Protocol Study

EDUcation, HEalth Literacy and Stroke in European Countries: EDUHELP Project

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Abstract

Objectives. The EDUHELP project aims to (1) assess stroke-related health literacy (HL) in the general populations of Albania and Italy and identify sociodemographic and behavioral determinants of low HL, and (2) linguistically and psychometrically validate stroke-related HL questionnaires for cross-cultural use in both countries.

Trial Design. This is a cross-sectional, two-phase, multicentre observational study. Phase 1 consists of a population-based survey to estimate levels and determinants of stroke-related HL. Phase 2 focuses on the linguistic, cultural, and psychometric validation of the instruments, following COSMIN and SPIRIT recommendations for measurement studies.

Participants and Settings. Approximately 1,000 adults (≥18 years) will be recruited in each country using a stratified convenience sampling approach with quota targets for age, sex, geographic region, and urban–rural residence. Participants will be recruited in public settings and through an online survey. Healthcare professionals and individuals unable to provide informed consent will be excluded.

Interventions. This is an observational study with no clinical intervention. Participants will complete a structured questionnaire including a sociodemographic survey, the Stroke Knowledge Test, the Awareness of Stroke Symptoms and Risk Factors Questionnaire, and the Stroke Risk Factor Knowledge and Perception Questionnaire. Questionnaires will undergo forward–backward translation, cognitive pretesting, and expert content validation.

Primary and Secondary Outcomes. The primary outcome is a latent stroke-related HL score derived from confirmatory factor analysis of combined questionnaire items. Secondary outcomes include identification of HL predictors through weighted multivariable regression models and evaluation of psychometric properties (content validity, reliability, factor structure, and measurement invariance across countries).
Conclusions. EDUHELP will provide population-level evidence on stroke-related HL in two European countries with differing healthcare contexts and deliver validated tools for cross-national HL assessment, supporting future public health education and prevention strategies.

Keywords: Health Literacy, Stroke, Cross-Sectional Study, Protocol, Validation, European Country

Introduction

Globally, it is estimated that between 10% and 15% of all early strokes occur in individuals aged 18 to 50 years (Ekker et al., 2018), leading to neurological deficiencies in motor, sensory, and cognitive functions (Wang et al., 2023). Despite the improvement in the prevention and treatment of cardiovascular diseases, studies (Chang et al., 2021; Ekker et al., 2018; Pandian et al., 2018) have suggested an increase in the incidence of stroke in young adults, in contrast to the decline observed in the elderly population (Ekker et al., 2019). While the incidence of stroke is decreasing in high-income countries, incidence rates have risen in low- and middle-income countries (Kono et al., 2023).

To understand the general knowledge of the population about stroke, it is essential to assess health literacy (HL) (Korv et al., 2013), defined as the degree to which individuals can access, understand, evaluate, communicate information that is necessary to promote and maintain good health throughout life (Nazar et al., 2019), as well as implement medical instructions and package inserts (Alimehmeti et al., 2016). As described in the literature, HL significantly impacts health outcomes (Cajita et al., 2016). HL is a factor that can influence the control and prevention of stroke recurrence through patient follow-up care (Sanders et al., 2014). However, the relationship between HL and incidence of stroke remains not fully understood (Sanders et al., 2014), and there is a substantial knowing-doing gap in stroke prevention (Faiz et al., 2019).

Benoit et al assessed, for the first time the effectiveness of a one-year pre-discharge educational intervention for stroke and found that knowledge of risk factors and warning signs improved within three months (Benoit et al., 2020). Improving stroke literacy may also be crucial in reducing stroke-related disparities (Ravenell et al., 2015).

