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Research article

PREVALENCE OF CHRONIC DISEASES IN INDIVIDUALS ASSISTED BY THE FAMILY HEALTH PROGRAM IN NITEROI, BRAZIL: EVALUATION OF SELECTION BIAS AND PROTOCOL

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ABSTRACT

Background: The strategy of the Family Health Program has been used as an alternative scenario for prevalence studies. This study intended to present the protocol of the Digitalis Study (DS), prevalence study of chronic diseases, to assess sources of possible selection bias and estimate their impact on the prevalence of self-reported hypertension, diabetes, and myocardial infarction. **Methods:** Randomization was performed between 38 160 registered individuals with 45 to 99 years by the Family Health Program .Differences between the sources of selection bias (non-acceptance, non-attendance, substitutions) were observed for gender and age. **Results:** Of the 1,190 residents contacted, 67.1% agreed to participate. There were 144 residents who were not randomly selected but whose participation was confirmed (substitutes). Women and individuals in the intermediate age groups and the prevalence of hypertension were higher among substitutes compared with the randomly selected individuals. **Conclusion:** The approach of the DS was adequate for the purposes of estimating prevalences, but there was a significant percentage of non-participation. The randomization strategy did not assume outdated records; alternative schedules for visits were not provided for; follow-up at the invitation stage was not sufficient to prevent substitutions and the inclusion of substitutes with a higher prevalence of hypertension.

Keywords: Epidemiological Methods, Epidemiology of chronic non communicable diseases, Kidney disease, Heart Failure.

INTRODUCTION

Few national surveys have been conducted in Brazil, and studies involving regional or citywide samples are scarce. During the last few years, performing such studies has become even more difficult due to problems associated with urban violence.[1]

The Family Health (FH) strategy has been adopted in many countries worldwide and is considered an alternative strategy for prevalence studies.[2-4] This strategy is currently being used in a large number of Brazilian municipalities and is conducted by

multidisciplinary teams, which keep records of all the residents in the areas covered by each unit. Physical facilities in these areas are available.[5-7] Health professionals who are known in the area have access to residents, which allows them to make invitations and provide visits close to the participants' places of residence, thus increasing adherence.

Prevalence studies rely on the voluntary participation of selected individuals and are more subject to selection bias. Non-participation in cross-sectional studies can reach over 50% and tends to increase.[8] Moreover, there is evidence that health professionals tend to favor individuals with the greatest need in clinical trials, thus violating the randomization strategy.[9] Drawing a parallel with studies in the Family Health Program, it can concluded that this alternative is more subject to selection bias, given that healthcare professionals have close ties with the local residents, thus making it more difficult to respect the impartiality of the rules of random selection even after training.

The objective of the present study is primarily to assess sources of possible selection bias and ascertain their impact on the prevalence of self-reported hypertension, diabetes, and myocardial infarction in the DIGITALIS STUDY, which was conducted using the population assisted by the Family Health Program [Programa Médico de Família (PMF)] in Niterói. Secondarily the the present study describes the study design, protocol, and the strengths and limitations of the strategy used in the DIGITALIS STUDY.

The digitalis study

Objective: The study was primarily designed to estimate the prevalence of heart failure and chronic kidney disease.

Design: This was a cross-sectional study that included 38 160 residents of both genders between 45 and 99 years of age who were registered at the Family Health Program in Niterói, State of Rio de Janeiro, Brazil.

Sample calculation: The sample size was calculated to estimate the prevalence and the measures of association, taking into consideration the feasibility of the study.[10] The calculations predicted that it would be possible to assess 600 individuals, plus 10% for incomplete assessments (losses), in 18 months. It was assumed that low prevalences, corresponding to a prevalence of less than 5% (heart failure, chronic kidney disease and diabetes), intermediate prevalences (microalbuminuria, obesity), and high prevalences, corresponding to a prevalence of more than 50% (hypertension), would be found.[11-14] Thus, the maximum relative accuracy would be 50%, 8%, and 8%, respectively. With respect to the estimation of the measure of association for the low (6%) and high prevalences (60%) of disease in the exposed group, the minimum prevalence ratios (PR) were 3 and 1.2, respectively. All calculations were performed at a 5% level of significance and 80% power using a two-tailed hypothesis test.

