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Assumptions of the European FRAILTOOLS project and description of the recruitment process for this study in Poland

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Abstract: Aim: The main purpose of this article is to present the main assumptions of the FRAILTOOLS project and the characteristics of the recruitment process in the Polish part of the study.
Material and Methods: The FRAILTOOLS project is a prospective observational study conducted in 5 European countries. The study included people aged 75 and older. Each participating center was required to recruit 388 patients, which corresponded to 97 subjects in each clinical setting by center. Recruitment took place in clinical settings (hospital geriatric acute care, geriatric outpatient clinic, primary health care) and in social conditions (nursing homes). The frailty syndrome was assessed among study participants using 7 different scales. The follow-up period was 18 months.
Results: In Poland, 268 elderly subjects took part in the study, which constituted 69.1% of planned recruitment. The majority of participants were acute care patients (108 participants). A high percentage of people successfully recruited for the study was seen in nursing homes (83.5% of predicted number). The lowest recruitment came from primary healthcare (53 participants) and geriatric outpatient clinic (26). About a quarter of recruited participants were lost during follow-up period. The poorest results of control visits were observed among patients from geriatric wards and geriatric outpatient clinic.
Conclusions: The recruitment process for older people in Poland was satisfactory, mainly in hospitalized and institutionalized patients. The worst enrollment result was observed among outpatients. A detailed analysis of enrollment problems among the older Polish population is necessary to determine the optimal recruitment strategy and retain eligible study participants.

Keywords: frailty syndrome, elderly, research, recruitment strategy.

Introduction

Europe is now the continent with the largest number of older adults and a higher dependency rate. According to predictions of 2060, this trend will be maintained [1]. In addition, in the 20th century life expectancy increased in developed countries [2]. Due to the growing aging of the population with complex needs and care requirements, new policies are needed, in particular to implement pension, health and social reforms. It is necessary to identify populations with a higher risk of disability and dependence to implement preventive actions that can be achieved by identifying older adults who require specialist care that can delay or avoid dependence. The aging process goes through permanent and irreversible changes in structures as well as a decrease in the entire physiological functional reserve and a decrease in cognitive functions. Elderly people who present a significant decline in the function of most body systems and who have multiple physical or mental disabilities are defined as frail older subjects [3].

Frailty increases the susceptibility to acute illness, falls, disability, institutionalization and mortality [4]. This condition is also associated with other adverse effects such as polypharmacy and the use of medical consultations or hospitalization [5]. It is estimated that frailty affects 7% of the population aged ≥65 years and 25–40% of those aged ≥80 years and is twice as high in women than men, with the majority of nursing home residents being identified as frail [3, 6, 7]. Frailty could be reversed spontaneously [4, 8] or through nutritional and exercise-based interventions [9]. In view of its prognostic ability to cause disability, its high incidence and potential reversibility, frailty is the ideal goal to address disability among older adults [4, 8]. Dozens of scales and questionnaires were used to detect frailty; however, there is still no universal definition or general screening and diagnostic method [10].

The FRAILTOOLS project: *"A comprehensive validation of frailty assessment tools to screen and diagnose frailty in different clinical and social settings and to provide instruments for integrated care in older adults"* meets these needs. The target groups of this project are all older adults at risk of frailty (pre-frail) and those who are currently frail and at risk of developing disability. The FRAILTOOLS project has been specifically designed to evaluate the usefulness of screening and diagnostic tools for some selected instruments to detect frailty in both clinical (in-hospital geriatric wards, hospital outpatient offices, primary care) and social (nursing homes) settings, providing sequential diagnostic algorithms that are clinically justified. The main outcomes assessed in the study were all-cause mortality, the presence of physical disability, falls and incident cognitive impairment. Moreover, it is supposed that the results of FRAILTOOLS project will allow to create a universal algorithm for the diagnostic procedure of frailty syndrome in clinical and social conditions.

Engaging older subjects as participants in research projects is a constant challenge. Many randomized clinical trials did not include a sufficient number of elderly patients to obtain conclusive results for such a population [11]. In addition, samples covering only older people were not representative of the actual elderly population [12]. Reviews of the recruitment process for clinical trials show that less than a third of trials achieved the desired recruitment goal and often required longer recruitment periods [13]. What is more, many eligible patients resign from participation in controlled trials or drop-out during follow-up [14]. Barriers encountered in the recruitment of older people include distrust, transport problems, caregiver burden, medical problems, sensory and cognitive limitations, and poor health [14, 15].

The aim of the article was to present the main assumptions of the FRAILTOOLS project and the characteristics of the recruitment process in the Polish part of the study.