Although several studies analyzed HL in chronic diseases (Gazmararian et al., 2003; Liu et al., 2020), there is lack of knowledge about HL in general population about stroke, particularly in low-middle countries in Europe. Understanding the level of HL also in Europe is especially important, as stroke remains a leading cause of death globally, with the burden rapidly increasing and resulting in an annual cost of 60 billion of euros (Luengo-Fernandez et al., 2020). It is essential to understand the clinical risk factors, evaluate health behaviors and raise awareness of sudden stroke symptoms. While improving HL in the general population can be challenging, as it requires changes in health behaviors, it is of utmost importance (Gibson et al., 2022). Studying HL levels in Albania and Italy can help identify knowledge gaps in the public's understanding of stroke, and determine how individuals would respond in the event of a stroke (Matsumoto et al., 2020). An accurate assessment of HL regarding stroke is critical to identifying predictors of low HL (Bitzer & Sorensen, 2018). By identifying these predictors, interventions can be developed to enhance HL levels, promote appropriate behaviors, and reduce the risk of stroke onset (Bitzer & Sorensen, 2018).

Comparing stroke HL between Albania and Italy requires consideration of several factors, including the education system, healthcare infrastructure, cultural context, and access to health information. Italy has a more developed healthcare system, more accessible public health campaigns, and higher levels of stroke literacy, with a general public more aware of stroke risks and symptoms (Giulio de Belvis et al., 2022). In contrast, while Albania has made strides in healthcare, it faces challenges in public health awareness, access to medical information, and education, which can result in lower stroke literacy compared to Italy (Lalo et al., 2023; Mustaqe et al., 2023). In Albania the burden of stroke has been rising over the years (Lalo et al., 2023). Given that stroke is a major public health issue in both countries, there are likely significant differences in stroke HL due to variations in healthcare systems, education, public health campaigns, and overall HL levels.

Improving HL among citizens can be challenging, as it often requires changes in health behaviors, but it is of utmost importance (Gibson et al., 2022). Studying the level of HL in Albania and Italy could help to better understand the general public's knowledge of stroke, identify potential gaps in the literature, and assess how people would respond in the event of a stroke. An accurate assessment of HL regarding stroke is essential for identifying predictors of low HL (Bitzer & Sorensen, 2018). Identifying these predictors allows for the development of interventions aimed at increasing knowledge and promoting behaviors that reduce the risk of stroke onset (Bitzer & Sorensen, 2018).

Objective

The aim of this EDUHELP protocol is to describe HL regarding stroke in European countries, specifically Albania and Italy. Two specific objectives have been developed:

Aim 1: To assess the level of HL related to stroke in the Albanian and Italian populations. This will involve ranking the distribution of HL across various regions, conducting correlation analyses, performing regression analysis to identify risk factors, and determining which subgroups within the population exhibit low HL levels. Additionally, the most vulnerable groups will be identified, along with their predictors.

Aim 2: To linguistically and culturally validate questionnaire for assessing HL related to stroke.

Methods

This study will adopt a cross-sectional design as part of the EDUHELP protocol. The protocol has been structured following the recommendations of Meursinge Reynders R. et al. (2017) (Meursinge Reynders et al., 2017) to ensure comprehensive protocol planning for cross-sectional studies. The first phase of the observational study will be reported according to the STROBE guidelines (Cuschieri, 2019; Vandenbroucke JP et al., 2007), as it is a study protocol for a cross-sectional survey. The second phase of the investigation will follow the COSMIN (COnsensus-based Standards for the selection of health status Measurement INstruments) checklist to assess the methodological quality of the psychometric properties in the cross-cultural adaptation of the scale (Mokkink et al., 2006; Mokkink LB et al., 2025). The timeline for the conduct of the study is described in detail in the Figure 1 and 2. In detail, Table 1 outlines the planned operational workflow of the EDUHELP project, specifying activities, timing, and responsibilities in accordance with SPIRIT 2013 recommendations for cross-sectional studies. The schedule provides transparent information on enrolment, translation, data collection, validation, and analysis activities. The study was approved on October 11 2021 by the Ethics Committee of the Catholic University Our Lady of Good Counsel," Tirana, Albania (Approval Nr° Pr.362/2021). The protocol adheres to the principles of the Declaration of Helsinki (2013 revision) and the European Union General Data Protection Regulation (GDPR 2016/679).

