Prospective GERiatric Observational (ProGERO) Study: Cohort Design and Preliminary Results

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Research article

Keywords: cohort study, outpatient, community-dwelling, older adult, comprehensive geriatric assessment, frailty, disability, survival

Posted Date: July 17th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-43877/v1

Version of Record: A version of this preprint was published on October 27th, 2020. See the published version at https://doi.org/10.1186/s12877-020-01820-4.

Abstract

Background: The demographic changes in Brazil as a result of population aging is one of the fastest in the world. The far-reaching new challenges that come with a large older population are particularly disquieting in low- and middle-income countries (LMICs). Longitudinal studies must be completed in LMICs to investigate the social and biological determinants of aging and the consequences of such demographic changes in their context. Therefore, we designed the Prospective GERiatric Observational (ProGERO) study, a longitudinal study of older adults in Brazil, to collect data both on healthy aging and chronic diseases, and investigate characteristics associated with adverse outcomes in this population.

Methods: The ProGERO study takes place in a geriatric outpatient clinic in the largest academic medical center in Latin America. We performed baseline health examinations in 2017 and will complete subsequent in-person visits every three years when new participants will also be recruited. We will use periodic telephone interviews to collect information on the outcomes of interest between in-person visits. The baseline evaluation included data on demographics, medical history, physical examination, and comprehensive geriatric assessment (CGA; including multimorbidity, medications, social support, functional status, cognition, depressive symptoms, nutritional status, pain assessment, frailty, gait speed, handgrip strength, and chair-stands test). We used a previously validated CGA-based model to rank participants according to mortality risk (low, medium, high). Our selected outcomes were falls, disability, health services utilization (emergency room visits and hospital admissions), institutionalization, and death. We will follow participants for at least ten years.

Results: We included 1,336 participants with a mean age of 82±8 years old. Overall, 70% were women, 31% were frail, and 43% had a Charlson comorbidity index score ≥3. According to our CGA-based model, the incidence of death in one year varied significantly across categories (low-risk=0.6%; medium-risk=7.4%; high-risk=17.5%; P<0.001).

Conclusion: The ProGERO study will provide detailed clinical data and explore the late-life trajectories of community-dwelling older patients during a follow-up period of at least 10 years. Moreover, the study will substantially contribute to new information on the predictors of healthy and pathological aging in older adults from LMICs.

Background

Brazil is currently facing one of the fastest population aging processes in the world. However, contrary to what happened in more developed countries, the Brazilian demographic transition occurs in a context of unfavorable economic, social, and health conditions [1–3]. In a country where 84% of the population lives in urban areas, Brazilian older adults are particularly vulnerable to experience adverse health outcomes and disparities [4–6]. In Sao Paulo, the largest city in the country, inhabited by more than 12 million people, the aging index has increased from 57% in 2010 to 80% in 2019 [7]. During the same period, the proportion of older adults living in the city went from 12 to 15% [7].

Such a fast-paced demographic shift determines multifaceted changes that are not fully understood. The far-reaching challenges that come with a large older population are particularly disquieting in low- and middle-income countries (LMICs), where health systems are often ill-prepared to cope with the increasing burden of chronic diseases and high disability-adjusted life expectancy [2, 8]. Therefore, longitudinal studies are still necessary to investigate the social and biological determinants of aging and its consequences in LMICs [2].

We have designed the Prospective GERiatric Observational (ProGERO) study, a longitudinal study of Brazilian older adults living in the community, to collect data both on healthy aging and prevalent chronic diseases, and to investigate

characteristics associated with adverse outcomes in this population. Our aim in this report was to describe our study design and share the baseline characteristics of our participants.

Methods

Study design and participants

The ProGERO is a prospective cohort study of community-dwelling older adults from an outpatient clinic at the Hospital das Clinicas of the University of Sao Paulo Medical School (HCFMUSP), in Sao Paulo, Brazil. The study aims to explore sociodemographic and clinical characteristics associated with adverse outcomes during the study follow-up, including falls, disability, emergency room (ER) visits, hospital admissions, institutionalization, and death.

HCFMUSP is the largest academic medical center in Latin America, following 1.5 million persons (28% of them are older patients) from the metropolitan area of Sao Paulo, Brazil. HCFMUSP geriatrics clinic operates 12 hours a day, five days a week, with a multidisciplinary team (geriatricians, registered nurses, social workers, and psychologists) offering regular appointments (usually every three months) for older outpatients.