Procedures for selecting participants: The units (sectors) to be included in the study were randomly selected from the official list of PMF sectors. For each sector, approximately 80 individuals of both genders between 45 and 99 years of age were randomly selected from the records of residents kept by the program. It was anticipated that 30 examinations would be conducted per visit. Thus, it was recommended that 50 residents be invited to account for non-attendance and that another 30 names be collected for possible substitutions. In the training for the professionals from the randomly selected sectors, the following items were clarified: a) the list should be followed until the end, including the order of the names; b) individuals with medical conditions that prevent them from attending the health facility should not be invited (exclusion); c) if the study failed to achieve the 50 participants using the names on the random selection list, the study coordinators could invite residents who were not on the list as long as they invited the occupant of the residence who was closest to the gender and age (+/- 5 years) of the randomly selected resident being replaced. Substitute alternatives were requested by the PMF professionals to speed up the process of inviting residents. In some sectors, primarily due flooding by rain, families moved and records had not yet been updated. During the training, the invitations were delivered, which included scheduling of the date and time of the visit for each resident to be completed by the professional in that sector. The invitation contained information about the examinations that would be performed during the visit, instructions as to fasting and what to hear, and a request for the participants to bring prescriptions and the packaging of the drugs/remedies they were using. Prior to the visits, the sectors returned the lists, which included information regarding the substitutions made and the

reason the randomly selected residents could not participate. Based on the list sent by the sectors, the field materials were prepared and personalized for each resident. The reasons for non-attendance or non-completion of the assessment were not collected.

Visit procedures: On the day of the visits, which were always held on Saturday's beginning at 7 am, the assessment was started after the resident read and signed the informed consent form. The first step was to collect blood, and the participant was then given a balanced snack selected by nutritionists, with options for diabetics. The evaluation consisted of the following procedures: blood and urine collection, resting electrocardiogram, resting tissue echo-Doppler, clinical consultation with a physical examination, nursing consultation, anthropometric evaluation (weight, height, and waist circumference), completing a food frequency questionnaire, and completing the DIGITALIS questionnaire. On the day of the visit, the participants were scheduled to take a bone densitometry test (Dual-energy X-ray absorptiometry - DXA) at the Laboratory of Nutrition and Functional Assessment (Lanuff) of the Fluminense Federal University (Universidade Federal Fluminense) .

The researchers received training based on procedures developed for the study and tested in the pilot study using a PMF unit not included in the study. The results of all of the examinations performed were forwarded to the family doctor of each of the individuals in envelopes addressed to the participants.

The blood tests included complete blood count, glucose, urea, creatinine, TSH, lipid profile, vitamin D, uric acid, brain natriuretic peptide (BNP). In addition, the levels of albumin, creatinine, sodium, and alkali reserve as well as the pH were measured in the urine samples collected during the visit. Blood was collected, labeled, centrifuged, stored at approximately 4 °C and sent to the Sergio Franco Laboratory [Laboratório Sérgio Franco (LSF)]. The urine was collected, labeled, stored at 4 °C and also sent to the LSF. The samples were delivered to the laboratory within 5 hours after collection following each visit. The analyses were performed using the LSF methodologies (www.lsf.com.br). All of the information that was collected was compiled into a single database, prepared and analyzed using SPSS software, versions 17 and 21.

Table 1 presents the primary and secondary objectives, examinations, and instruments used to diagnose or classify each disease, factor, or risk marker.

METHODS

Assessment of the magnitude of selection bias: The DIGITALIS STUDY has three potential sources of selection bias: non-confirmation, non-attendance, and substitutions. To examine the differences between these three sources, we used the variables gender and age, which are available in the Brazilian census and in the PMF registration records. Data from the 2010 Brazilian census for the population between 45 and 99 years of age residing in the neighborhoods where randomly selected sectors are located were compared to the data for the randomly selected individuals. The objective was to identify possible differences due to chance, given that the reference population would be the group of randomly selected individuals.