Setting and sample

The study will involve residents of Albania and Italy, with approximately 1,000 participants aged 18 and older recruited from each country. Recruitment will occur in public places (e.g., streets, cafés, hospitals), and two interviewers (MY and FK) will conduct in-person surveys to assist older adults who may have difficulty understanding the questions or using the internet. An online questionnaire will be available for younger, digitally-savvy participants. To improve representativeness, quota targets will be applied within each country to ensure a balanced distribution of participants by age group (18–34, 35–54, ≥55 years), sex (male/female), geographic region (north/center/south in Italy; north/center/

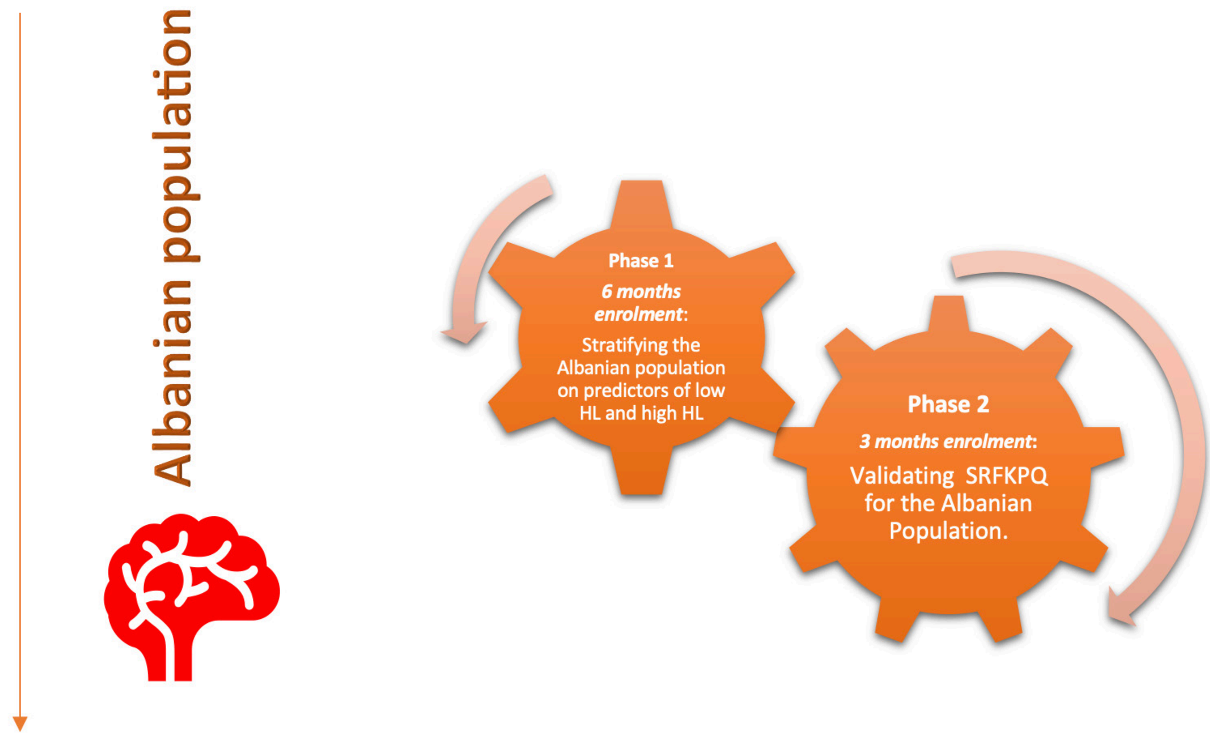

Figure 1. Chronology of the study phases of the EDUHELP project on the Albanian population.

Figure 2. Chronology of the study phases of the EDUHELP project on the Italian population.

Table 1. SPIRIT-style operational timeline of the EDUHELP protocol (months counted from study initiation).