Materials and Methods

The FRAILTOOLS project is an observational, longitudinal and prospective study. The description of precise study protocol was published in BMC Geriatrics in 2019 [16]. In short, it was planned to recruit 1,940 subjects aged 75 years and older from various clinical (hospital or primary care) and social (nursing homes) conditions located in five regional coordination centers in Europe (Poland, Spain, United Kingdom, France and Italy), who signed informed consent after accepting participation in the study. Each participating center was required to recruit 388 patients, which corresponded to 97 subjects in each clinical setting by center. The main exclusion criteria were: a Mini Mental State Examination (MMSE) score below 20 points or a terminal illness (life expectancy <6 months). Subjects included from the hospital ward (acute care and geriatric outpatient clinic) and primary care had additional exclusion criteria: they were excluded if they scored less than 90 points while nursing home residents were excluded if they gained less than 40 points in the Barthel Index.

The following information was collected in the Query-Case Report Form: sociodemographic data; comorbidity was assessed using the Charlson Comorbidity Index [17]; functional status was evaluated by the Barthel Index [18], Lawton Index [19] and Short Physical Performance Battery [20]; cognitive status was measured by Mini Mental State Examination — MMSE [21] and frailty syndrome was diagnosed on the basis of selected frailty assessment scales: L.P. Fried's criteria [3], Frailty Trait Scale [22], SHARE-FI scale [5], 35-Items Rockwood Frailty index [23], FRAIL scale [24], Gérontopôle Frailty Screening Tool [25] and Clinical Frailty Scale [26].

The observation period was 18 months. Falls were assessed every 6 months (three times during the study) by phone call at 6 months and a direct interview at 12 and 18 months.

Polish project participants were recruited from among patients hospitalized at the Department of Internal Medicine and Gerontology (Geriatric Acute Care) at the Jagiellonian University Medical College in the University Hospital in Kraków; in the Geriatric Outpatient Clinic and from the practice of family doctors at the University Hospital; and selected long-term care facilities in Kraków. The recruitment process carried out in each setting is presented in Figure 1. In the hospital ward — Geriatric Acute Care and Geriatric Outpatient Clinic, the researchers talked directly to patients older than 75 years and after obtaining initial approval, conducted screening tests using MMSE and the Barthel Index. After fulfilling the initial qualification criteria, the patient signed an informed consent to participate in the project and conducted a detailed assessment. Primary care patients were pre-qualified by their family doctors and then reported to the clinic for further testing. From all long-term care facilities in Kraków, 6 centers for elderly and chronically ill people were selected, in which the number of inhabitants exceeded 100 people. Initial qualifications for the project were carried out by nurses and psychologists from qualified nursing homes. Then the researcher went to the nursing home to obtain informed consent and conduct tests.

The Bioethics Committee of the Jagiellonian University agreed to carry out the study by decision No 122.6120.227.2016. The data was recorded and analyzed while maintaining the anonymity of personal data protection. Descriptive statistics methods were used to present the recruitment process.

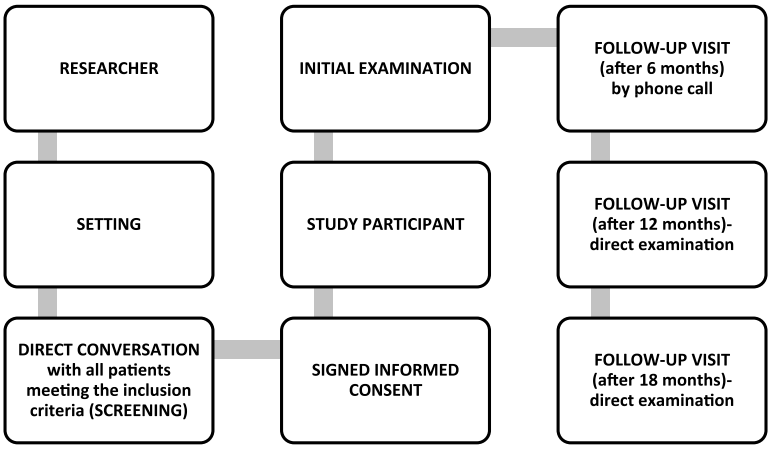

Fig. 1. The recruitment process carried out in each setting.

Results

The recruitment process was completed in all participating centers in September 2017. A total of 1,483 people were recruited for the study, which constituted 76.4% of the assumed number of recruited. The Polish center enrolled 268 elderly subjects, which was 69.1% of planned recruitment. A summary of the recruitment process in Poland is presented in Table 1. In Poland, the majority of participants were acute care patients and the least patients were from geriatric outpatient clinic.

Table 1. A summary of the recruitment process in Poland.

Setting	Estimated number to recruit in each center	Enrollment in Poland (number)	Percentage of predicted number
Acute care	97	108	111.3
Outpatient care	97	26	26.8
Primary care	97	53	54.6
Long-term care	97	81	83.5
Totally	388	268	69.1

During follow-up we have lost about one quarter of recruited participants (Table 2). The worst results of control visits were observed among patients from geriatric wards and geriatric outpatient clinic.