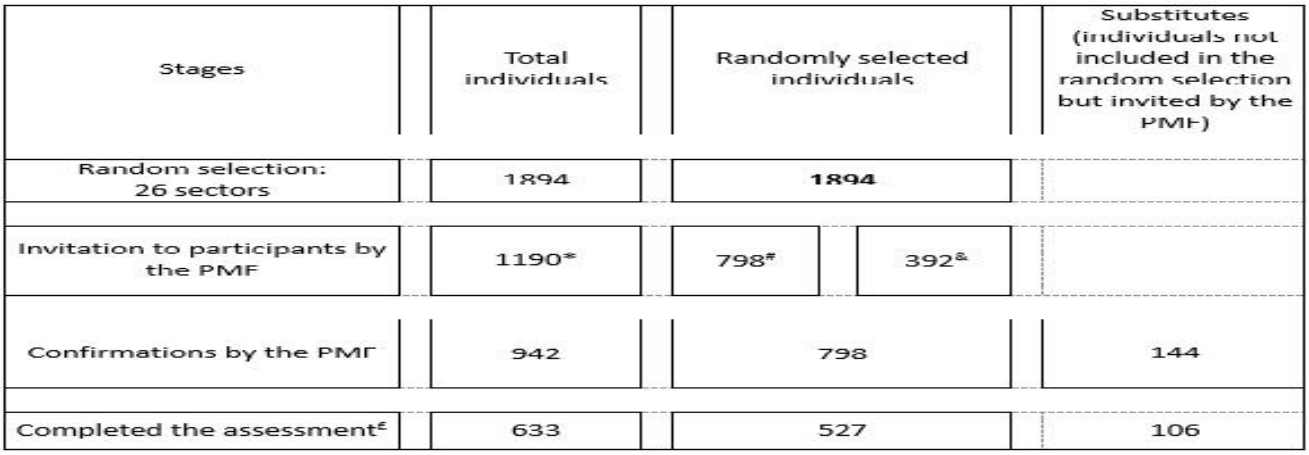
We used hypertension (high prevalence), type 2 diabetes (intermediate prevalence), and self-reported acute myocardial infarction (low prevalence) to determine the impact of substitutions in the estimations of prevalence.

The chi-square test was used to assess differences in proportions, and the Yates' correction for continuity was used in the case of 2x2 tables. Student's t-test was used to test for differences between means. The level of significance was set at 5% and a power of 80% using the two-tailed hypothesis test.

RESULTS

The stages of participant selection are presented in Figure 1. In total, 26 sectors and 1,894 individuals were randomly selected. Overall, 1,190 residents were contacted, including 798 (67.1%) who agreed to participate and whose participation was confirmed by the PMF and 392 (32.9%) individuals who were not found or refused to participate. Of the 1,894 randomly selected residents, 704 did not need to be contacted. Of the 942 individuals invited to participate and confirmed by the sectors, 144 (15.3%) residents were not randomly selected and were designated as substitutes. Of the 633 residents who attended and completed the cardiac assessment, 106 (16.7%) were substitutes. Considering the 942 individuals invited, 67.2% attended and completed

the cardiac assessment. In total, 66.0% of the randomly selected individuals and 73.6% of the substitutes participated in the study. Non-participation reached 56% among the 1,190 randomly selected and contacted residents, including 392 residents who could not be found or refused to participate and 271 who did not attend or did not complete the cardiac assessment.



*704 names on the random selection were not used, #798 accepted the invitation, &392 were not found or did not accept the invitation, £Completed the heart failure assessment.

Fig 1: Flow chat of participant selection

Table: 1. Primary and secondary objectives of the Digitalis study, measurement instruments, and classification criteria

Objectives	Measurement instruments	Classification
Primary		
Prevalence of heart failure (CF): stages and phenotypes	Clinical history, analysis of the prescription and physical examination, electrocardiogram, tissue echo-Doppler, BNP.[15]	Stages of HF HF with reduced ejection fraction HF with normal ejection fraction
Prevalence of chronic kidney disease (CKD) by stage	Clinical history, glomerular filtration, urinary albumin excretion, prevalence of a history of urolithiasis.[16]	CKD and stages
Secondary		
Prevalence of hypertension	Clinical history, use of antihypertensive medication, blood pressure measurements: three measurements, right arm, sitting position, 1-minute interval between measurements, taking the average of the 2nd and 3rd measurements. Device: OMRON 711 HC.[17]	Hypertension
Prevalence of type 2 diabetes	Clinical history, analysis of prescriptions, fasting glucose, fasting insulin.[18]	Type 2 diabetes
Prevalence of obesity	BMI waist circumference.[19]	
Prevalence of subclinical thyroid disease	TSH.[20]	
Prevalence of osteoporosis/sarcopenia	Dual-energy X-ray absorptiometry: iDXA (General Electric Company/Lunar Prodigy, Madison, WI), *software* enCORE 2010 - version 13.40.[21]	Osteoporosis; sarcopenia
Prevalence of mood disorders	PHQ-9.[22]	
Prevalence of cognitive disorders	Mini Mental.[23]	
Prevalence of sleep disorders	Berlin Questionnaire.[24]	
Prevalence of nursing diagnoses	NANDA .[25]	
Association with risk factors/markers		
✓ Lifestyle		
Eating habits	Food frequency questionnaire (FFQ).[26]	
Physical activity	Short International Physical Activity Questionnaire (IPAQ).[27]	
Tobacco use	Specific questions.[28]	
Alcohol consumption	Specific questions.[29]	
Health-related quality of life assessment	SF36 .[30]	

Some participants failed to submit urine samples, which reduced the number of patients who completed the renal assessment to 602. The analysis of bias for this objective was not addressed in this article.