Study phase / activity	Time window	Country	Responsible team	Description and Outputs
Preparation phase	Months 0–2	Albania, Italy	Principal investigators; bilingual translators	Translation and back-translation of SKT, Awareness, and SRFKPQ tools; ethics submission and approvals.
Pre-testing	Month 3	Both	Senior researchers; 2 field interviewers	Cognitive pre-test on ~32 participants to assess comprehension and equivalence.
Phase 1 – Population survey	Months 4–9	Albania, Italy	Field interviewers (2 per country); supervisors	Cross-sectional data collection (≈1,000 participants per country); quota-controlled convenience sampling.
Data cleaning and verification	Months 10–11	Both	Data manager, statistician	Quality control, missing data analysis, MI setup.
Phase 2 – Validation study	Months 12–14	Both	Psychometric analysis team	CFA and measurement invariance testing for SRFKPQ and related instruments.
Statistical analyses and reporting	Months 15–17	Both	PI, biostatistician	Weighted regression, sensitivity analyses, preparation of manuscript.
Dissemination and archiving	Months 18–20	Both	PI, co-investigators	Results submission, anonymization, destruction of linkage key.

south in Albania), and urban–rural residence. Recruitment will continue until each quota cell is approximately filled. This stratified convenience approach aims to mitigate selection bias inherent in non-probabilistic sampling. Quota cells will be defined by the cross-classification of sex (male/female) × age group (18–34, 35–54, ≥55 years) × region (north/center/south) × area of residence (urban/rural), yielding 3 × 2 × 3 × 2 = 36 cells per country. The targeted number of respondents in each cell will reflect the relative population proportions derived from official national statistics (Fund, 2024; ISTAT, 2024). Within each country, recruitment will proceed sequentially until each quota cell is filled to within ±5 % of its expected share, ensuring approximate balance across strata (Division, 2005).

Post-stratification (raking) weights will subsequently be computed to align the achieved sample distributions with the national population margins for sex, age, macro-region, and urban–rural residence using iterative proportional fitting. Weights will be normalized to retain the original sample size (Σw = N) and applied in all descriptive and regression analyses to yield population-representative estimates (Lumley, 2010).

Weighted analyses will constitute the main analytical results, while unweighted analyses will be reported as sensitivity checks to evaluate potential bias from differential non-response or over-representation of specific strata (Lumley, 2010).

Health professionals are excluded to avoid professional knowledge bias, as their exposure to stroke-related information and health campaigns differs substantially from that of the general population, which could artificially elevate average HL estimates. The focus of this study is to describe HL among lay citizens.

Exclusion criteria include non-citizens of Albania or Italy, individuals under 18, healthcare professionals, and patients with cognitive decline or sensory deficits that prevent informed consent. Healthcare professionals are excluded to prevent bias due to specialized knowledge of stroke, while individuals with severe cognitive decline or sensory deficits are excluded as these conditions may affect comprehension and response accuracy. Participants will be selected using a convenience criterion and will be surveyed to assess HL related to stroke and its prevention in the general population

Sample size

Since this study will be conducted on the general population, a large sample will be necessary to reduce the risk of selection bias.

The enrolment period will last approximately six months (Figure 1 and 2). A minimum sample size of 1,000 subjects is required, as a smaller sample may not adequately represent the desired differences (Martinez-Mesa et al., 2014). It is recommended that researchers use the largest sample size feasible, as larger samples provide more reliable estimates than smaller ones (Tsang et al., 2017). The sample size was calculated using G*Power (version 3.1.9.7) based on Ronán Conroy's guidelines (Conroy, n.d.). For Italy's population of 58.990,000 (ISTAT, 2024) and Albania's estimated population of 2.800,000 (Fund, 2024) , with a 3% margin of error, 95% confidence level, and 50% response distribution, 1.068 and 1.067 respondents are required, respectively. However, an approach based on margin of error alone is not sufficient to support the power of multivariate models and psychometric tests. Therefore, additional power analyses will be performed for the two key analytical objectives:

(a) Multivariable regression: Based on G*Power 3.1.9.7, assuming up to 10 predictors (sociodemographic and behavioral covariates) and an anticipated small-to-moderate effect size ($f^2 = 0.02$; equivalent to $\Delta R^2 = 0.02$), with $\alpha = 0.05$ and $1–\beta = 0.80$, a minimum of 485 participants per country would be required. Our planned sample of approximately 1,000 per country more than doubles this requirement, ensuring >95% power to detect small changes in explained variance in HL scores.

