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Functional Health Literacy in a population-based sample in Florence: an assessment using the Newest Vital Sign

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ABSTRACT

Objectives To assess the level of functional health literacy (HL) and its antecedents and consequences in an adult population-based sample, using the Italian version of Newest Vital Sign (NVS-IT)

Design Cross-sectional randomized study

Setting General population

Participants: 984 subjects were randomly selected from the registries of eleven general practitioners; 452 subjects completed the study. Inclusion criteria were the following: 18–69 years of age and Italian speaking. Exclusion criteria included cognitive impairment, severe psychiatric diseases and end-stage diseases.

Outcome measures: HL levels as assessed by the NVS-IT and the following potential HL predictors and consequences were assessed using logistic regression models: sociodemographic characteristics, body mass index, presence of long-term illnesses, self-reported health status, health services use in the last 12 months.

Results: High likelihood of limited HL, possibility of limited HL and adequate HL were found in 11.5%, 24.6% and 63.9% of the sample, respectively. The results of the multivariate logistic model for the antecedents showed that the risk of having high likelihood or possibility of limited HL levels increases with age (OR = 1.07, 95% CI 1.05 to 1.09), lower educational level (OR = 4.03; 95% CI 3.41 to 7.49) and with worse financial situation (OR 1.64; 95% CI 1.17-2.63). As far as health outcomes are concerned, HL resulted to be positively associated with self-reported health status (OR = 2.25, 95% CI 1.75 to 2.75).

Conclusions: findings show a good level of functional HL in the population. However, older, less educated and poorer population groups showed to have a higher likelihood of suffering from limited or inadequate HL. Efforts should be made to design and implement public health policies and interventions tailored to different HL levels.

Trial registration number Local Health Unit of Central Tuscany, Careggi University hospital and Meyer University Children's Hospital; Ref. CEAVC:10113, 01 December 2016

STRENGTHS AND LIMITATION OF THIS STUDY

- This study provide a measure of functional health literacy in a population-based sample in Florence
- The sample has not been randomly selected among people living in Florence, but from individuals registered as patients with eleven general practitioners
- Differently from other studies, the Italian version of the Newest Vital Sign (NVS-IT) was administered through phone-interview
- The concordance between face-to-face and phone-administered NVS-IT interviews was pre-tested on 35 participants
- Predictors and outcomes of NVS-IT were analyzed using logistic regression models, with results quite different from other published studies

INTRODUCTION

Health literacy (HL) can be defined as "the capacities of people to meet complex demands of health in a modern society and it concerns the ability of citizens to make sound decisions concerning health in daily life- at home, at work, in health care, [..]".[1] Several studies have shown that limited HL among adults is a major public health problem. Limited HL has been shown to be associated with several health-related consequences such as adverse health behaviors and outcomes, increased mortality risk, poor management of chronic diseases, lower use of preventive services and higher health care costs.[2-4] As far as predictors of HL (i.e. antecedents) are concerned, several proximal (*i.e.* personal and situational) and distal (*i.e.* societal and environmental) factors have been proposed.[2-4]

Functional HL is one dimension of the concept of HL that entails the ability to interpret, calculate and act on oral and written information in health care settings. Several tools have been proposed for assessing functional HL,[5, 6] however most of them take several minutes to administer. This is an issue that poses barriers in their use outside of academic contexts, especially for time-demanding clinical settings or for interventions in the general population. In 2005, the Newest Vital Sign (NVS) was proposed as a brief and easy to administer screening tool for measuring HL.[7] The NVS is a six-items screening tool that requires the participants to interpret the information presented on a nutrition label; it assesses reading, numeracy and comprehension skills. The NVS shows high sensitivity in detecting limited literacy.[8]

The NVS was originally developed and is still mainly used in the clinical setting.[7, 9-11] Until today, there have been only limited studies on HL assessed with the NVS and its antecedents and consequences carried out in the general population. Furthermore, since most studies have been conducted in clinical settings,[7, 9-11] the assessed individuals have specific demographic and characteristics that pertain to the environment of the studies. Moreover, the included samples typically tend to over-represent socially disadvantaged groups.[12]

In 2011, the HLS-EU survey was the first study assessing HL at the general population level in several European countries. [3] The HL measure used in this study was specifically designed for the study (*i.e.* HLS-EU-Q47), however translated versions of the NVS were also included in the study. The study reported that around 12% of the sample was very likely to have limited literacy. Age and education resulted to significantly predict NVS scores in all the countries included in the study. However, several causal inferences for HL measured with the NVS were not examined as the NVS tool was mainly used for comparing and validating the newly developed HL measure. Furthermore, in this study the Italian population was not included. A study recently conducted in Portugal found that people with limited HL were significantly older and less educated.[13] Whereas a study conducted in Australian population reported also male gender, foreign nationality and socioeconomic status as predictors of inadequate HL, and, for what concern HL consequences, the study found that low HL levels were associated with a higher risk of chronic diseases and a lower access to primary care services. [14] As far as the Italian population is concerned, the Italian version of the NVS (NVS-IT) has been recently validated and a few studies have been conducted using this tool.[15] However, these studies were either conducted in small convenience samples or in specific clinical contexts.[16, 17]

Due to still limited evidence in the literature, there is no general consensus on antecedents and consequences of HL when measured with the NVS in the general population. Furthermore, as HL and its antecedents and consequences may vary from one country to another, results are not generalizable. In order to deepen knowledge on HL in the general population and to provide reliable and specific

information on the Italian population, a research project that aimed at assessing HL levels in a population-based sample, and to validate different HL measures in Italian language was carried out. This study is the first output of this research project, of which a full protocol has been published and detailed elsewhere.[18] Specifically, the aim of the present study was to evaluate the levels and the associations of HL in an adult general population using the Italian version of the Newest Vital Sign (NVS-IT).

METHODS

For more detailed information regarding the methods, the reader is referred to the study protocol published elsewhere.[18] The study was approved by the Ethics Committee of the "*Area Vasta Centro* " (Local Health Unit of Central Tuscany, Careggi University hospital and Meyer University Children's Hospital; Ref. CEAVC:10113, 01 December 2016) and was conducted according to the principles described in the Declaration of Helsinki.

Study population and sampling criteria

The study at hand is a cross-sectional study that was carried out in a population-based sample. Participants were randomly selected from the registries of eleven general practitioners (GPs) working in primary healthcare centers of the municipality of Florence—a sampling method that has been also suggested by other authors.[19] The GPs were recruited using convenience criteria. Both the president of the Provincial Medical Council and the representative of the GPs at the University Hospital of Florence informed their colleagues to join the study either via email, phone or in person. The first eleven, who voluntarily joined the study, were included. Each GP was asked to randomly select 80 subjects among those registered as patients with them. Inclusion criteria were the following: 18–69 years of age and Italian speaking (since the survey was conducted in Italian only). Exclusion criteria included cognitive impairment, severe psychiatric diseases and end-stage diseases.

Procedures: data collection and measurements

Data were collected between February 2017 and December 2017. Each selected subject was contacted via postal mail. Subjects received an information sheet signed by both the GP and the person in charge of the study. The letter also included a short description of the study, an invitation to participate and a consent form. Participants were asked to sign the consent form and return it via mail to the researchers in charge. The mail also contained the nutritional label of the Newest Vital Sign-Italian (NVS-IT). After receipt of the signed consent forms, the subjects were contacted over phone for the computer-assisted interview. Nine interviewers conducted the phone interviews. A shared written protocol on how to conduct the interview was followed in order to standardize the interviews and to limit interviewer bias. Each subject was randomly assigned to one of the nine interviewers and contacted a maximum of six times before being considered unreachable. The interviews took about 20–25 minutes.

The following "antecedents" variables were collected: gender, birth year, nationality, number of years living in Italy (for those who were born abroad), educational level, marital status, number of family members living in the same household. Furthermore, the questionnaire also explored whether one has ever received training or is/has been employed in the field of healthcare, employment status (currently having a paid job), financial situation, and whether a family member or a friend normally accompanies him/her to medical appointments.

As for health outcomes, the following variables were investigated: self-reported health status (excellent, very good, good, so-so/fair, bad), referred weight and height to calculate the body mass index (BMI), health services used in the last 12 months (number of doctor visits, hospital admissions, emergency department visits). Responses were coded as follows: 0, 1–2 times, 3–5 times, 6 times or more, don't know, refusal). The use of other healthcare services in the 12 last months were also investigated (overall number of dentist, physiotherapist, psychologist, dieticians and optician visits). To measure health status, subjects were also asked about long-term illnesses (illnesses that have lasted or are expected to last for at least 6 months), coded in five categories: yes, more than one; yes, one; no; don't know, refusal.

The NVS-IT consists of an ice cream nutrition label, with seven associated questions that measure literacy and numeracy. It produces a final score ranging from 0 to 6, allowing subjects to be classified into three categories—high likelihood of limited HL (score: 0–1), possibility of limited HL (score: 2–3) and adequate HL (score: 4–6). To the best or our knowledge, no published studies have reported NVS data collected through telephone interviews. Due to that, the concordance between face-to-face and phone-administered NVS-IT interviews was pre-tested in a convenience sample of 35 participants of different age, gender and educational level. For testing the concordance between face-to-face and phone-administered NVS-IT two study arms were defined. In both arms, the participants received both the telephone and the face-to-face interview with a washout period of 10 days between them. The two arms differed only in the sequence in which the participants received the telephone or the face-to-face interview first. Each participant was randomly assigned to one of the two arms.