Of the 392 unconfirmed residents, 215 (54.8) had moved to a different address, 77 (19.6) had no reason recorded for non-attendance, and 54 (13.8) had died, the highest percentage of whom were women. Illness, travel, work, alcoholism, prior commitments, healthcare plan, and a birth date outside the preset age group were less common reasons.

When comparing both genders, a greater number of women were confirmed and attended the assessment (p = 0.03 and <0.01, respectively). The mean age for both genders was lower among those who were confirmed compared with those who were unconfirmed (p <0.01 among women) and slightly higher among those who attended and completed the cardiac assessment compared with those who did not attend or did not complete the cardiac assessment (p = 0.04 among men) (Table 2).

Table 2: Difference in the percentages according to gender* and mean age by gender# and according to the confirmation and completion of the assessment for both the randomly selected individuals and the substitutes

	Confirmed n(%)	Unconfirmed n(%)	p-value	Attended and completed the cardiac assessment n(%)	Did not attend or did not complete the cardiac assessment n(%)	p-value
Men	384 (67,4)	186 (32,6)	0.03	243 (63,3)	141 (36,7)	<0,01
Women	558 (73,0)	206 (27,0)		390 (69,9)	168 (30,1)	
Total	942 (70,6)	392 (29,4)		633 (67,2)	309 (32,8)	
	Mean±SD	Mean±SD		Mean±SD	Mean±SD	
Men	59.42±10.4	60,66±12,0	0,23	60,22±10,6	57,9±10,0	0,04
Women	58.90±10.7	62,96±13,8	<0,01	59,11±10,2	58,41±11,9	0,52
Total	59.11±10.7	61,87±13,0	<0,01	59,59±10,4	58,14±11,00	0,08

*Difference tested using the chi-square test, with correction for continuity

Difference tested using Student's t-test

As expected, there were no statistically significant differences for the distribution by gender or age group according to census [A] or random selection [B] . The results of the analysis for each group, i.e., randomly selected individuals and substitutes, are presented in Table 3. The largest differences between the percentages of women occurred between the randomly selected individuals [B] and the confirmed substitutes [D] (66%) as well as the substitutes who attended and completed the cardiac assessment [F] (69.8%) (p = 0.01 and p <0.01). The distribution pattern per age group was similar between both the group of randomly selected individuals and the group of substitutes. Among the confirmed randomly selected individuals and those who attended and completed the cardiac assessment, there was an overrepresentation of individuals between 50 and 59 years of age and an underrepresentation of individuals between 70 and 84 years of age (p = 0.061 and p = 0.014, respectively, when compared with the randomly selected individuals [B]). Among the confirmed substitutes and those who completed the cardiac assessment, there was a higher percentage of individuals in the 50-54 and 65-74 age groups than in the 60-74 age group (p = 0.364 and p = 0.053, respectively, compared with the randomly selected individuals [B]).Among those who did not participate (both those who were unconfirmed and those who did not complete the cardiac assessment among the randomly selected individuals), there was a slight overrepresentation of individuals between 45 and 54 years of age, an underrepresentation of those between 55 and 64 years of age, and no significant differences in the other age groups (p = 0.36 and p = 0.05, respectively, compared with the randomly selected individuals [B]).

Table 3: Distribution by gender and age group& according to the census, random selection, confirmation by the PMF, and completion of the cardiac assessment