(b) Confirmatory factor analysis (CFA) and measurement invariance across languages: for CFA, simulation studies indicate that stable parameter estimation and adequate model fit evaluation require at least 10–15 participants per estimated parameter (Jackson, 2001). Given that our questionnaire include approximately 50–60 free parameters, a minimum of 500–600 cases per language group is recommended. Our planned sample of ≥1,000 participants per country provides more than adequate power for both within-country CFA and multi-group invariance testing between the Italian and Albanian versions, exceeding the recommended minimum ratio of 10:1 (participants: parameters) for robust cross-cultural validation.

In summary, the final sample size is powered for detecting small-to-moderate associations in regression analyses and for stable estimation in multi-group CFA models assessing measurement equivalence across languages.

Procedures: data collection

The timelines of data collection and evolution of the EDUHELP project are depicted in Figure 1 and 2. Indeed, following the publication of the protocol, we will move on to phase one of data collection where the observational study of stroke-related HL will be conducted on the two populations and then to the validation of the questionnaire.

Before being used with the Italian and Albanian populations, two nurses with expertise in stroke care and fluency in English and Italian will translate the scales from English into Italian and Albanian. An English teacher, fluent in both Albanian and Italian and with expertise in medical translation, will then back-translate the Italian and Albanian versions into English. The translator will be blinded to the original version of the scales. The back-translated versions will be reviewed by the scale developer to ensure that the original item content is accurately reflected in the Italian and Albanian versions. If necessary, modifications will be made.

Before the administration of the questionnaire, the items will be pre-tested on a small sample of 32 respondents. This sample size is required to achieve 80% power for the questionnaire in the future population to be surveyed (Perneger et al., 2015). This will allow the researcher to ensure that the original and translated items convey the same meaning and to verify that there is no confusion between the original and the translated questionnaire. The respondents will be asked to explain their understanding of each questionnaire item, assess its readability, and provide any suggestions they may have. During pre-testing, a cognitive interviewing approach will be applied with 32 participants (16 per country) purposively selected to represent diverse age, sex, and education profiles. The concurrent probing method will be used: after each item, interviewers will ask participants to verbalize their understanding, recall processes, and decision-making ("think-aloud" technique). Notes will be taken on comprehension difficulties, ambiguous wording, and culturally specific interpretations (Koskey, 2016).

Item modifications will be implemented only when at least 20% of participants report misunderstanding or unclear meaning. Revised items will be re-evaluated for clarity by two bilingual researchers (B, 2015; Beatty & Willis, 2007).

Content validity will be further assessed by an expert panel of six professionals (three per country) with expertise in stroke prevention, nursing, and public health. Each expert will independently rate item relevance and clarity on a 4-point Likert scale. The Content Validity

Index (CVI) will be calculated at the item (I-CVI) and scale (S-CVI/Ave) levels, with acceptable thresholds set at I-CVI ≥ 0.78 and S-CVI/Ave ≥ 0.90, in line with Polit & Beck's recommendations (Polit et al., 2007).

The questionnaire will be predominantly administered face-to-face. Two interviewers (MY and FK) will ask questions of respondents in person, as it may be difficult for some, especially older adults, to understand the questions or use the internet.

Each section of the questionnaire will include written instructions on how to conduct the interview, making it easier for the participants and addressing potential sources of bias. To minimize selection bias, face-to-face interviews will be conducted first. The remaining subjects will be interviewed using an electronic web survey via Google Forms, a freely available platform for creating and distributing web-based questionnaires. Google Forms has been used in other primary prevention studies (Barakat et al., 2021; Hamzah et al., 2023). An automatic web URL for the questionnaire will be generated, and the link will be distributed via social networking sites and email. It will take approximately 15 minutes to complete this questionnaire.

The names in the questionnaires used for face-to-face interviews will be coded with an encoding key. These sensitive data will be securely archived in a restricted location with no public access. Data collected through the electronic database will be anonymized by assigning a unique numeric code to each participant. These sensitive data will be stored in the electronic database by the principal investigator (GP).

Both open- and closed-ended questions will be included. General demographic information about the participants, such as gender, age, nationality, educational level, marital status, and occupation, will also be collected. As the sample is relatively large, missing data may occur.