Statystical analysis

Collected variables were tested for normality using Kolmogorov-Smirnov test.

In the pre-testing phase, NVS-IT scores obtained using the telephonic and face-to-face interviews were compared. Specifically, between the two arms, NVS-IT score distributions were compared both at T0 and at T1 using unpaired Student's t-test or Mann–Whitney U test; within the two arms, NVS-IT score distributions at T0 were compared with respect to those obtained at T1 using paired Student's t-test or Wilcoxon paired test for matched data.

The internal consistency of NVS-IT was assessed through the Cronbach's alpha coefficient.

For all the analyses, subjects with high likelihood of limited HL and those with possibility of limited HL were grouped together in a single group, referred to "Inadequate and at-risk HL" and compared with the adequate HL group.[14]

A descriptive univariate analysis using χ^2 test for categorical and ordinal data and unpaired Student's t-test, ANOVA or the corresponding non-parametric tests for continuous data were performed in order to evaluate significant associations between NVS-IT categories and all the variables considered. To analyze the predictors of HL, antecedents significantly correlated with NVS-IT categories at the univariate analysis were entered into a multivariate logistic regression model considering the NVS-IT categories ("Inadequate and at-risk HL"" vs "adequate HL") as the dependent variable. NVS-IT as a predictor of health related outcomes (self-reported health status, BMI categories, health services used in the last 12 months) was tested in several multivariate logistic regression models. Specifically, health related outcomes significantly associated with NVS-IT categories at the univariate analysis were entered into different multivariate logistic regression models as dependent variables (one for each), dichotomizing the categories as follow: "excellent or good" vs "average or poor" for self-reported health status; "underweight or normal" vs "overweight or obese" for BMI categories; "never" vs "one or more times" for health services used in the

last 12 months. In each model, predictors (antecedents) of NVS-IT categories were included as covariates. Each multivariate regression model was performed using a backward stepwise procedure. For each analysis, an α level of 0.05 is considered as significant. The statistical softwares IBM SPSS Statistics for Windows, V.25.0 and StataIC V.11 (StataCorp) were used for data analyses.

Patient and public involvement

The study population was not directly involved in the design, recruitment and conduct of this study. However, the Florence Health Literacy Research Group involved representatives from Provincial Medical Council, Local Health Unit and University Hospital of Florence. All of these representatives were involved in the study design and questionnaire development and will disseminate the results from this work.

RESULTS

Pre-testing phase: face-to-face versus phone-administered interviews

Thirty-five volunteers (48.6% females; mean age: 44.3±15.8 years;) were included in the pre-testing phase, with a similar distribution in the two arms: for 18 subjects (51.4%), NVS-IT was administered face-to-face first. Both mean age and educational level were not significantly different between the two arms (respectively, Mann-Whitney U test: p=0.946, χ 2 test: p=0.07) . At T0, NVS-IT score for the face-to-face administered interviewed was 4.11±1.66 while for the phone administered interviewed it was 4.76±1.43, without statistically significant differences (Mann-Whitney U test: p=0.207). At T1, with the different administration, both groups increased the mean NVS-IT scores (from 4.11±1.66 to 4.67±1.49 and from 4.76±1.43 to 5.10±1.43) but not in a statistically significant way (Wilcoxon paired test for matched data: p=0.065 and p=0.160, respectively). At T1, the NVS-IT scores were not significantly different between the two groups as well (Mann-Whitney U test: p=0.335).

Sample characteristics

A total of 984 individuals were invited to participate in the study, of which 454 (46.1%) were interviewed. As far as non-participation reasons are concerned, 151 (15.3% of the total sample) subjects refused to participate for lack of time or interest in the study and 376 (38.2% of the total sample) subjects resulted to be unreachable either because the number was not answering or in service anymore. Non-participants resulted to be on average two year younger than participants (51.2 ±11.8 years and 53.3±11.7 years, respectively). No significant gender differences emerged between participants and non-participants. Two interviews resulted to have several data missing and were excluded from the study; a total sample of 452 subjects were considered for the analyses.

The participants' characteristics are presented in Table 1. The mean age of the sample is 53.2±11.7 years and males represent 41.2% of the sample. Graduated participants represent the 41.2% of the sample and 17.3% of the participants easily get at the end of the month with their income.

Table 1. Socio-Demographic characteristics and Newest Vital Sign (NVS) (N = 452)^

	High likelihood of limited HL n(%)	**Possibility of limited HL** n(%)	**Adequate HL** n(%)	**Total** n(%)
All	52(11.5)	111(24.6)	289(63.9)	452(100)

Female	30(11.3)	62(23.3)	174(65.4)	266(58.8)
Male	22(11.8)	49(26.3)	115(61.8)	186(41.2)
Age°	59.44 ± 9.61	57.79±9.88	50.40±11.77	53.25±11.72
Nationality				
Italian	50(11.3)	110(24.8)	283(63.9)	443(98)
Foreign	2(22.2)	1(11.1)	6(66.7)	9(2)
Educational level*				
Bachelor's degree and higher	9(4.8)	33(17.7)	144(77.4)	186(41.1)
High school degree	26(13.5)	49(25.5)	117(60.9)	192(42.5)
Less than high school diploma	17(23.0)	29(39.2)	28(37.8)	74(16.4)
Employment status*				
Empoyed	27(9.0)	57(19.1)	215(71.9)	299(66.2)
Unemployed or retired	25(16.3)	54(35.3)	74(48.4)	153(33.8)
Retired	20(20.6)	37(38.1)	40(41.2)	97(21.5)
Marital status				
Single	7(10)	15(21.4)	48(68.6)	70(15.5)
Married/domestic partnership	36(11.2)	79(24.7)	205(64.1)	320(70.8)
In a relationship	1(8.3)	1(8.3)	10(83.3)	12(2.7)
Divorced or separated	3(8.8)	10(29.4)	21(61.8)	34(7.5)
Widowed	5(33.3)	6(40)	4(26.7)	15(3.3)
Refusal	0(0.0)	0(0.0)	1(100)	1(0.2)
Self-reported health status*				
Excellent/good	33(9.5)	74(21.3)	241(69.2)	348(77)
Average/ poor	19(18.4)	36(35.0)	48(46.6)	103(22.8)
Refusal	0(0.0)	1(100)	0(0.0)	1(0.2)
Long-term illness*				
No	27	50	160	237
One	11	43	93	147
More than one	14	17	36	67
Refusal	0	1	0	1
BMI class				
Underweight	2(13.3)	1(6.7)	12(80)	15(3.3)
Normal	28(11.2)	59(23.6)	163(65.2)	250(55.3)
Overweight	16(10.7)	40(26.7)	94(62.7)	150(33.2)
Obese	6(16.7)	11(30.6)	19(52.8)	36(8.0)
Family members in the household*				
Alone	6(9.0)	20(29.9)	41(61.2)	67(14.8)
2 people	23(15.2)	40(26.5)	88(58.3)	151(33.4)
3 or more people	22(9.6)	51(20.5)	156(68.1)	229(50.7)
Experience in the healthcare field				
Yes	10(10.2)	22(22.4)	66(67.3)	98(21.7)
No	42(11.9)	89(25.1)	223(63.0)	354(78.3)
Financial resources at disposal from own or family income enough to get to the end of the month *				
More than enough/Enough	29(12.8)	75(16.7)	212(70.5)	316(17.3)
Barely enough/Not enough	23(17.4)	34(25.8)	75(56.2)	132(29.2)
Refusal	0(0.0)	2(50.0)	2(50.0)	4(0.9)
Family or friends support to go to doctors visit (if needed)				
Yes	44(11.3)	98(25.3)	246(63.4)	388(85.8)
No	8(13.1)	11(18.0)	42(68.9)	61(13.5)
Refusal	0(0.0)	2(66.7)	1(33.3)	3(0.7)
Doctor visits				
0	5(16.7)	6(20.0)	19(63.3)	30(6.6)
1-2 times	19(9.7)	43(21.9)	134(68.4)	196(43.4)
3 or more times	28(12.4)	62(27.4)	136(61.3)	226(50.0)

Hospitalizations				
0	37(10.5)	83(23.6)	231(65.8)	351(77.7)
1-2 times	14(15.4)	26(28.6)	51(56.0)	91(20.1)
3 or more times	1(10.0)	2(20.0)	7(70.0)	10(2.2)
Emergency department admissions				
0	43(10.7)	100(24.9)	258(64.3)	401(88.7)
1-2 times	9(19.6)	9(19.6)	28(60.9)	46(10.2)
3 or more times	0(0.0)	2(40.0)	3(60.0)	5(1.1)
Outpatients specialist care access				
0	9(14.8)	16(26.2)	36(59.0)	61(13.5)
1-2 times	15(9.3)	42(25.9)	105(64.8)	162(35.8)
3 or more times	28(12.3)	53(23.2)	147(64.5)	228(50.4)
Refusal	0(0.0)	0(0.0)	1(100)	1(0.2)

^Difference between 100% and the sum of the percentages of each variable corresponds to missing values
°Kruskal-Wallis test: p<0.05; *Fisher exact test: p<0.05

Health literacy distribution and its associations with antecedents and consequences

The Cronbach alpha coefficient for the NVS-IT in this study was 0.741. The NVS-IT score was J-shaped (Figure 1), with mean value of 4.05±1.88 and median value of 4; 25% of the participants presented NVS-IT scores lower than 3. As far as the HL levels distribution in the sample are concerned, high likelihood of limited HL, possibility of limited HL and adequate HL were found in the 11.5%, 24.6% and 63.9% of the sample, respectively.