In our recruitment, we invited every patient aged 60 years and over who had a medical appointment at the clinic between April and December 2017. We excluded subjects according to the following criteria: (1) need for immediate hospital admission or emergency care on baseline (e.g., hemodynamic instability, acute respiratory symptoms, delirium); (2) inability to be reached by telephone for follow-up assessments between visits; or (3) refusal to consent with the study.

Eligible patients who consented to participate underwent a baseline clinical assessment with a standardized interview and physical examination. After recruitment, baseline characteristics will be reassessed every three years during in-person follow-up visits. We plan to invite new patients to participate in the study in each new wave of in-person visits and estimate to include approximately 700 new participants per recruitment cycle. We will also complete 6-month telephone interviews to collect data on our outcomes of interest between visits. Finally, we plan to follow participants for at least ten years, or until their deaths. The study design is further detailed in Fig. 1.

Clinical assessment

A multidisciplinary team of four registered nurses and four geriatricians completed the baseline clinical assessments. The nurses were responsible for undertaking the interviews and questionnaires, while geriatricians monitored data quality (review of missing data and information reliability), elucidated queries during assessments, and reviewed electronic medical records to collect data on multimorbidity and medications. When participants were unable to communicate, we interviewed family members and caregivers to obtain the best information available.

We collected and managed the data using the Research Electronic Data Capture (REDCap) [9].

Demographics. We collected the following sociodemographic data: age; sex; race/ethnicity; marital status; level of literacy; occupation; annual household income per capita, expressed both as a continuous variable and as categories according to the Brazilian minimum wage in 2017 [1 minimal wage = 4000 United States dollar (USD) per year]; and neighborhood. We also recorded whether participants lived alone or with other persons.

Multimorbidity and medications. We measured multimorbidity using the Charlson comorbidity index [10] and the Functional Comorbidity Index (FCI) [11], based on information retrieved from medical records. We also used medical records to compile the lists of medications in use.

The Charlson comorbidity index includes 19 clinical conditions, with various scoring weights, and the final score is defined by the total sum of items (range: 0–37 points; 37 = worst) [10]. We analyzed the Charlson comorbidity index both as a continuous variable and stratified in ordinal categories (0, 1–2, and ≥ 3 points) [12]. The FCI is a comorbidity scale designed to predict functional decline. It includes 18 clinical conditions, and its score corresponds to the total disease count (range: 0–18; 18 = worst) [11].

Anthropometry, physical examination, and sensory evaluation. Anthropometric and physical examination measures included: blood pressure, pulse rate, weight, height, and calf circumference.

Blood pressure and pulse rate were measured at the heart level, using an electronic manometer and a standardized cuff (Omron Hem-7113 Automatic Blood Pressure Monitor, Omron Healthcare Co., Ltd.). Values were recorded after 5 minutes of rest while sitting. Three readings were taken in succession, with at least one-minute intervals, and the average was used for the analyses [13].

We asked participants to wear light clothing and no shoes when anthropometric measures were taken. We calculated body mass index (BMI) using the metric system (kg/m^2) and measured the calf circumference (cm) using an inelastic tape placed on the broadest possible section of the left calf [14].

Finally, we screened for the presence of visual and auditive deficits ("yes" or "no") using the following questions, extracted from the Alzheimer's Disease Cooperative Study - Activities of Daily Living - Prevention Instrument (ADCS-ADL-PI) Questionnaire [15]: (1) "Can you see well enough to recognize a friend across the street?"; and (2) "Can you usually hear and understand another person when they talk in a normal voice?".

Comprehensive Geriatric Assessment. The 10-minute Targeted Geriatric Assessment (10-TaGA)[14] is a validated multi-domain hands-on instrument that was developed to screen geriatric syndromes and estimate the global impairment of patients, using the

cumulative deficit model. In previous research, 10-TaGA provided adequate

validity and good accuracy in discriminating between frail and

non-frail individuals and good predictive power for one-year mortality, disability and hospitalization[14, 16, 17]. The 10-TaGA evaluates: (1) social support (living arrangements and availability of help) [18]; (2) emergency department visits and hospitalizations in the previous six months; (3) the number of falls in previous 12 months; (4) the number of medications; (5) dependence in activities of daily living (ADLs) (Katz index)[19]; (6) 10-point Cognitive Screener (10-CS) [20]; (7) self-rated health; (8) 4-item Geriatric Depression Scale (GDS-4) score [21]; (9) nutritional status (weight loss in the previous 12 months, BMI and calf circumference); (10) gait speed [14]. Each domain is categorized and scored as normal (0 points), mild impairment (0.5 points), or severe impairment (1 point), based on conventional cut-off points derived from the literature for singular items. A single numerical score [range: 0 (no deficit); 1 (presence of all deficits)] is calculated, dividing the total sum of points by the number of evaluated domains [14]. Based on previous work demonstrating the good predictive power of 10-TaGA for one-year mortality, we classified participants as having low (0-0.24), medium (0.25–0.49), or high (0.50-1) risk of death [17].