Table 2. Effectiveness of follow-up visits to Poland within 6, 12 and 18 months after the first visit.

	Acute care	Outpatient care	Primary care	Long-term care	Totally
Baseline, number	108	26	53	81	268
Follow-up, number (%)					
6 months	96 (88.9%)	23 (88.5%)	45 (85%)	79 (97.5%)	243 (90.7%)
12 months	57 (52.8%)	22 (84.6%)	40 (75.5%)	78 (96.3%)	197 (73.5%)
18 months	63 (58.3%)	15 (57.7%)	41 (77.4%)	62 (76.5%)	181 (67.5%)

Discussion

Overall, recruitment in Poland for the FRAILTOOLS project was good and amounted to almost 70%. However, significant differences were observed between groups of qualified patients, with the best results among those hospitalized and institutionalized,

and the weakest in both specialist and primary outpatient care. In prospective observation, the weakest effectiveness of follow-up visits was observed among patients covered by the project in the hospital ward and geriatric outpatient clinic.

Poland belongs to the population of European countries with a large number of people with frailty syndrome. In the SHARE study, in which the presence of frailty syndrome was assessed using the Frailty Index (deficiency accumulation index), the frequency of this syndrome was the highest in Poland and amounted to around 40% [5, 27]. The incidence of frailty syndrome in both high (16%) and lower (28%) income countries far exceeded the average.

Despite such widespread dissemination of this geriatric syndrome in the Polish population, recruitment to the project proved to be only good. The review of research on the recruitment of patients with frailty syndrome for health promotion programs found that neither the presence of frailty syndrome nor the intensity of intervention were the main predictors of recruitment results [28]. Analyzing data on problems with recruitment of the older population for prospective studies, health problems come to the fore.

People with severe chronic diseases, as well as their caregivers, are less likely to participate in research or at a distance [29]. Particularly important are movement problems, sensory organ disorders, mood or memory disorders and multimorbidity. These factors were probably also significant in our study with poor recruitment of outpatient patients and may affect the effectiveness of follow-up visits to patients who were initially hospitalized or were under the care of a geriatric outpatient clinic. The importance of these parameters is confirmed by both good recruitment and very good participation in follow-up visits in long-term care centers, where both qualification and control visits took place in a nursing home and did not require transport to the examination center. In our study, the best recruitment was observed among hospitalized patients and residents of nursing homes. It is likely that medical or nursing staff may influence a patient's decision to participate in the study [29]. Therefore, it is emphasized that establishing good cooperation with management and staff of the facility can be of great importance for obtaining good recruitment and keeping the patient under observation.

The analysis conducted by Crawford *et al.* also showed that the recruitment of elderly people for research was favored by obtaining support from caregivers along with face-to-face recruitment to reduce fear and build trust and understanding of the research process [30]. McHenry *et al.* revealed that the successful recruitment was related to cultivating relationships with community-based organizations, direct contacts with potential study participants, and providing services as an access point for eligible participants [31].

Social and cultural factors play a significant role in the recruitment process and observation period. The problem may be distrust and unwillingness to participate in research, fear of being used or experimenting [29].

Reducing the uncertainty of potential participants and their caregivers to participate in research requires conducting information and educational activities. The FRAILTOOLS study was not associated with undertaking therapeutic activities, but only with initial assessment and observation, so this aspect had a limited impact on the recruitment process. However, the reluctance to participate in research observed in Polish society has some significance.

The results of the survey showed that Poles are afraid of clinical trials [32]. The most common barriers include: fear, distrust of pharmaceutical companies and researchers, and information about a clinical trial. In Poland, there is a lack of information and educational campaigns that would provide reliable knowledge about clinical trials, inform about the opportunities and threats arising from participation in this type of research. There is also a need for medical staff to improve their qualifications and extend the scope of clinical trials. Kammerer *et al.* presented a step model to gain access to the elderly, which was based on literature and qualitative analysis of the recruitment processes of two studies from the German research consortium [33]. They identified four stages of the recruitment process: (1) building trust, (2) offering incentives, (3) identifying individual barriers, and (4) responding. The authors emphasize, however, that its implementation requires time, financial resources, flexibility and suitably qualified employees.

Conclusion

The recruitment process for older people in Poland for the FRAILTOOLS project was satisfactory, mainly in hospitalized and institutionalized patients. The lowest enrollment was observed among outpatient subjects. It is necessary to report recruitment problems in detail among the older Polish population in order to determine the optimal recruitment strategy and retain eligible study participants.

Conflict of interest

None declared.

Trial registration

Comprehensive validation of frailty assessment tools in older adults in different clinical and social settings (FRAILTOOLS), NCT02637518 (date of registration: 12/18/2015).

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