	Census* [A]		Randomly selected individuals [B]		Confirmed randomly selected individuals# [C]		Confirmed substitutes¢ [D]		Randomly selected individuals: completed the cardiac assessment£ [E]		Substitutes: completed the cardiac assessment£ [F]		Non-Participa-tion @$ [G]	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N (%)	
Sex														
Men	27440	(42,5)	842	(44,5)	335	(42,0)	49	(34,0)	**211**	**(40,0)**	32	(30,8)	310	(46,76)
Women	37049	(57,5)	1052	(55,5)	463	(58,0)	95	(66,0)	**316**	**(60,0)**	74	(69,8)	353	(0,53)
Total	64489	(100,0)	1894	(100,0)	798	(100,0)	144	(100,0)	**527**	**(100,0)**	106	(100,0)	663	(100,0)
Age (years)														
45-49	13559	(21,0)	385	(20,3)	161	(20,2)	24	(16,7)	**97**	**(18,4)**	**13**	**(12,3)**	143	(21,57)
50-54	12672	(19,6)	359	(19,0)	170	(21,3)	24	(16,7)	**100**	**(19,0)**	**16**	**(15,1)**	137	(20,66)
55-59	10661	(16,5)	308	(16,3)	144	(18,0)	24	(16,7)	**111**	**(21,1)**	**20**	**(18,9)**	94	(14,18)
60-64	8396	(13,0)	232	(12,2)	113	(14,2)	22	(15,3)	**82**	**(15,6)**	**13**	**(12,3)**	68	(10,26)
65-69	6184	(9,6)	170	(9,0)	69	(8,6)	14	(9,7)	**46**	**(8,7)**	**13**	**(12,3)**	63	(9,50)
70-74	4987	(7,7)	154	(8,1)	58	(7,3)	16	(11,1)	**41**	**(7,8)**	**14**	**(13,2)**	45	(6,79)
75-79	3797	(5,9)	129	(6,8)	46	(5,8)	15	(10,4)	**28**	**(5,3)**	**13**	**(12,3)**	51	(7,69)
80-84	2437	(3,8)	78	(4,1)	19	(2,4)	3	(2,1)	**10**	**(1,9)**	**2**	**(1,9)**	30	(4,52)
85-89	1253	(1,9)	45	(2,4)	11	(1,4)	0	(0,0)	**7**	**(1,3)**	**0**	**(0,0)**	17	(2,56)
90-94	455	(0,7)	22	(1,2)	5	(0,6)	2	(1,4)	**4**	**(0,8)**	**2**	**(1,9)**	7	(1,06)
95-99	118	(0,2)	12	(0,6)	2	(0,3)	0	(0,0)	**1**	**(0,2)**	**0**	**(0,0)**	8	(1,21)
Total	64519	(100,0)	1894	(100,0)	798	(100,0)	144	(100,0)	527	(100,0)	106	(100,0)	663	(100,0)

Differences were tested using the chi-square test. Differences between genders were tested using the correction for continuity. For the age categories, the last two age groups were combined. *p-value for the comparison between A and B for gender = 0.098 and age = 0.153. #p-value for the comparison between B and C for gender = 0.255 and age = 0.061. ¢p-value for the comparison between B and D for gender = 0.015 and age = 0.364. £p-value for the comparison between B and E for gender = 0.07 and age = 0.014. §p-value for the comparison between B and F for gender = 0.005 and age = 0.053. @p-value for the comparison between B and G for gender = 0.319 and age = 0.660. $Randomly selected individuals who were not found or did not accept as well as individuals who were confirmed but did not attend or did not complete the cardiac assessment.

Table 4: Prevalence of hypertension, diabetes and infarction* in individuals who completed the cardiac assessment for the randomly selected individuals and substitutes

Hypertension£		pvalue	DM2#		pvalue	Infarction§		pvalue
Randomly selected individuals n (%)	Substitutes n (%)		Randomly selected individuals n (%)	Substitutes n (%)		Randomly selected individuals n (%)	Substitutes n (%)	
378 (71,3)	82 (79,6)	0,09	137 (25,8)	23 (22,3)	0,54	23 (4,3)	4 (3,9)	0,83

*Difference tested using the chi-square test with correction for continuity

The prevalence of hypertension, type 2 diabetes, and self-reported myocardial infarction among those who completed the cardiac assessment and were either randomly selected or substitutes is presented in Table 4. The prevalence of hypertension was higher among the substitutes for both genders (p = 0.09). The opposite was true for type 2 diabetes and self-reported acute myocardial infarction, although the trend was not statistically significant.

DISCUSSION

The DIGITALIS STUDY examined 633 individuals registered in 26 sectors of the PMF in an effort to estimate the prevalence of heart failure, reaching the number of individuals required based on the sample size calculation. The performance of numerous evaluations using qualified and previously trained researchers suggested the possibility of assessing different associations, allowing one to construct hypotheses for different health fields.

The decision to perform the examinations at the PMF units near the residences of participants proved to be feasible for all procedures performed. We conclude that the approach used in this study was positive, although the approach needs to be refined to increase the internal validity of future studies.