Functional status. We examined detailed information on functional disability using the Brazilian version of the Older Americans Resources and Services Multidimensional Functional Assessment Questionnaire (BOMFAQ) [22] and the Katz index [19]. The BOMFAQ (range: 0–30; 30 = worst) evaluates dependency in 15 ADLs and instrumental activities of daily living (IADLs). For each item, a score from zero to two is assigned (0: unable to perform the activity; 1: needs supervision or help to perform the activity; 2: completely independent to perform the activity) [22].

We additionally used the Katz index to evaluate ADLs (feeding, dressing, bathing, toileting, transferring, and continence). Each activity is scored as either zero (unable to perform the activity) or one (completely independent to perform the activity) [14, 19].

Pain. We screened for pain complaints and their intensity using the 5-point Verbal Descriptor Scale: no pain; mild pain; moderate pain; severe pain; or worst possible pain [23]. Participants identified as having any pain were also asked the following question: "Did the pain occur on most days in the past three months?". A negative answer defined sporadic pain, while a positive answer defined persistent pain [24, 25]. We further investigated participants with persistent pain using the multidimensional Geriatric Pain Measure [26, 27].

Frailty. We defined frailty using the Study of Osteoporotic Fractures (SOF) [28] index for frailty, and the FRAIL scale [29, 30]. The SOF index includes three items: weight loss of 5% or more; inability to rise from a chair five times; and reduced energy level. The score ranges from zero to three points, and classifies patients as: robust (0 points); pre-frail (1 point); or frail (2–3 points) [28]. The FRAIL scale includes five mnemonic questions on fatigue, resistance, ambulation, illnesses, and loss of weight. The score ranges from zero to five points, and classifies patients as: robust (0 points); pre-frail (1–2 points); or frail (≥ 3 points) [29, 30]. Although the phenotypic criteria for the diagnosis of frailty[31] were not used in our study, recent studies have shown that the SOF index and FRAIL scale have similar performances to predict adverse outcomes in vulnerable older adults [32–34].

Physical performance. We measured gait speed instructing participants to walk 4.5 meters at their usual pace and used the faster of two measurements in our analyses. Participants were allowed the use of assistive devices whenever necessary [14].

We measured handgrip strength using a Saehan dynamometer. We requested that participants sit on armless chairs, with their spines erect, shoulders positioned in adduction and neutral rotation, elbows flexed at 90°, forearms in half pronation, and neutral wrists. They would then squeeze the device using their dominant hand, applying their maximum strength. We used the mean value of three measurements in our analyses [35].

Finally, we requested that those who were able to sit and stand independently do the chair-stands test. We asked that participants do their best to complete five sit-to-stand repetitions, without the help of the arms, and recorded the total time in seconds [36].

Telephone follow-up

We follow participants with telephone interviews every six months. A team of trained research assistants, blinded to the baseline assessments, conduct the contacts. They interview participants (or their proxy) following structured questionnaires designed to collect data on falls, functional status, frailty, pain, use of health services, institutionalization, and death. Medical investigators adjudicate the quality of the telephone interviews. The adjudication process includes the review of missing data, information reliability and periodic feedback meetings between medical investigators and research assistants.

Outcomes

Our primary longitudinal outcomes are the time to death (survival) and time to incident disability. We defined incident disability as the need for assistance in an ADL that was preserved on baseline (including bathing, toileting, dressing, transferring, and eating). Participants who were completely dependent for ADLs on baseline will be excluded from this analysis. Also, we will not assess incontinence as a measure of disability, given the high frequency and multifaceted meaning of this condition in older adults [37].

We additionally selected the following secondary outcomes: hospital admissions, defined as unplanned hospital stays of 24 hours or more; ER visits, defined as any ER visit during the follow-up; falls, defined as an unintentional displacement of the body to a lower level, with an inability to correct said displacement on time [38]; and institutionalization. We will also measure BOMFAQ scores in our telephone follow-up and use it as a repeated measures outcome.