Inadequate and at-risk HL was significantly associated with the following variables at the univariate analyses (see Table 1): age, educational level, employment status, financial situation, number of family members in the household, self-reported health status, and the presence of long-term illnesses.

The variables statistically associated with inadequate and at-risk HL in the univariate analyses were included in the multivariate logistic regression model. The results of the multivariate logistic regression model for the antecedents are shown in table 2. In particular, the risk of having inadequate and at-risk HL levels increases with age (OR = 1.07, p <0.001), with a lower educational level (OR = 2.02, p =0.004 and OR = 4.03; p<0.001 comparing the bachelor's degree and higher educational level group with high school degree group or with less than a high school diploma group, respectively) and with a worse financial situation (OR 1.64; p = 0.041).

Table 2. Multivariate logistic regression analysis for antecedents of HL (HL is the outcome variable). OR is calculated as "Inadequate and at-risk HL" vs "adequate HL".

	Odds Ratio	*p*	95% Confidence interval
Age	1.07	*0.000*	1.05-1.09
Education			
Bachelor's degree and higher	1.000	-	-
High school graduates	2.01	*0.004*	1.53-3.61
Less than a high school diploma	4.03	*0.000*	3.41-7.49
Financial situation			
More than enough/Enough	1	-	-
Barely enough/Not enough	1.639	*0.041*	1.17-2.63

N= 448; Pseudo R^2=0.1404

As far as health outcomes are concerned, HL resulted to be significantly associated only with self-reported health status at the univariate analysis. Besides HL, age, educational level, nationality, long-term illness, employment and financial status resulted to be significantly associated with self-reported health status (data not shown). These variables were included in the multivariate logistic regression model with self-reported health status as dependent variable. Results of the final model are reported in table 3. Participants with inadequate and at-risk HL were about two times more likely than participants with adequate HL to report a worse self-reported health status (OR = 2.25, p = 0.002). The presence of one or more long-term illnesses and a worse financial situation remained significantly associated with a worse self-reported health status in the final model (see table 3).

Table 3. Multivariate logistic regression analysis with self-reported health status as dependent variable

	Odds Ratio	*p*	95% Confidence interval
Health literacy (HL)			
Adequate HL	1	-	-
Inadequate and at-risk HL	2.25	*0.002*	1.75-2.75
Long-term illness			
No	1	-	-
One	4.04	*0.000*	3.46-4.62
More than one	12.78	*0.000*	12.1- 13.45
Financial situation			
More than enough/Enough	1	-	-
Barely enough/Not enough	2.14	*0.004*	1.62-2.66

N=448; Pseudo R^2=1.179

DISCUSSION

The aim of this study was to assess the level of HL in a population-based sample using the Italian validated version of the NVS and the association of HL with antecedents and health outcomes.[15] A total of 11.5% of the surveyed sample had inadequate level of health literacy. According to multivariate analyses, the following antecedents resulted significantly associated with the level of HL: age, educational level and financial situation. As far as health outcomes are concerned, only self-reported health status resulted significantly associated with HL in the multivariate analysis.

Our results showed the presence of a good level of HL score in the population when compared to what has been registered in other European countries involved in the European Health Literacy Project.[3] Indeed, it is possible to observe that the functional HL level in our population is higher than in the European countries considered, with the exception of Austria and the Netherlands (i.e. the average score of the European countries is 3.5 varying from a minimum of 2.6 of Spain to a maximum of 4.5 of Netherlands). Furthermore, the observed standard deviation of the HL score mean is well below the European countries average, probably indicating a relatively homogeneity in terms of distribution of HL in our population.

As far as the assessment of HL in Italian population, to best of our knowledge our study is the first that has set the assessment of HL with a validated NVS tool in a population-based sample as primary outcome. Indeed, in the literature only a study of Palumbo *et al.*[20] have used the NVS tool in a population-based sample in Italy, however in this study the primary outcomes were to assess HL and its antecedents and consequences with HLS-EU-Q47 and NVS was used to check the validity of self-reported literacy skills (HLS-

EU-Q47). As a result of this, several data of the NVS in the population are not reported (i.e. NVS score) and it is not possible to compare our findings with this study.

In the literature, many studies have described several antecedents that may positively or negatively impact on health literacy, however to date there is no consistency in discussing these predictors.[4] Furthermore, demographic and socio-economic factors may impact differently on HL depending on the national and cultural contexts.[3, 13, 14, 21] In light of this, our findings on antecedents of HL not only contribute with evidences to the current debate in the literature, but also may be considered as the first attempt to highlight the independent predictors of HL in the Italian context.

Age and education in the literature seem to be important predictors of HL and our finding confirmed it also in the Italian context.[3, 13, 14] In our study, a higher education level resulted to be independently associated to higher HL levels; on the contrary, having received training or being employed in the field of healthcare does not impact on HL level. As the NVS tool mainly measures document literacy and numeracy, these findings may suggest that these skills are mainly developed in the context of general education with little influence by further and more specific education. Regarding age, results showed a negative independent association with HL suggesting that as age increases, a diminished mental alertness and/or cognitive impairment (e.g. memory-retrieval problems and inadequate numeracy) may play a crucial role in limiting the HL skills. As older and less-educated people are those who experiment the highest burden and consequences of chronic diseases,[22-25] these results urge to design and implement health policies tailored on HL skills in these populations in order to allow them to better prevent and cope with the challenges posed by these conditions.

Our findings have highlighted also that a worse financial situation is associated with lower level of HL. Literature, reports contrasting results concerning the association between socioeconomic status and HL measured through NVS score;[13-14, 26] however these variables has been little investigated by population-based studies which considered also the measure of functional HL. It may be hypothesized that socioeconomic status is a moderator or a mediator in the causal pathway between education level and document literacy and numeracy skills and thus may probably influence the HL measured with NVS; however, further studies that take into consideration mechanisms underlying these causal relationships are needed to draw a definite conclusion on the role played by the socioeconomic status.

As regards to health outcomes, self-reported health status was found to be significantly associated with HL, but also with financial situation and the presence of long-term illnesses. In the literature the underlying mechanism through which HL influences the health-related outcomes is not entirely known and several theoretical models have been proposed to explain the underlying mechanism through which HL influence the health status.[4, 27-29] A recent conceptual model proposed by Sørensen et al.[4] posits that the HL dimensions (the competencies related to the process of accessing, understanding, appraising and applying health-related information) influence the ability of a person to navigate in the three domains of the health continuum (Health care, Disease prevention and Health promotion) which in turn have an impact on health outcomes. However, none of these models has been fully validated and further studies examining the mechanisms underlying the relationship between HL and health outcomes are needed.

No other health outcomes resulted to be significantly associated with HL in our study. Although several HL associations with health outcomes have been proposed in the literature, most of them have been evaluated in the clinical context and only few at the general population level.[3, 13-14] Because NVS was primarily designed to detect illiteracy, it may show a ceiling effect when used in general populations.[30]

This ceiling effect could have skewed the distribution of NVS scores significantly, and lead to attenuated or absent correlations between HL and health outcomes in studies using NVS tool at the general population level. A more in-depth evaluation of the presence and effects of skewed distribution of NVS is needed in order to better adjust and calibrate this HL screening tool to use it appropriately in the general population, which in turn may permit to draw more robust conclusions on the presence and strengths of HL associations with health outcomes.

In this study, telephone interviews were used to collect NVS-IT data, while in almost all the studies face-to-face interviews were used. To date, to the best of our knowledge, our study is the first in reporting the comparison of NVS data collected using different methods of administration. The comparison of the NVS score between face-to-face and telephone interviews showed higher concordance degree with no significant difference between the NVS scores. Compared with face-to-face interviews, telephone interviews offer several advantages,[31] in particular the elimination of any bias caused by the appearance of the interviewer. Moreover, there is some evidence that people are more likely to report health-related events on the phone rather than in face-to-face interviews.[31] The main potential risk with telephone interview compared with face-to face is that the respondent may seek help from another person at home; however, this risk is minor,[31] since the interviewer would be able to notice the involvement of other people (*i.e.*, the person on the phone would have to repeat each question or use the hands-free mode).

This is the first study in Italy that comprehensively attempts to assess HL and its related antecedents and outcomes with NVS in a population-based sample. This consideration, together with the evaluation of various potential HL consequences, antecedents, and confounding factors, should be considered as the strengths of this study.