Instruments

To assess stroke-related HL in the study participants, a combination of validated questionnaire will be employed to gather comprehensive data across several dimensions. The questionnaire used in this study include a socio-demographic questionnaire developed by the research team, the Stroke Knowledge Test (SKT), the Awareness of Stroke Symptoms and Risk Factors Questionnaire, and the Stroke Risk Factor Knowledge and Perception Questionnaire (SRFKPQ). These questionnaires are designed to measure participants' stroke-related knowledge, attitudes, and behaviors, thereby providing a clear understanding of the role of HL in stroke prevention and management. A summary of the questionnaire, including their constructs,

Table 2. Overview of the instruments used in the EDUHELP study, including construct, number of items, response format, scoring approach, and psychometric properties.

Instrument	Construct assessed	# Items	Response format	Scoring	Prior psychometrics	Planned reliabiliy/ fit indices
Socio-demographic questionnaire (ad hoc)	Background information: age, sex, marital status, education, family history of stroke, etc.	16	Mix of open- and multiple-choice questions	Descriptive variables, categorical coding	Developed for this study	Internal consistency not applicable; descriptive summary only
Stroke Knowledge Test (SKT) (Sullivan & Dunton, 2004)	Knowledge of stroke signs, symptoms, risk factors, and response actions	15	Multiple-choice (single/multiple correct answers) and few open-ended	Total score = # correct answers (0–15)	Cronbach's α = 0.71; test–retest r = 0.83	α and ω ≥ 0.70; CFA fit RMSEA ≤ 0.08, SRMR ≤ 0.08
Awareness of Stroke Symptoms and Risk Factors Questionnaire (Ahmed et al., 2019).	Awareness of symptoms and risk factors; household and educational context	14	Closed-ended (yes/no/don't know) and categorical	Total knowledge score = # correct responses	Cronbach's α = 0.76; validated in general population	α and ω ≥ 0.70; CFA for cross-cultural adaptation
Stroke Risk Factor Knowledge and Perception Questionnaire (SRFKPQ) (Madubuko, 2018).	Knowledge of risk factors, personal and family medical history, and lifestyle practices	27	5-point Likert (Strongly agree–Strongly disagree) and yes/no items	Mean item score and subscale totals	Cronbach's α = 0.79; factor structure confirmed (3 factors)	α and ω ≥ 0.70; RMSEA ≤ 0.08; CFI ≥ 0.90; invariance across languages

number of items, response options, scoring procedures, previous psychometric evidence, and planned reliability and model fit indices, is presented in Table 2. Respondents will be asked to provide an email address or telephone number before beginning the questionnaire.

Socio-Demographic Characteristics Questionnaire: An ad hoc questionnaire developed by the research team will gather socio-demographic data, including variables such as age, sex, marital status, education, and health-related factors like family history of stroke. It will consist of 16 items, with items 1, 4, and 9 being open-ended questions, while the remaining items are multiple-choice questions.

The *SKT* (Sullivan & Dunton, 2004) will assess participants' knowledge of stroke signs, symptoms, risk factors, and behaviors related to prevention and treatment. It comprises multiple-choice questions with both single and multiple correct answers, as well as a few open-ended questions. It consists of 15 items, items 3 and 4 consist of open answers, in part also item 12, while the remaining part are multiple choice questions in part with only one correct answer or more than one.

The Awareness of stroke symtoms and risk factor Questionnare (Ahmed et al., 2019) is a 14-item questionnaire that will assess knowledge of stroke symptoms and risk factors, in addition to gathering routine data on participants' personal characteristics, such as family education level and household structure. It is divided into two sections. In the first session, questions are asked to obtain information about the participants' knowledge of the signs, symptoms and risk factors of stroke. The second section will include routine questions about the individual's personal characteristics such as the educational level of the parents and with how many people they currently live with.

The SRFKPQ (Madubuko et al., 2018) is 27-item questionnaire that will assess knowledge of stroke symptoms and risk factors, in addition to gathering routine data on participants' personal characteristics, such as family education level and household structure. Consisting of 27 items, the SRFKPQ explores the participant's clinical condition, family medical history, and lifestyle.

Data analysis and statistics

Descriptive statistics (mean, standard deviation, median, interquartile range, and frequencies) will be used to summarize socio-demographic, clinical, and scale data.