Analyses plan

Sample size calculations. Based on the 10-TaGA classification for mortality risk, we estimated our sample size using the log-rank test for comparisons of 12-month survival across three groups (low, medium, and high risk), with a proportion between groups of 1: 2: 1, respectively [17]. Assuming a one-year mortality rate of 2.5% in the lowest risk group [17], an alternative bilateral hypothesis, an alpha error of 0.05%, a beta error of 0.20 and an estimated sample loss of 15%, we projected that a total sample of 1,081 participants would be required to detect 5% differences between the groups.

Statistical analyses. We described continuous variables using means and standard deviations (SD) or medians and interquartile ranges (IQR), according to their distribution. We reported categorical variables using counts and percentages. Further, we presented the characteristics of participants and one-year incidence of death across the three 10-TaGA categories. We used a one-way analysis of variance (ANOVA) or its non-parametric equivalent (Kruskal-Wallis) to compare continuous variables across categories. We used the trend chi-square test ($\chi 2$) to compare independent proportions. For missing data, we used the complete-case analysis approach, as only two participants didn't complete the first-year telephone follow-up. All statistical tests were two-tailed, and an alpha level of 0.05 was used to determine significance.

Ethics

All subjects provided their written informed consent. If a participant was diagnosed with dementia or had a 10-CS score of zero, consent was obtained from a legal guardian. The study and informed consent form have been approved by the local ethics committee of São Paulo University School of Medicine (CAAE: 65809517.3.0000.0068).

Attending physicians working in our clinic do not have access to the study data. The decision to participate or not in the study did not affect in any way the patients' standard of care.

Data sharing

To enhance reporting transparency, this study will be reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology Statement (STROBE): Guidelines for Reporting Observational Studies [39]. Data and resources will be shared with other eligible investigators through academically established means. The datasets used during the study will be available from the corresponding author on reasonable request.

Results

We identified 1,348 study candidates in our outpatient clinic between April and December 2017. We did not include 12 participants for the following reasons: refusal to participate in the study (n = 7), baseline clinical symptoms requiring hospital admission or immediate emergency care (n = 2), or inability to comply with telephone follow-up interviews (n = 3). Consequently, we included and assessed 1,336 older adults on baseline (Fig. 2).

Participants had a mean (SD) age of 82 ± 8 years, 70% were women, 57% identified as being white, 52% were widowed, and 52% had an annual household income per capita between 4000 and 8000 USD (Table 1). Overall, 83% of our

participants lived in Sao Paulo city, coming from all the different regions of the city. Figure 3 illustrates an even broader area represented in the ProGERO Study, with patients living in at least 28 cities in the metropolitan area of Sao Paulo.

Table 1
Baseline sample sociodemographic characteristics (2017) of Prospective GERiatric Observational (ProGERO) Study, according to the 10-minute Target Geriatric Assessment (10-TaGA) risk categories (n = 1,336).

Sociodemographic characteristics		10-TaGA risk categories				
		Total	Low (n = 160)	Medium (n = 735)	High (n = 441)	P-value
Age (years), mean (SD)		82.22 (7.58)	78. 74 (7.67)	82.35 (7.34)	83.26 (7.59)	< 0.001
Female Gender, n (%)		938 (70.21)	97 (60.62)	520 (70.75)	321 (72.79)	0.014
Ethnicity, n (%)	White	758 (56.74)	100 (62.50)	415 (56.46)	243 (55.10)	0.488
	Black	376 (28.14)	17 (10.62)	85 (11.56)	51 (11.57)	
	Mixed	153 (11.45)	35 (21.88)	207 (28.17)	134 (30.39)	
	Asian	45 (3.37)	8 (5.00)	26 (3.54)	11 (2.49)	
	Indigenous	4 (0.30)	0 (0.00)	2 (0.27)	2 (0.45)	
Marital status, n (%)	Widowed	698 (52.25)	57 (35.62)	391 (53.20)	250 (56.69)	< 0.001
	Married	457 (34.21)	83 (51.87)	249 (33.88)	125 (28.34)	
	Single	92 (6.89)	11 (6.88)	42 (6.12)	36 (8.16)	
	Divorced	89 (6.66)	9 (5.53)	50 (6.80)	30 (6.81)	
Level of literacy (years), median (IQR)		4 (1–5)	4 (3–10)	4 (2–5)	4 (1–4)	< 0.001
Annual household income per capita*, n (%)	< 4000 USD	345 (26.18)	38 (24.36)	191 (26.27)	116 (26.67)	0.028
	4000–8000 USD	684 (51.90)	75 (48.08)	364 (50.07)	245 (56.32)	
	> 8000 USD	289 (21.92)	43 (27.56)	172 (23.66)	74 (17.01)	

* annual household income was classified according to the Brazilian minimum wage in 2017 (1 minimal wage = 4000 USD per year).