Nevertheless, the study has several limitations. Indeed, as the variables have been self-reported by the participants through interviews, the study may have suffered the recognized limitations of using this approach, such as recall or social desirability bias. However, the telephone interview may have limited this potential bias especially for those variables potentially more influenced by social desirability such as the BMI and socioeconomic Status. Moreover, results may have been influenced by a non-response bias, however the extent of this potential bias – if present - is limited as participants and non-participants showed only a small difference in the mean age: since participants were older of two years on average than non-participants the HL level resulted in our sample may be slightly lower than in the general population. Finally, although participants were randomly selected from the registries of the GPs, the GPs were selected using a convenience criteria, which may have introduced a selection bias. To limit this potential bias, GPs were chosen according to their geographical location in the aim of covering different districts of Florence, and - in order to extend the geographical coverage of the sample - the foreseen number of GPs recruited in the original protocol[18] has been augmented to eleven.

CONCLUSION

Our study is the first in measuring the HL with NVS tool and its associations with antecedents and consequences at population level in Italy. Our findings highlighted the presence of good level of HL in the population compared to the EU average. However, older, less educated and poorer population groups resulted at higher risk of limited or inadequate HL. These results suggest the need to design and implement health policies and interventions tailored on different HL levels in order to allow the more vulnerable population groups to better cope with the health challenges. As far as health outcomes are concerned, only

self-reported health status was found to be significantly associated with HL among the considered health outcomes. The underlying mechanisms through which HL influences the health-related outcomes are not entirely known and a more in-depth evaluation of these relationships are needed. As NVS test was originally developed in the clinical context, a ceiling effect that may skew the HL levels distribution in the population may occur when NVS is used at the general population level, ultimately leading to attenuated correlation between HL and its potential predictors and consequences. Further studies investigating the presence and effects of this ceiling effect is needed in order to confirm the validity or better calibrate the NVS tool for the general population studies and to draw more robust conclusions on the presence and strengths of HL associations.

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COMPETING INTERESTS

The authors declare no competing interests

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AUTHOR CONTRIBUTION

GB: conception and design; drafted the article; gave final approval of the version to be submitted.
VL: conception and design; data collection; data interpretation; drafted the article; gave final approval of the version to be submitted; final preparation and submission.
VV: conception and design; data collection; data interpretation; drafted the article; gave final approval of the version to be submitted.
CL: conception and design; data analysis and interpretation; drafted the article; gave final approval of the version to be submitted.
Florence Health Literacy Research Group: conception and design; data collection; gave final approval of the version to be submitted

FIGURE LEGEND

Figure 1. Distribution of NVS-IT score

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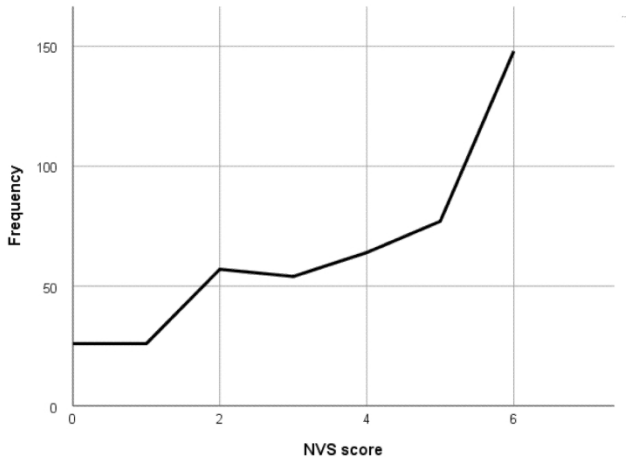

Figure 1. Distribution of NVS-IT score

209x148mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1; 2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4; 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4; 5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4; 5
Bias	9	Describe any efforts to address potential sources of bias	4; 5; 6
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5; 6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5; 6
		(*b*) Describe any methods used to examine subgroups and interactions	5; 6
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7
		(b) Indicate number of participants with missing data for each variable of interest	7
Outcome data	15*	Report numbers of outcome events or summary measures	7
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7; 8; 9
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10; 11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Functional Health Literacy in a population-based sample in Florence: a cross-sectional study using the Newest Vital Sign

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Functional Health Literacy in a population-based sample in Florence: a cross-sectional study using the Newest Vital Sign

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ABSTRACT

Objectives To assess the level of functional health literacy(HL) and its antecedents and consequences in an adult population-based sample, using the Italian version of Newest Vital Sign(NVS-IT)

Design Cross-sectional study

Setting General population

Participants: 984 people were randomly selected from the resident registers of eleven general practitioners; a total of 452 (46,2%) of the selected people completed the study. Inclusion criteria were the following: 18–69 years of age and Italian speaking. Exclusion criteria included cognitive impairment, severe psychiatric diseases and end-stage diseases.

Outcome measures: HL levels as assessed by the NVS-IT and the following potential HL predictors and consequences were assessed using logistic regression models: sociodemographic characteristics, body mass index, presence of long-term illnesses, self-reported health status, health services use in the last 12 months.

Results: High likelihood of limited HL, possibility of limited HL and adequate HL were found in 11.5%, 24.6% and 63.9% of the sample, respectively. The results of the multivariate logistic model for the antecedents showed that the risk of having high likelihood or possibility of limited HL levels increases with age (OR = 1.07, 95%CI 1.05 to 1.09), lower educational level (OR = 4.03; 95%CI 3.41 to 7.49) and with worse financial situation (OR 1.64; 95%CI 1.17-2.63). As far as health outcomes are concerned, HL resulted to be positively associated with self-reported health status (OR = 2.25, 95%CI 1.75 to 2.75).

Conclusions: Findings show a good level of functional HL in the population. However, older, less educated and poorer population groups showed to have a higher likelihood of suffering from limited or inadequate HL. Efforts should be made to design and implement public health policies and interventions tailored to different HL levels.

Trial registration number Local Health Unit of Central Tuscany, Careggi and Meyer University Hospitals; Ref. CEAVC:10113, 01 December 2016

STRENGTHS AND LIMITATION OF THIS STUDY

- This study provides a measure of functional health literacy in a population-based sample in Florence
- The population based sample was obtained with a combination of convenience and probability sampling procedures
- Differently from other studies, the Italian version of the Newest Vital Sign (NVS-IT) was administered through phone-interview
- The concordance between face-to-face and phone-administered NVS-IT interviews was pre-tested on 35 participants
- Predictors and outcomes of NVS-IT were analyzed using logistic regression models, with results quite different from other published studies

INTRODUCTION

Health literacy (HL) is closely linked to empowerment and concerns the knowledge and competences of individuals necessary for meeting the complex health demands of modern society. HL can be defined as "the ability of citizens to make sound decisions concerning health in daily life- at home, at work, in health care, at the market place and in the political arena".[1] HL has been identified as a priority area for policy action in the strategy of the World Health Organization and in the policy documents of the European Commission. [2, 3] Indeed, several studies have shown that limited HL among adults is a major public health problem; limited HL has been shown to be associated with several health-related consequences such as adverse health behaviors and outcomes, increased mortality risk, poor management of chronic diseases, lower use of preventive services and higher health care costs.[4-6] As far as predictors of HL (i.e. antecedents) are concerned, several proximal (*i.e.* personal and situational) and distal (*i.e.* societal and environmental) factors have been proposed.[4-6]

Functional HL is one dimension of the concept of HL that entails the ability to interpret, calculate and act on oral and written information in health care settings. Several tools have been proposed for assessing functional HL,[7, 8] however most of them take several minutes to administer. This is an issue that poses barriers in their use outside of academic contexts, especially for time-demanding clinical settings or for interventions in the general population. In 2005, the Newest Vital Sign (NVS) was proposed as a brief and easy to administer screening tool for measuring HL.[9] The NVS is a six-items screening tool that requires the participants to interpret the information presented on a nutrition label; it assesses reading, numeracy and comprehension skills. The NVS demonstrated a high degree of correlation with other functional HL measures.[10]

The NVS was originally developed and is still mainly used in the clinical setting.[9, 11-13] To date, there have been only limited studies on HL assessed with the NVS and its antecedents and consequences carried out in the general population. Furthermore, since most studies have been conducted in clinical settings,[9, 11-13] the assessed individuals have specific demographic and characteristics that pertain to the environment of the studies; moreover, the included samples typically tend to under-represent socially disadvantaged groups.[14]

In 2011, the HLS-EU survey was the first study assessing HL at the general population level in several European countries.[5] The HL measure used in this study was specifically designed for the study (*i.e.* HLS-EU-Q47), however translated versions of the NVS were also included in the study. The study reported that around 12% of the sample was very likely to have limited literacy. Age and education resulted to be associated with NVS scores in all the countries included in the study. However, several causal inferences for HL measured with the NVS were not examined as the NVS tool was mainly used for comparing and validating the newly developed HL measure. Furthermore, in this study the Italian population was not included. A study recently conducted in Portugal found that people with limited HL were significantly older and less educated,[15] and a study conducted in Australian population also reported male sex, foreign nationality and socioeconomic status as predictors of inadequate HL.[16] As regards HL consequences, low HL levels were reported to be associated with a higher risk of chronic diseases and a lower access to primary care services.[16] As far as the Italian population is concerned, the Italian version of the NVS (NVS-IT) was developed from the European version used in the HLS-EU survey and its validation study was

recently published.[17, 18] To date, few studies have been conducted using the NVS-IT. However, these studies were either conducted with small convenience samples or in specific clinical contexts.[19, 20]

In the literature few studies have used the NVS to investigate HL and its associations in the general population.[5, 15, 16, 21] Furthermore, as HL and its antecedents and consequences may vary from one country to another, results are not generalizable. In order to deepen knowledge on HL in the general population and to provides reliable and specific information on the Italian population, a research project that aimed at assessing HL levels in a population-based sample, and to validate different HL measures in Italian language was carried out. This study is the first output of this research project, of which a full protocol has been published and detailed elsewhere.[22] Specifically, the aim of the present study was to evaluate the levels and the associations of HL in an adult general population using the Italian version of the Newest Vital Sign (NVS-IT).

