.

Study procedures

From the baseline of January 2020 to March 2020, every six months the data will be collected, until accomplishing the 2-year follow-up, in March 2022. The data is provided by the NHs staff and the NHs who previously agreed to participate in the study signing the informed consent to access the records and the variables of mortality and causes, hospitalizations and causes, falls, functional capacity evaluated by means of the Barthel scale, frailty evaluated by the Clinical Frailty Scale, COVID-19 diagnostic by test (PCR or serological), suspected case of COVID-19 and modifications in the medication in the last 6 months. Due to COVID-19 restrictions, interviews are conducted by phone call or email with the NHs staff every six months.

Data collection

Functional status will be assessed by the modified (5-point Likert scale) Barthel's index. Continence status will be assessed using the section H of Minimum Data Set (MDS) 3.0. Falls will be registered continuously taking into account the date, location and consequences of falls. Dates and causes of hospitalizations and mortality (dates and causes) will be also registered retrospectively during the 6-month assessments. For the COVID-19-related variables the following information will be collected: date and results of diagnosis tests of COVID-19 (PCR or serological antibody test), suspected case (symptoms of cough, fever and/or breathing difficulties during the previous 6 months) and room lockdown (duration in days). The levels of frailty of the resident will be assessed with the Clinical Frailty Scale (62). Finally, any new comorbidity diagnosis as well as any change in the regular medication (registered according to ATC classification (65)) in the last 6 months will be assessed.

Statistical Analysis

The actuarial method will be utilized to analyse functional and continence decline throughout the 5-wave cohort. The Kaplan-Meier method will be used for falls, hospitalizations and deaths. Log-rank test will be applied for bivariate analysis. Those variables with $p<0.25$ and variables "age" and "sex" will be considered susceptible for testing in the multiple model. Multivariate analysis will be performed using Cox regression. Forward selection will be utilized to introduce covariables in the model, firstly introducing those variables with higher hazard ratio (HR) values and observing the behaviour and adjustment of the model (stepwise forward). Risk measurements will be presented for HR, with the respective confidence intervals (CI) and p values. Finally, the proportionality test will be carried out for the final model, followed by Schoenfeld residual analysis to verify validity of Cox's semiparametric model. The ROC curve will be analysed to determine the predictive ability of the created functionality decline index. The inferential statistical analysis will be performed at a 95% confidence level.

Ethics and dissemination

The study received the following approvals: University of Vic - Central University of Catalonia (UVic-UCC) Ethics and Research Committee (92/2019 and 109/2020), Clinical Research Ethics Committee of the Osona Foundation for health research and education (FORES) (code 2020118/PR249). On December 2019 the UVic-UCC's Ethics and Research Committee approved an amendment to the project that consisted of adding questionnaires on physical activity, loneliness, social network and number of visits to residents. Later, modifications due to Covid-19 restrictions were evaluated and approved by the same Ethics and Research Committee on November 2020 with registry number 009.

Every NHs director accepted the participation in the project with a formal consent. Then, NHs staff were informed about the project and the ones who accepted to participate signed the informed consent. Finally, the selected residents or their legal guardians were informed about the project and those who accepted to participate signed the informed consent. Participants also had been informed that they could withdraw from the study at any time without giving any reasons.

Study results will be disseminated at conferences, meetings and through peer-reviewed journals. The researchers may also communicate the results to NHs, NHs staff, residents and resident's families.

Author Contributions: PFG, JJ, MGG and EMM were involved in designing of the study and the writing of the manuscript. AES, MM, PMM, SRC, SRF and MY were involved in the acquisition of data. DB participated in the design and the sample size calculation. EGR, LCP, MRM, MTM, JNM, DB, JB, DS and the rest of authors reviewed drafts of the paper, and approved the final draft.

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Competing interests statement: None.

Data availability statement: Data are available upon reasonable request. The dataset from this study will be made available on request to eduard.minobes@uvic.cat.

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	11
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 11

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	n/a

Objectives	#7	Specific objectives or hypotheses	4
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4,5
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6, 10
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6,10
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7,11
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	n/a

		change in response to harms, participant request, or improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7, 11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7,11
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6, 10
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6, 10

Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a

Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7, 11
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	7, 11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	n/a
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9, 11

Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	9, 11
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	9, 11
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a

Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	2
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	n/a
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	n/a
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	11

Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	11
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	n/a
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a