10-TaGA = 10-minute Target Geriatric Assessment; SD = standard deviation; IQR = interquartile range; USD = United States dollar. To compare the 10-TaGA risk categories, we used one-way analysis of variance (ANOVA), its non-parametric equivalent (Kruskal-Wallis), and the trend chi-square test. All statistical tests were two-tailed, and an alpha level of 0.05 was used to determine significance.

The 10-TaGA scores ranged from 0 to 0.9, with a mean of 0.4 ± 0.2 points. According to our risk categories, 160 (12%) participants were classified as having low risk (0-0.24), 735 (55%) had medium risk (0.25–0.49), and 441 (33%) had high risk (0.5-1.0) of death.

Participants had a mean BMI of 27.2 ± 5.2 kg/m², walking speed of 0.7 ± 0.2 m/s, and handgrip of 13.5 ± 7.5 kg. We observed that 59% of the participants had difficulty in at least one ADL on the baseline, 31% were frail according to the SOF index criteria, 21% were frail by the FRAIL scale criteria, and 43% had Charlson comorbidity index scores > 2 points. The most prevalent comorbidities were hypertension (81%), persistent pain (44%), diabetes (36%), dementia (37%), congestive heart failure (21%), chronic kidney disease (21%), cerebrovascular disease (20%), coronary artery disease (20%), cancer (excluding non-melanoma skin cancer) (14%), and chronic obstructive pulmonary disease (7%). Visual impairment was verified in 66% of our sample, and hearing impairment in 78%. Also, 15% reported being current or past smokers. Additional characteristics of our population can be found in Table 2. Also, Table 3 summarizes the baseline characteristics of participants in the ProGERO study and other LMICs cohort studies.

Table 2
Baseline clinical and functional sample characteristics (2017) of Prospective GERiatric Observational (ProGERO) Study, according to the 10-minute Target Geriatric Assessment (10-TaGA) risk categories (n = 1,336).

Clinical and functional characteristics		10-TaGA risk categories				
		Total	Low (n = 160)	Medium (n = 735)	High (n = 441)	P value
BOMFAQ, median (IQR)		21 (15–26)	28 (26–30)	22 (18–26)	14 (9–19)	< 0.001
Katz, median (IQR)		5 (4–6)	6 (6–6)	5 (5–6)	3 (1–5)	< 0.001
SOF index, n (%)	Robust	442 (33.08)	115 (71.88)	278 (37.82)	49 (11.11)	< 0.001
	Pre-frail	474 (35.48)	42 (26.25)	298 (40.55)	134 (30.39)	
	Frail	420 (31.44)	3 (1.87)	159 (21.63)	258 (58.50)	
FRAIL scale, n (%)	Robust	305 (22.83)	66 (41.25)	167 (22.72)	72 (16.33)	< 0.001
	Pre-frail	709 (53.07)	85 (53.13)	421 (57.28)	203 (46.03)	
	Frail	322 (24.10)	9 (5.62)	147 (20.00)	166 (37.64)	
Handgrip (kg), mean (SD) (n = 1,136)		13.48 (7.53)	18.23 (7.69)	13.49 (7.53)	11.14 (6.25)	< 0.001
Inability to do the 5-repetition Sit-to-stand test, n (%)		572 (42.81)	13 (8.13)	243 (33.06)	316 (71.66)	< 0.001
Walking speed (m/s), mean (SD) (n = 1,012)		0.69 (0.22)	0.90 (0.20)	0.68 (0.19)	0.56 (0.22)	< 0.001
BMI (kg/m²), mean (SD) (n = 1,199)		27.15 (5.24)	27.56 (4.15)	27.44 (5.30)	26.38 (5.51)	< 0.001
Calf circumference (cm), mean (SD) (n = 1,325)		33.70 (4.44)	34.95 (3.53)	34.28 (4.32)	32.28 (4.57)	0.001
Charlson comorbidity index, n (%)	0 points	192 (14.37)	51 (31.87)	111 (15.10)	30 (6.80)	< 0.001
	1–2 points	568 (42.51)	69 (43.13)	324 (44.08)	175 (39.68)	
	≥ 3 points	575 (43.11)	40 (25.00)	300 (40.82)	236 (53.52)	

10-TaGA = 10-minute Target Geriatric Assessment; BOMFAQ = Brazilian version of the Older Americans Resources and Services Multidimensional Functional Assessment Questionnaire; IQR = interquartile range; SOF = Study of Osteoporotic Fractures; SD = standard deviation; BMI = body mass index; FCI = Functional Comorbidity Index. To compare the 10-TaGA risk categories, we used one-way analysis of variance (ANOVA), its non-parametric equivalent (Kruskal-Wallis), and the trend chi-square test. All statistical tests were two-tailed, and an alpha level of 0.05 was used to determine significance.