METHODS

For more detailed information regarding the methods, the reader is referred to the study protocol published elsewhere.[22] The study was approved by the Ethics Committee of the "*Area Vasta Centro* " (Local Health Unit of Central Tuscany, Careggi University hospital and Meyer University Children's Hospital; Ref. CEAVC:10113, 01 December 2016) and was conducted according to the principles described in the Declaration of Helsinki.

Study population and sampling criteria

This is a cross-sectional study that was carried out in a population-based sample. Participants were randomly selected from a list of residents available from the registers of eleven general practitioners (GPs) working in primary healthcare centers of the municipality of Florence. According to the regulations of the National Healthcare System and the Constitution of the Italian Republic, in Italy every Italian and Foreign resident over the age of 18 has to be registered in a general practice, and people are enrolled in the general practices according to their place of residence (percentage of resident population registered 98.8%). This sampling method was chosen with the aim of increasing the population participation rate as the invitation letter was jointly signed by the general practitioners and the researcher in charge of the study.[23]

The GPs were recruited using convenience criteria. All the GPs of the municipality of Florence were invited to join the study by both the Provincial Medical Council and the University Hospital of Florence. A total of 11 GPs based in different districts of Florence were recruited on a first-come basis. The number of GPs recruited in the study was increased from what had been originally proposed in the study protocol (*i.e.* n= 8) in order to extend the geographical coverage of the study.[22] The recruited general practices were based in the city center and in the inner and outer suburban areas of Florence.

Each GP selected 80 people from its register through a random number generator. Inclusion criteria were the following: 18–69 years of age and Italian speaking (since the survey was conducted in Italian only). Exclusion criteria included cognitive impairment, severe psychiatric diseases and end-stage diseases. Inclusion and exclusion criteria were applied by each GP independently.

Procedures: data collection and measurements

Data were collected between February 2017 and December 2017. Each selected person was contacted via postal mail. The selected people received an information sheet signed by both the GP and the person in charge of the study. The letter also included a short description of the study, an invitation to participate and a consent form. Participants were asked to sign the consent form and return it via mail to the researchers in charge. The mail also contained the nutritional label of the Newest Vital Sign-Italian (NVS-IT) designed to be easy readable (*i.e.* large font size and line-spacing). After receipt of the signed consent forms, the participants were contacted over phone for the computer-assisted interview. If the consent form was not received within two weeks, a follow-up phone call was made by the research group. The phone call served to clarify any questions and to identify and support people with difficulties in completing the consent form (*e.g.* reading difficulties). Nine interviewers conducted the phone interviews. A shared written protocol on how to conduct the interview was followed in order to standardize the interviews and to limit interviewer bias. Each participant was randomly assigned to one of the nine interviewers and contacted a maximum of six times before being considered unreachable. The whole interview took about 20–25 minutes.

The following "antecedents" variables were collected: sex, birth year, nationality, number of years living in Italy (for those who were born abroad), educational level, marital status, number of family and non-family members living in the same household. Furthermore, the antecedents variables also included whether one has ever received training or is/has been employed in the field of healthcare, employment status (currently having a paid job), financial situation, and whether a family member or a friend normally accompanies him/her to medical appointments.

As for health outcomes, the following variables were investigated: self-reported health status (excellent, very good, good, so-so/fair, bad), self-reported weight and height to calculate the body mass index (BMI), health services used in the last 12 months (number of doctor visits, hospital admissions, emergency department visits). Responses were coded as follows: 0, 1–2 times, 3–5 times, 6 times or more, don't know, refusal). The use of other healthcare services in the 12 last months was also investigated (overall number of dentist, physiotherapist, psychologist, dieticians and optician visits). To measure health status, participants were also asked about long-term illnesses (illnesses that have lasted or are expected to last for at least 6 months), coded in five categories: yes, more than one; yes, one; no; don't know, refusal.

The NVS-IT consists of an ice cream nutrition label, with seven associated questions that measure literacy and numeracy.[18] It produces a final score ranging from 0 to 6, allowing participants to be classified into three categories—high likelihood of limited HL (score: 0–1), possibility of limited HL (score: 2–3) and adequate HL (score: 4–6). To the best or our knowledge, no published studies have reported NVS data collected through telephone interviews; for this reason, the concordance between face-to-face and phone-administered NVS-IT interviews was pre-tested in a convenience sample of 35 participants of different age, sex and educational level. This sample size was established considering a number of participants of about 5 times the number of the items of the tool (i.e. NVS-IT) as suggested by Parker.[24] Furthermore, this sample size was chosen in line with the sample size requirements for estimating the value of intraclass correlation coefficient and the Cohen's kappa agreement test as proposed by Bujang.[25, 26]

For testing the concordance between face-to-face and phone-administered NVS-IT two study arms were defined. In both arms, the participants received both the telephone and the face-to-face interview with an interval period of 10 days. The two arms differed only in the sequence in which the participants received

the telephone or the face-to-face interview first. Each participant was randomly assigned to one of the two arms.

Statistical analysis

Collected variables were tested for normality using Kolmogorov-Smirnov test.

For all the analyses, participants with high likelihood of limited HL and those with possibility of limited HL were grouped together in a single group, referred to "Inadequate and at-risk HL" and compared with the adequate HL group.[16]

In the pre-testing phase, NVS-IT scores obtained using the telephonic and face-to-face interviews were compared. Specifically, between the two arms, NVS-IT score distributions were compared both at T0 and at T1 using unpaired Student's t-test or Mann–Whitney U test; within the two arms, NVS-IT score distributions at T0 were compared with respect to those obtained at T1 using paired Student's t-test or Wilcoxon paired test for matched data. Intraclass correlation coefficient (ICC, two-way random, single measures, absolute agreement) was calculated in order to assess the correlation between the NVS scores obtained at T0 and T1, in the whole sample and in the two subgroups (telephonic *vs* face-to-face interviews; face-to-face *vs* telephonic interviews). χ2 test was used to evaluate the association between the classification into two groups of HL (inadequate and at risk HL *vs* adequate HL) and the mode of administration at T0 and at T1, respectively. Moreover, Cohen's kappa was calculated to assess the agreement in the classification into two groups of HL (inadequate and at risk HL *vs* adequate HL) at T0 and T1, in the whole sample and in the two subgroups (telephonic *vs* face-to-face interviews; face-to-face *vs* telephonic interviews). For Cohen's kappa and ICC, the following interpretation was considered: poor agreement for values lower than 0.40, fair agreement for values comprised between 0.40 and 0.59, good agreement for values comprised between 0.60 and 0.74, excellent agreement for values comprised between 0.75 and 1.00. [27]

The internal consistency of NVS-IT was assessed through the Cronbach's alpha coefficient.

A descriptive univariate analysis using χ^2 test for categorical and ordinal data and unpaired Student's t-test, ANOVA or the corresponding non-parametric tests (Mann–Whitney U test or Kruskal-Wallis test) for continuous data were performed in order to evaluate significant associations between NVS-IT categories and all the variables considered. To analyze the predictors of HL, all the evaluated antecedents (*i.e.* sex, age, nationality, educational level, marital status, number of family and non-family members in the same household, experience in the field of healthcare, employment status, financial situation, and family or friend support) were entered into a first multivariate logistic regression model considering the NVS-IT categories ("Inadequate and at-risk HL"" vs "adequate HL") as the dependent variable; a backward stepwise procedure was applied to obtain the final model of significant predictors of HL.

NVS-IT as a predictor of health related outcomes (self-reported health status, BMI categories, health services used in the last 12 months) was tested in several multivariate logistic regression models. Specifically, health related outcomes significantly associated with NVS-IT categories at the univariate analysis were entered into different multivariate logistic regression models as dependent variables (one for each), dichotomizing the categories as follows: "excellent, very good or good" vs "so so/fair or bad" for self-reported health status; "underweight or normal" vs "overweight or obese" for BMI categories; "never" vs "one or more times" for health services used in the last 12 months. In each model, all the evaluated predictors (antecedents) of NVS-IT categories were included as covariates. Each multivariate regression

model was performed using a backward stepwise procedure. For each analysis, an α level of 0.05 was considered as significant. The statistical softwares IBM SPSS Statistics for Windows, V.25.0 and StataIC V.11 (StataCorp) were used for data analyses.

Patient and public involvement

The study population or the public were not involved in the conceptualization or carrying out of this research.