Non-participation results from the inability to recruit sampled individuals, and as non-participation increases, a study's vulnerability to selection bias also increases. However, approximately 50% of epidemiologic studies published in renowned journals do not report the percentage of non-participation.[8] Analysis and reporting of sources of potential bias allow for a more careful interpretation of prevalence results.

As expected, there were no significant differences between the distribution by gender and age group between the census and the randomly selected individuals. More women were confirmed and attended/completed the cardiac assessment, i.e., men had higher rates of non-participation; this is a common finding in the literature.[30-35] The reasons for non-participation were studied in an Australian cohort study on osteoporosis in which there was greater participation of women.[32] As a reason for non-participation, more men than women claimed to have time constraints. For other less-cited aspects, including disinterest, illness, travel, fear of examination results, and a lack of comprehension, there were no differences between genders, or the reasons were more cited by women. In a Chinese survey published in 1997, two years of demographic and mortality data were compared between those who agreed to participate and those who did not. There was greater participation of women and younger people, and the mortality in this population group was lower.[31] In two Swedish surveys, the percentage of participation among selected individuals was higher for women and those with higher levels of education and income.[33-34] In the study presented here, although the residents who confirmed their participation were younger than those who did not confirm their participation ($p < 0.01$), the opposite was true for attendance/completion of the cardiac assessment ($p = 0.08$).

The DIGITALIS STUDY has some aspects that differ from those of other studies that discuss the characteristics of non-participation. The target population is less economically privileged than the average Brazilian population. Although everyone had access to primary care services, some blood tests as well as echo-Doppler and DXA were not always available. Participation in the study would allow such tests to be performed and medical reports to be available in a short time period. This information was provided in the invitation. Perhaps this scenario increased the participation of less healthy people, both among the confirmed individuals and among those who attended and completed the study.

A similar trend was observed between the distribution by gender and age groups within the groups of randomly selected individuals and the substitutes for the confirmation and completion of the cardiac assessment. This result indicates that the randomly selected individuals and substitutes were different groups. The participation of women was higher among the substitutes, which was also overrepresented by individuals in the intermediate age groups, especially among those who completed the assessment, although these age differences were not statistically significant.

Given that the prevalence of hypertension is higher among women and increases with age (data not shown), it appears that the characteristics of the substitutes contributed to this increased prevalence. Among the randomly selected individuals, there was an overrepresentation of individuals in the younger age groups, which may have reduced the impact that the substitutes had on the increased prevalence of hypertension. This evidence indicates that most hypertensive patients were invited as substitutes.

This trend was reversed in the case of type 2 diabetes and self-reported myocardial infarction, i.e., the prevalence among the substitutes was lower than the prevalence among the randomly selected individuals. This result could contradict the hypothesis suggested above. However, these two diseases have very low

prevalence, making it difficult to include affected individuals among the substitutes.

The assessment into possible sources of bias performed here exhibited several limitations. Only the influence of gender and age were evaluated, which limited our understanding of the reasons for non-participation and thus the possible interventions needed to reduce non-participation. Although training has been conducted and there has been a commitment on the part of PMF professionals to respect the rules for substitutions, the results indicate that this did not happen. Substitutes attended the assessment more than those who were selected randomly and had a higher prevalence of hypertension.

Was the larger attendance observed because the substitutes were sicker or because they were simply more cooperative with PMF professionals? This is a question that remained unanswered.

CONCLUSION

Using the results of all the examinations performed, the approach of the DIGITALIS STUDY proved to be adequate for the purposes of estimating prevalence, achieving the number of participants indicated by the sample size calculation. However, there was a significant percentage of non-participation. The randomization strategy did not presuppose outdated records; alternative schedules for visits were not provided for individuals who worked on Saturday mornings; and follow-up at the invitation stage was insufficient to prevent substitutions and the inclusion of substitutes with a higher prevalence of hypertension. An evaluation of the selection bias will allow for a better interpretation of the estimated prevalences.

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Competing interests: The authors have no competing interests to declare.

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Ethical approval: Digitalis study was conducted according to the principles established by Resolution 196/96 of the National Research Ethics Committee [Comissão Nacional de Ética em Pesquisa (CONEP)] and approved by the Research Ethics Committee of the Antonio Pedro University Hospital, Fluminense Federal University [Universidade Federal Fluminense (UFF)] (CAAE:0077.0.258.000-10).

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