Clinical and functional characteristics	10-TaGA risk categories				
	Total	Low (n = 160)	Medium (n = 735)	High (n = 441)	P value
FCI, median (IQR)	3 (2–4)	2.5 (1–4)	3 (2–4)	3 (2–5)	< 0.001

10-TaGA = 10-minute Target Geriatric Assessment; BOMFAQ = Brazilian version of the Older Americans Resources and Services Multidimensional Functional Assessment Questionnaire; IQR = interquartile range; SOF = Study of Osteoporotic Fractures; SD = standard deviation; BMI = body mass index; FCI = Functional Comorbidity Index. To compare the 10-TaGA risk categories, we used one-way analysis of variance (ANOVA), its non-parametric equivalent (Kruskal-Wallis), and the trend chi-square test. All statistical tests were two-tailed, and an alpha level of 0.05 was used to determine significance.

Table 3
Sociodemographic and clinical characteristics of low- and middle-income countries (LMICs) main cohort studies.

Sociodemographic and clinical characteristics		LMICs cohort studies				
		ProGERO	ELSI-Brazil	SABE	MHAS	CHARLS
Country		Brazil	Brazil	Brazil	Mexico	China
Total participants		1,336 (≥ 60 years)	9,412 (≥ 50 years)	2,143 (≥ 60 years)	15,186 (≥ 50 years)	17,708 (≥ 45 years)
Year of Baseline Assessment		2017	2015–2016	2000	2001	2011–2012
Age (years)		Mean (SD): 82.2 (7.58)	Mean (CI): 62.9 (62.1–63.8)	Mean (range): 68 (60–100)	Mean (SD): Men: 62.3 (9.59); Women: 62.3 (9.67)	Mean (SD): Men: 59.8 (0.24); Women: 59.6 (0.29)
Female Gender, %		70.2	54.0	58.6	53.3	49.4
Marital status, %	Widowed	52.25	14.7	62.9	Men: 10.8; Women: 27.5	20.6
	Married	34.21	63.5	30.0	Men: 78.8; Women: 55.4	77.2
	Single/ Divorced	13.54	21.8	7.1	Men: 10.4; Women: 17.1	2.2
Hypertension, %		80.8	63.2	53.3	Men: 26.4; Women: 44.1	32.1
Diabetes, %		35.7	15.8	17.6	Men: 12.5; Women: 16.7	7.2
Cardiovascular disease, %		19.6	11.7	19.5	Men: 2.6; Women: 2.9	16.3
Cerebrovascular disease, %		19.9	5.3	8.2	Men: 2.6; Women: 2.6	3.1
Cancer, %		14.0	5.3	4.6	Men: 1.2; Women: 2.5	0.9
Difficulty in at least 1 ADL, %		58.9	23.2	22.1	Men: 8.6; Women: 10.8	18.8
Frailty, %		31.4	9	8.5	24.9	7.0

LMICs = low- and middle-income countries; ProGERO = Prospective GERiatric Observational Study; ELSI-Brazil = The Brazilian Longitudinal Study of Aging; SABE = The health, well-being and aging project; CHARLS = The China Health and Longitudinal Study; MHAS = The Mexican Health and Aging Study; SD = standard deviation; CI = confidence interval; ADL = activities of daily living.

Finally, the one-year incidence of death was considerably different across the 10-TaGA categories (low-risk = 0.6%; medium-risk = 7.4%; high-risk = 17.5%; $P < 0.001$).

Discussion

In this study, we describe the design and preliminary results of the ProGERO study, which aims to investigate the determinants of healthy and pathological aging in adults from LMICs.