RESULTS

Pre-testing phase: face-to-face versus phone-administered interviews

Thirty-five volunteers (48.6% females; mean age: 44.3±15.8 years; 11.4% with less than high school degree and 45.7% with high school degree) were included in the pre-testing phase, with a similar distribution in the two arms: for 18 participants (51.4%), NVS-IT was administered face-to-face first. Both mean age and educational level were not significantly different between the two arms (respectively, Mann-Whitney U test: p=0.946, χ 2 test: p=0.07) . At T0, NVS-IT score for the face-to-face administered interviewed was 4.11±1.66 while for the phone administered interviewed it was 4.76±1.43, without statistically significant differences (Mann-Whitney U test: p=0.207). At T0, the classification into two groups of HL (inadequate and at risk HL; adequate HL) did not significantly differ in the two arms (χ^2 test, p=0.328) (Table 1).
At T1, with the different administration, both groups increased the mean NVS-IT scores (Figure 1) (from 4.11±1.66 to 4.67±1.49 and from 4.76±1.43 to 5.10±1.43) but not in a statistically significant way (Wilcoxon paired test for matched data: p=0.065 and p=0.160, respectively). At T1, the NVS-IT scores and the classification into two groups of HL (inadequate and at risk HL; adequate HL) were not significantly different between the two arms as well (Mann-Whitney U test: p=0.335; χ^2 test, p=0.939) (Table 1).
Two scatterplots for the NVS score are reported in Figure 1. The ICC in the whole sample, in group I (face-to-face vs telephone interview) and in group II (telephone *vs* face-to-face interview) were 0.837 (p<0.001), 0.824 (p<0.001),and 0.843 (p<0.001), respectively. Therefore, the agreement was excellent both in the whole sample and in the two subgroups. As far as the classification into two groups of HL (inadequate and at risk HL; adequate HL) is concerned, the agreement in the whole sample and in the two subgroups was fair (Cohen's Kappa values were 0.471, p=0.003; 0.478, p=0.017; and 0.463, p=0.05 in the whole sample, in group I and in group II, respectively) (Table 1).

Table 1. Pre-testing phase: classification into two groups of HL (inadequate and at risk HL ; adequate HL) at T0 and T1. Whole sample and two subgroups (face-to-face *vs* telephone interview; telephone *vs* face-to-face interview).

	First administration (T0)	Total	Cohen's kappa

			Inadequate and at-risk HL	*Adequate HL*		
Whole sample	**Second administration (T1)**	***Inadequate and at-risk HL***	5	1	6	0.471 (*p=0.003*)
		Adequate HL	6	23	29	
	Total		11	24	35	
Group I (face-to-face vs telephone)*°	**Second administration (T1)**	***Inadequate and at-risk HL***	3	0	3	0.478 (*p=0.017*)
		Adequate HL	4	11	15	
	Total		7	11	18	
Group II (telephone vs face-to-face)*°	**Second administration (T1)**	***Inadequate and at-risk HL***	2	1	3	0.463 (*p=0.05*)
		Adequate HL	2	12	14	
	Total		4	13	17	

*Distribution at T0 (group I vs group II): χ^2 test=0.957 (1 df); p=0.328

°Distribution at T1 (group I vs group II): χ^2 test=0.006 (1 df); p=0.939

Sample characteristics

A total of 984 individuals were invited to participate in the study, of which 493 agreed to be interviewed (50,1%) and 454 (46.1%) were effectively interviewed. As far as non-participation reasons were concerned, 151 (15.3% of the total sample) people refused to participate, 340 (34.5% of the total sample) people did not respond to any contact attempts, and a further 39 (4% of the total sample) people initially agreed to be interviewed, but subsequently it was not possible to arrange an interview. Non-participants resulted to be on average two year younger than participants (51.2 ±11.8 years and 53.3±11.7 years, respectively). No significant sex differences emerged between participants and non-participants. Two interviews resulted to have several data missing and were excluded from the study; a total sample of 452 participants were considered for the analyses.

The participants' characteristics are presented in Table 2. The mean age of the sample was 53.2±11.7 years and males represented 41.2% of the sample. Participants with bachelor's degree or higher represented the 41.2% of the sample, and 17.3% of the participants easily got at the end of the month with their income.

Table 2. Socio-Demographic characteristics and Newest Vital Sign (NVS) (N = 452)^

	Total n(% for column)	**Health Literacy (HL) levels** n(% for raw)		
		High likelihood of limited HL	**Possibility of limited HL**	**Adequate HL**
All	452(100)	52(11.5)	111(24.6)	289(63.9)
Female	266(58.8)	30(11.3)	62(23.3)	174(65.4)
Male	186(41.2)	22(11.8)	49(26.3)	115(61.8)
Age*	53.25±11.72	59.44 ± 9.61	57.79±9.88	50.40±11.77
Nationality				
Italian	443(98)	50(11.3)	110(24.8)	283(63.9)
Foreign	9(2)	2(22.2)	1(11.1)	6(66.7)
Educational level*				
Bachelor's degree and higher	186(41.1)	9(4.8)	33(17.7)	144(77.4)
High school degree	192(42.5)	26(13.5)	49(25.5)	117(60.9)
Less than high school diploma	74(16.4)	17(23.0)	29(39.2)	28(37.8)
Employment status*				
Empoyed	299(66.2)	27(9.0)	57(19.1)	215(71.9)
Unemployed or retired	153(33.8)	25(16.3)	54(35.3)	74(48.4)
Retired	97(21.5)	20(20.6)	37(38.1)	40(41.2)
Marital status				
Single	70(15.5)	7(10)	15(21.4)	48(68.6)
Married/domestic partnership	320(70.8)	36(11.2)	79(24.7)	205(64.1)
In a relationship	12(2.7)	1(8.3)	1(8.3)	10(83.3)
Divorced or separated	34(7.5)	3(8.8)	10(29.4)	21(61.8)
Widowed	15(3.3)	5(33.3)	6(40)	4(26.7)
Refusal	1(0.2)	0(0.0)	0(0.0)	1(100)
Self-reported health status*				
Excellent	27(6)	3(11.1)	4(14.8)	20(74.1)
Very good	113(25)	9(8)	17(15)	87(77)
Good	208(46)	21(10.1)	53(25.5)	134(64.4)
So-so/fair	93(20.6	15(16.1)	32(34.4)	46(49.5)
Bad	10(2.2)	4(40)	4(40)	2(20)
Refusal	1(0.2)	0(0)	1(100)	0(0)
Long-term illness*				
No	237(52.4)	27(11.4)	50(21.1)	160(67.5)
One	147(32.5)	11(7.5)	43(29.2)	93(63.3)
More than one	67(14.8)	14(20.9)	17(25.4)	36(53.7)
Refusal	1(0.2)	0(0.0)	1(100)	0(0.0)
Body Mass Index class				
Underweight/Normal	265(58.6)	30(11.3)	60(22.6)	175(66.0)
Overweight/Obese	186(41.2)	22(11.8)	51(27.4)	113(60.8)
Refusal	1(0.2)	0(0.0)	0(0.0)	1(100)
Family and non-family members in the household*				
Alone	67(14.8)	6(9.0)	20(29.9)	41(61.2)
2 people	151(33.4)	23(15.2)	40(26.5)	88(58.3)
3 or more people	229(50.7)	22(9.6)	51(20.5)	156(68.1)
Experience in the healthcare field				
Yes	98(21.7)	10(10.2)	22(22.4)	66(67.3)
No	354(78.3)	42(11.9)	89(25.1)	223(63.0)
Financial resources at disposal from own or family income enough to get to the end of the				

month *				
More than enough/enough	316(69.9)	29(12.8)	75(16.7)	212(70.5)
Barely enough/Not enough	132(29.2)	23(17.4)	34(25.8)	75(56.2)
Refusal	4(0.9)	0(0.0)	2(50.0)	2(50.0)
Family or friends support to go to doctors visit (if needed)				
Yes	388(85.8)	44(11.3)	98(25.3)	246(63.4)
No	61(13.5)	8(13.1)	11(18.0)	42(68.9)
Refusal	3(0.7)	0(0.0)	2(66.7)	1(33.3)
Doctor visits				
0	30(6.6)	5(16.7)	6(20.0)	19(63.3)
1-2 times	196(43.4)	19(9.7)	43(21.9)	134(68.4)
3 or more times	226(50.0)	28(12.4)	62(27.4)	136(61.3)
Emergency department admissions				
0	351(77.7)	37(10.5)	83(23.6)	231(65.8)
1-2 times	91(20.1)	14(15.4)	26(28.6)	51(56.0)
3 or more times	10(2.2)	1(10.0)	2(20.0)	7(70.0)
Hospitalizations				
0	401(88.7)	43(10.7)	100(24.9)	258(64.3)
1-2 times	46(10.2)	9(19.6)	9(19.6)	28(60.9)
3 or more times	5(1.1)	0(0.0)	2(40.0)	3(60.0)
Outpatients specialist care access				
0	61(13.5)	9(14.8)	16(26.2)	36(59.0)
1-2 times	162(35.8)	15(9.3)	42(25.9)	105(64.8)
3 or more times	228(50.4)	28(12.3)	53(23.2)	147(64.5)
Refusal	1(0.2)	0(0.0)	0(0.0)	1(100)

^Difference between 100% and the sum of the percentages of each variable corresponds to missing values
*p<0.05

Health literacy distribution and its associations with antecedents and consequences

The Cronbach alpha coefficient for the NVS-IT in this study was 0.741. The NVS-IT score was J-shaped (Figure 2), with mean value of 4.05±1.88 and median value of 4; 25% of the participants presented NVS-IT scores lower than 3. As far as the HL levels distribution in the sample was concerned, high likelihood of limited HL, possibility of limited HL and adequate HL were found in the 11.5%, 24.6% and 63.9% of the sample, respectively.