In comparison with other cohort studies of community-dwelling older adults in Brazil [2, 40–46] and LMICs [47–52], our participants were older, had a more significant burden of disease, and a higher prevalence of frailty. The result was expected since our sample is mostly comprised of multimorbid older adults, followed in an academic medical center. Despite the profile of ProGERO participants bringing some drawbacks to our study, we have significant advantages over other LMICs population-based cohorts in a few aspects: (1) superior statistical power to explore patient-centered outcomes, considering the elevated incidence of these outcomes in a cohort of vulnerable older adults; (2) higher prevalence of the oldest old, ensuring a favorable opportunity to study these fast-growing age group; (3) higher accuracy and availability of clinical information provided by a teaching environment; and (4) small loss of outcome data guaranteed by telephone interviews between in-person visits. Furthermore, the ProGERO study is a prospective cohort study with an expected follow-up of several years. Therefore, our investigation may assist in determining reliable predictors of adverse outcomes in older adults, and in characterizing their functional trajectories over time.

Nevertheless, the study has a few limitations, and our preliminary results should be interpreted with some caution. We used a convenience sample from a geriatric outpatient clinic. Despite including patients from several different areas of Sao Paulo, their sociodemographic and clinical profile might limit the external generalizability of our results. Although we expect that our future results will be sufficiently robust to improve knowledge in the field, further testing and confirmation are likely to be required in different contexts and populations.

Conclusions

In conclusion, the ProGERO study is a prospective cohort study that will collect and explore comprehensive, long-term clinical data of geriatric outpatients from an LMIC. It will investigate how sociodemographic and clinical factors affect the health and functional trajectories of older adults, providing clinicians, administrators, and researchers with important new information to support their work.

Abbreviations

10-CS
10-point Cognitive Screener
10-TaGA
10-minute Target Geriatric Assessment
ADCS-ADL-PI
Alzheimer's Disease Cooperative Study - Activities of Daily Living - Prevention Instrument
ADL
activities of daily living
BMI
body mass index
BOMFAQ
Brazilian version of the Older Americans Resources and Services Multidimensional Functional Assessment Questionnaire
CGA
comprehensive geriatric assessment
ER
emergency room
FCI
Functional Comorbidity Index

GDS-4
4-item Geriatric Depression Scale
HCFMUSP
Hospital das Clinicas, University of São Paulo Medical School
IADL
instrumental activities of daily living
IQR
interquartile range.
LMICs
low- and middle-income countries
ProGERO
Prospective GERiatric Observational
REDCap
Research Electronic Data Capture
SD
standard deviation
SOF
Study of Osteoporotic Fractures
STROBE
Strengthening the Reporting of Observational Studies in Epidemiology Statement
USD
United States dollar

Declarations

Ethics approval and consent to participate

All subjects provided their written informed consent to their voluntary participation in this study and for the publication of their data. When participants were diagnosed with dementia, or their 10-CS scores were equal to zero, consent was obtained from their legal guardians. The study and informed consent form have been approved by the local ethics committee of São Paulo University School of Medicine (CAAE: 65809517.3.0000.0068).

Consent for publication

Not applicable

Availability of data and materials

The datasets used and analyzed in the study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

None.

Authors' contributions

MDS, LFR, JLLC, TCAR: study concept and design, data acquisition, data analysis, data interpretation, manuscript preparation. CD, EJBK: data acquisition, manuscript preparation. MJRA, TJAS, DA, CKS, WJF: study concept and design, data analysis, data interpretation, manuscript preparation.

ACKNOWLEDGMENTS

We would like to thank Aliny Gomes de Araújo, Expedita Ângela Henrique, Juliana de Paula Santoro, Talita da Silva Nascimento and Stephanie de Souza Costa Viana for participating in the clinical assessment and telephone follow-up of our participants.

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Figures

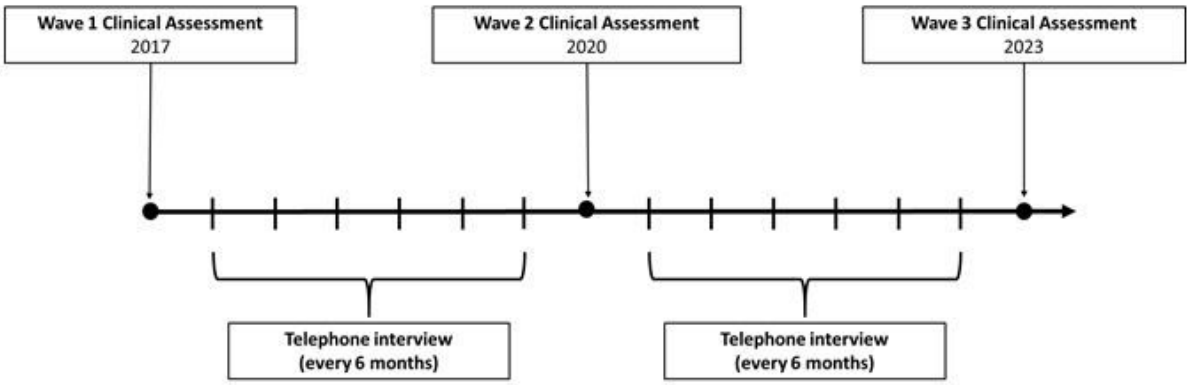

Figure 1

Schematic of study design. Clinical assessments are in-person with follow-up visits every three years for the reassessments of baseline characteristics and the inclusion of new participants.

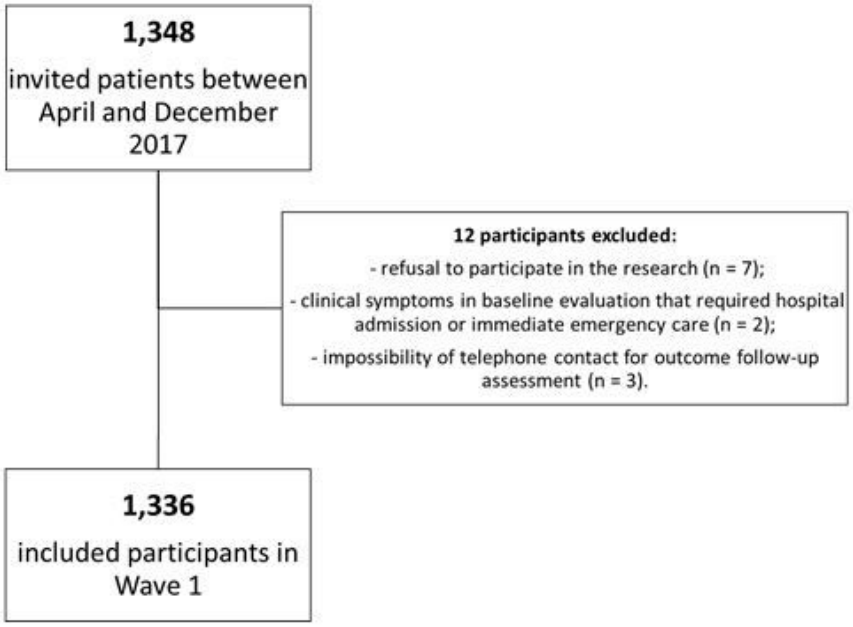

Figure 2

Flowchart of Wave 1 Baseline Clinical Assessment of Prospective GERiatric Observational (ProGERO) Study baseline participants (2017).

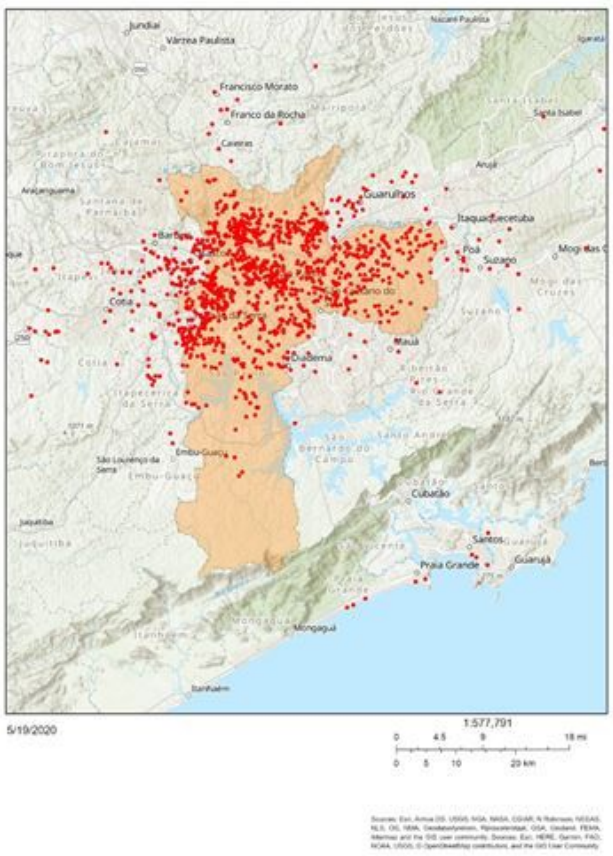

Figure 3

Distribution of Prospective GERiatric Observational (ProGERO) Study baseline participants (2017) in the metropolitan area of São Paulo, Brazil.

Supplementary Files

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