HL was significantly associated with the following variables (see Table 2): age, educational level, employment status, financial situation, number of family and non-family members in the household, self-reported health status, and the presence of long-term illnesses. Specifically, the percentage of subjects with high likelihood of limited HL was higher in the lower educational level, in the worse health status, in unemployed or retired people, in people with more than one long-term illnesses, in people living with another person, and in people with a worse financial situation.

All the potential predictors of HL were included in the first multivariate logistic regression model. The final multivariate logistic regression model for the antecedents was obtained thought backward stepwise method (table 3). In particular, the risk of having inadequate and at-risk HL levels increased with age (OR = 1.07, p <0.001), with a lower educational level (OR = 2.02, p =0.004 and OR = 4.03; p<0.001 comparing the bachelor's degree and higher educational level group with high school degree group or with less than a high school diploma group, respectively) and with a worse financial situation (OR 1.64; p = 0.041).

Table 3. Multivariate logistic regression analysis for antecedents of HL (HL is the outcome variable) - final model. OR is calculated as "Inadequate and at-risk HL" vs "adequate HL".

	Odds Ratio	*P*	95% Confidence interval
Age	1.07	*<0.001*	1.05-1.09
Education			
Bachelor's degree and higher	1.000	-	-
High school graduates	2.01	*0.004*	1.53-3.61
Less than a high school diploma	4.03	*<0.001*	3.41-7.49
Financial situation			
More than enough/Enough	1	-	-
Barely enough/Not enough	1.639	*0.041*	1.17-2.63

N= 448; Pseudo R^2=0.1404

As far as health outcomes were concerned, HL resulted to be significantly associated only with self-reported health status at the univariate analysis. Besides HL, age, educational level, nationality, long-term illness, employment and financial status resulted to be significantly associated with self-reported health status (data reported in the Supplementary file). All the potential predictors of self-reported health status were included in the first multivariate logistic regression model with self-reported health status as the dependent variable. Results of the final model are reported in table 4. Participants with inadequate and at-risk HL were about two times more likely than participants with adequate HL to report a worse self-reported health status (OR = 2.25, p = 0.002). The presence of one or more long-term illnesses and a worse financial situation remained significantly associated with a worse self-reported health status in the final model (see table 4).

Table 4. Multivariate logistic regression analysis with self-reported health status as the dependent variable – final model. OR is calculated as "so-so/fair or bad health status" *vs* "excellent, very good or good health status".

	Odds Ratio	*P*	95% Confidence interval
Health literacy (HL)			
Adequate HL	1	-	-
Inadequate and at-risk HL	2.25	*0.002*	1.75-2.75
Long-term illness			
No	1	-	-
One	4.04	*<0.001*	3.46-4.62
More than one	12.78	*<0.001*	12.1- 13.45
Financial situation			
More than enough/Enough	1	-	-
Barely enough/Not enough	2.14	*0.004*	1.62-2.66

N=448; Pseudo R^2=0.1860

DISCUSSION

The aim of this study was to assess the level of functional HL in a population-based sample using the Italian version of the NVS and explore the association of functional HL with antecedents and health outcomes.[18] Our results showed the presence of a high mean HL score in the population, and inadequate level of functional HL was present in a relatively small proportion of the population. According to multivariate analyses, the following antecedents resulted significantly associated with the level of functional HL: age, educational level and financial situation. As far as health outcomes are concerned, only self-reported health status resulted significantly associated with functional HL in the multivariate analysis.

To best of our knowledge our study is the first that has set the assessment of functional HL with the NVS tool in a population-based sample as primary outcome in Italy. However, it should be pointed out that results of our study are based on a non-representative Italian population sample (a limitation described further below). In the literature only a study of Palumbo *et al.*[28] have used the NVS tool in a population-based sample in Italy, however in this study the primary outcomes were to assess HL and its antecedents and consequences with HLS-EU-Q47 and NVS was used to check the validity of self-reported literacy skills (HLS-EU-Q47). As a result of this, several data of the NVS in the population are not reported (i.e. NVS score) and it is not possible to compare our findings with this study.

In the literature, many studies have described several antecedents that may positively or negatively impact on health literacy, however to date it is difficult to draw definitive conclusions on this topic as a variety of sampling frame, design and HL measures have been adopted in the literature.[6] Furthermore, demographic and socio-economic factors may impact differently on HL depending on the national and cultural contexts.[5, 15, 16, 29] In light of this, our findings on antecedents of functional HL not only contribute to the current debate in the literature, but also may be considered as the first attempt to highlight the independent predictors of functional HL in the Italian context.

Age and education are reported to be important predictors of HL levels in the literature.[5, 15, 16] As far as education is concerned, in our study, a higher education level resulted to be independently associated to higher functional HL levels; on the contrary, having received training or being employed in the field of healthcare does not impact on functional HL level. As the NVS tool mainly measures document literacy and numeracy, these findings may suggest that these skills are mainly developed in the context of general education with little influence by further and more specific education. Regarding age, results showed a negative independent association with functional HL suggesting that as age increases, a diminished mental alertness and/or cognitive impairment (e.g. memory-retrieval problems and inadequate numeracy) may play a crucial role in limiting the functional HL skills. Indeed, a recent study by Fawns-Ritchie *et al* argued that functional health literacy measures may, in part, assess fluid-type cognitive abilities; furthermore, Kobayashi *et al* fund that age-related differences in functional HL skills are largely explained by cognitive ageing.[30, 31] Further research on this topic suggested that also educational differences may influence age-related differences in functional HL skills as education has changed over the time.[32] Considering that people with low education and older people have the highest burden of chronic diseases,[33-36] and that these diseases require a broad range of reading and numeracy skills for their management, the described associations of functional HL with education and age highlight the need to design and implement health policies tailored on HL skills in these populations.

Our findings have highlighted also that a worse financial situation is associated with lower level of functional HL. Literature, reports contrasting results concerning the association between socioeconomic status and HL measured through NVS score;[15-16, 21] however these variables has been little investigated by population-based studies which considered also the measure of functional HL. Further studies are needed to elucidate the mechanisms underlying the relationship between socioeconomic status and HL.

As regards to health outcomes, self-reported health status was found to be significantly associated with functional HL, but also with financial situation and the presence of long-term illnesses. In the literature the underlying mechanisms through which HL influences the health-related outcomes are not entirely known, and several theoretical models have been proposed to explain these mechanisms.[6, 37-39] However, none of these models have been fully validated, and further studies examining the mechanisms underlying the relationship between HL and health outcomes are needed.

No other health outcomes were found to be significantly associated with functional HL in our study. Although several HL associations with health outcomes have been proposed in the literature, most of them have been evaluated in the clinical context and only few at the general population level.[5, 16-17] Because NVS was primarily designed to detect illiteracy, it may show a ceiling effect when used in general populations.[40] A ceiling effect occurs when a high proportion of participants in a study have maximum scores on the observed variable. This issue makes discrimination among participants among the top end of the scale impossible and may lead to attenuated or absent correlations between HL and other variables,[41] as described also by other Authors. [42-44] In our sample, about 30% of the participants reported the higher score at the NVS-IT. For this reason, A more in-depth evaluation of the presence and effects of skewed distribution of NVS is needed in order to better adjust and calibrate this HL screening tool to use it appropriately in the general population, which in turn may permit to draw more robust conclusions on the presence and strengths of HL associations with health outcomes.

In this study, telephone interviews were used to collect NVS-IT data, while in almost all the studies face-to-face interviews were used. To date, to the best of our knowledge, our study is the first in reporting the comparison of NVS data collected using different methods of administration. The comparison of the NVS score between face-to-face and telephone interviews showed an excellent agreement with no significant difference between the NVS scores. Compared with face-to-face interviews, telephone interviews offer several advantages,[45] in particular the elimination of any bias caused by the appearance of the interviewer. Furthermore, it should be pointed out that the application of NVS may cause stress and shame feelings in people with low numeracy/low literacy skills, possibly discouraging their participation in the interview. In this light, it may be argued that the willingness to participate to an interview that may cause shame and stress is higher if the interview is phone-administered.[45] However, to the best of our knowledge, no studies have specifically compared the participation rates between telephone and face-to-face NVS interviews, and future research is needed to elucidate whether the telephone mode may encourage the participation of people with low literacy/numeracy skills in NVS interviews. On the other hand, the main potential risk with telephone interview compared with face-to face is that the respondent may seek help from another person at home; however, this risk is minor,[45] since the interviewer would be able to notice the involvement of other people (*i.e.*, the person on the phone would have to repeat each question or use the hands-free mode).

This is the first study in Italy that comprehensively attempts to assess functional HL and its related antecedents and outcomes with NVS in a population-based sample. This consideration, together with the evaluation of various potential functional HL consequences, antecedents, and confounding factors, should be considered as the strengths of this study.

Nevertheless, the study has several limitations. First, the population-based sample was obtained with a combination of convenience and probability sampling procedures. Thus, data cannot be considered representative of the overall Italian or Florentine adult population, and this is a major limitation for external comparison of the study results. Secondly, as the variables have been self-reported by the participants through interviews, the study may have suffered the recognized limitations of using this approach, such as recall or social desirability bias.[45] However, the telephone interview may have limited this potential bias especially for those variables potentially more influenced by social desirability such as the BMI and socioeconomic Status. As for recall bias, it should be underlined that the length of recall period for health services use (*i.e.* last 12 months) may have affected the accuracy or completeness of the information retrieved from study participants, especially for GPs visits. This period was selected in order to allow for comparability with other studies.[5, 16] Thirdly, results may have been influenced by a non-response bias, however the extent of this potential bias – if present - is limited as participants and non-participants showed only a small difference in the mean age: since participants were older of two years on average than non-participants the functional HL level resulted in our sample may be slightly lower than in the general population. Lastly, although participants were randomly selected from the registers of the GPs, the GPs were selected using a convenience criteria, which may have introduced a selection bias. However, it should be pointed out that the geographical coverage of the sample included residents of different areas of Florence as the selected GPs were based in different districts of the city.

CONCLUSION

Our study is the first in measuring the functional HL with NVS tool and its associations with antecedents and consequences at population level in Italy. Our findings highlighted the presence of good level of functional HL in the population compared to the EU average. However, older, less educated and poorer population groups resulted at higher risk of limited or inadequate functional HL. These results suggest the need to design and implement health policies and interventions tailored on different HL levels in order to allow the more vulnerable population groups to better cope with the health challenges. As far as health outcomes are concerned, only self-reported health status was found to be significantly associated with functional HL among the considered health outcomes. The underlying mechanisms through which HL influences the health-related outcomes are not entirely known and a more in-depth evaluation of these relationships are needed. As NVS test was originally developed in the clinical context, a ceiling effect that may skew the HL levels distribution in the population may occur when NVS is used at the general population level, ultimately leading to attenuated correlation between HL and its potential predictors and consequences. Further studies investigating the presence and effects of this ceiling effect is needed in order to confirm the validity or better calibrate the NVS tool for the general population studies and to draw more robust conclusions on the presence and strengths of functional HL associations.

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COMPETING INTERESTS

The authors declare no competing interests

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DATA SHARING STATEMENT

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

AUTHOR CONTRIBUTION

GB: conception and design; drafted the article; gave final approval of the version to be submitted.
VL: conception and design; data collection; data interpretation; drafted the article; gave final approval of the version to be submitted; final preparation and submission.
VV: conception and design; data collection; data interpretation; drafted the article; gave final approval of the version to be submitted.
CL: conception and design; data analysis and interpretation; drafted the article; gave final approval of the version to be submitted.
Florence Health Literacy Research Group: conception and design; data collection; gave final approval of the version to be submitted

FIGURE LEGEND

Figure 1. Scatterplots of the NVS-IT scores at T0 and T1 of the pre-testing phase.
Figure 2. Distribution of NVS-IT score

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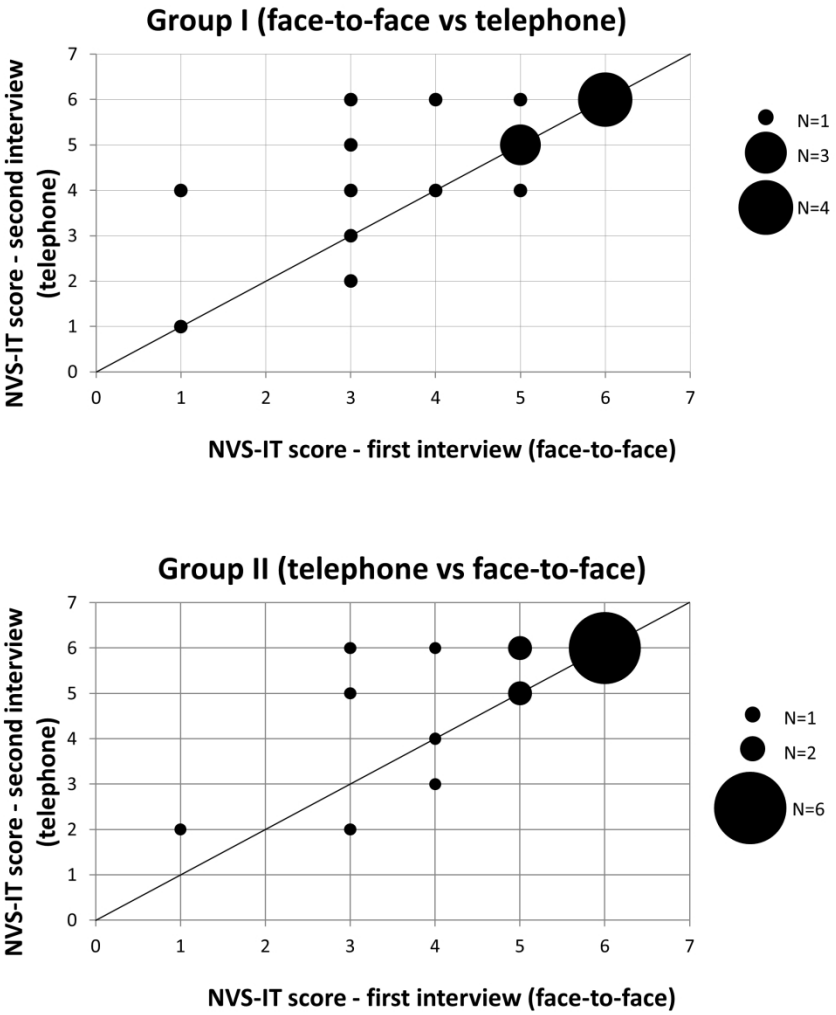

Figure 1. Scatterplots of the NVS-IT scores at T0 and T1 of the pre-testing phase.

190x254mm (300 x 300 DPI)

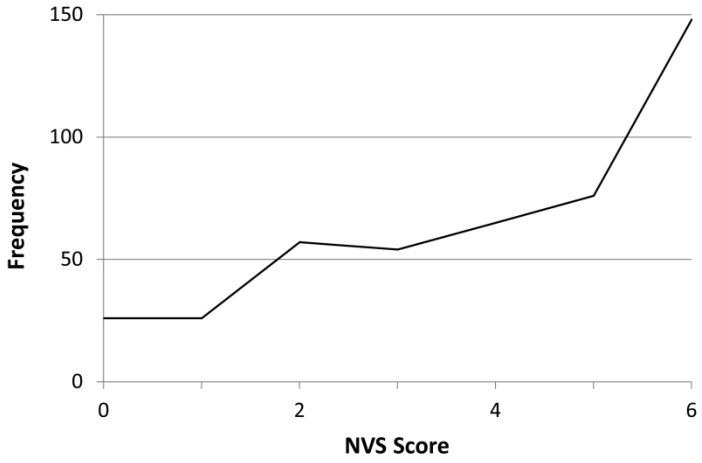

Figure 2. Distribution of NVS-IT score

254x190mm (300 x 300 DPI)

Supplementary table: self-perceived health status (excellent or good; average or poor) by associated factors

	Self-perceived health status		
	Excellent/good N (%)	**Average/poor N (%)**	**Total N (%)**
Educational level (Chi2 test, p<0.01)			
Bachelor's degree and higher	157 (84.4)	29 (15.6)	186 (100)
High school degree	146 (76.4)	45 (23.6)	191 (100)
Less than high school diploma	45 (60.8)	29 (39.2)	74 (100)
Employment status (Chi2 test, p=0.028)			
Empoyed	242 (80.9)	57 (19.1)	299 (100)
Unemployed or retired	39 (69.6)	17 (30.4)	56 (100)
Retired	67 (69.8)	29 (30.2)	96 (100)
Long-term illness (Chi2 test, p<0.01)			
No	215 (90.7)	22 (9.3)	237 (100)
One	105 (71.4)	42 (28.6)	147 (100)
More than one	28 (41.8)	39 (58.2)	67 (100)
Financial resources at disposal from own or family income enough to get to the end of the month (Chi2 test, p=0.01)			
More than enough/Enough	258 (81.6)	58 (18.4)	316 (100)
Barely enough/Not enough	88 (66.7)	44 (33.3)	132 (100)
	Excellent/good mean ± SD	**Average/ poor mean ± SD**	**Total mean ± SD**
Age (Mann-Whitney U test for independent sample, p=0.001)	52.1 ± 12.2	57.1 ± 8.9	53.23 ± 11.7

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1; 2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4; 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4; 5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4; 5
Bias	9	Describe any efforts to address potential sources of bias	4; 5; 6
Study size	10	Explain how the study size was arrived at	4; 5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5; 6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5; 6
		(*b*) Describe any methods used to examine subgroups and interactions	5; 6
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7; 8; 9; 10
		(b) Indicate number of participants with missing data for each variable of interest	9; 10
Outcome data	15*	Report numbers of outcome events or summary measures	7; 9; 10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8; 9;10; 11
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12; 13; 14
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	15

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.