The primary outcome is the latent HL factor score derived from the confirmatory factor analysis (CFA) of the combined items from the Stroke Knowledge Test (SKT), Awareness of Stroke Symptoms and Risk Factors Questionnaire, and Stroke Risk Factor Knowledge and Perception Questionnaire (SRFKPQ). This latent HL construct represents overall stroke-related literacy.

Covariates included in multivariable analyses will be: age, sex, educational attainment, socioeconomic status, marital status, urban–rural residence, geographic region, and prior personal or family history of stroke. Lifestyle factors (smoking, physical activity, diet, and alcohol use) will also be considered as independent predictors.

Regression models will use multiple linear regression to estimate associations between covariates and the HL factor score. Model diagnostics will assess multicollinearity, residual normality, and heteroscedasticity. Statistical significance will be set at $p < 0.05$, with false discovery rate (FDR) correction applied for multiple hypothesis testing. To enhance population representativeness, post-stratification weights will be calculated based on national census data for age, sex, and region distributions in each country. Weighted and unweighted analyses will be compared to assess robustness. Sensitivity analyses will be performed excluding online-only respondents to evaluate potential differences between digital and face-to-face recruitment modes, and between urban and rural strata.

The multiple imputation (MI) procedure will include all variables used in the main regression analyses—namely, the outcome variable (latent HL factor score), sociodemographic covariates (age, sex, education, marital status, socioeconomic status, region, and urban–rural residence), and health-related predictors (lifestyle behaviors, prior stroke experience, and family history of stroke). In addition, auxiliary variables that are correlated with missingness (e.g., digital literacy, mode of administration, and self-rated health) will be included in the imputation model to improve accuracy and satisfy the missing-at-random (MAR) assumption.

We will perform multiple imputation by chained equations (MICE) with $m = 20$ datasets, using predictive mean matching for continuous variables and logistic or ordinal logistic regression for categorical variables. Analyses of association (e.g., weighted multiple regression) will be based on pooled estimates following Rubin's rules (Burgess et al., 2013).

Imputation will be restricted to regression analyses; it will not be applied to CFA models with categorical indicators. Instead, CFA and measurement invariance analyses will handle missingness using the WLSMV estimator's pairwise approach for categorical data. Sensitivity analyses will compare results from complete-case and imputed datasets to verify robustness.

CFA will be conducted using Mplus Version 8 (Muthen & Muthen, 2010) to assess the dimensionality of each instrument and test measurement invariance across the Italian and Albanian samples. Given the categorical nature of the indicators, all CFAs (including multi-group invariance) will use a robust weighted least squares estimator (WLSMV, θ-parameterization) in Mplus v8. Missingness will be handled under WLSMV's default for categorical data; if item-level missingness exceeds ~5%, we will repeat analyses on multiply imputed datasets as a sensitivity analysis. Regression analyses will continue to use MI and FIML as previously stated, but FIML will not be used for CFA with categorical items. Goodness-of-fit will be evaluated using the following primary thresholds: CFI/TLI ≥ .95 (acceptable ≥ .90), RMSEA ≤ .06 (acceptable ≤ .08), SRMR ≤ .08. Competing models will be compared with fit indices, parsimony, and theoretical coherence. We will evaluate configural, metric (loading), scalar (threshold) invariance for categorical indicators using the DIFFTEST option under WLSMV(Dubravka Svetina, 2019). Invariance decisions will follow ΔCFI ≤ .010 and ΔRMSEA ≤ .015 between nested models, alongside absolute fit indices. If full scalar invariance is not achieved, we will adopt partial invariance by freeing a minimal set of non-invariant loadings/thresholds based on modification indices and content. Latent mean comparisons will only be made at (partial) scalar invariance(Dubravka Svetina, 2019). Model comparisons for cross-language invariance will follow the ΔCFI ≤ 0.010 and ΔRMSEA ≤ 0.015 criteria (Dubravka Svetina, 2019). Weighted and unweighted analyses will be compared to evaluate representativeness. Sensitivity analyses will test the robustness of results by excluding online-only respondents and examining potential mode (online vs. face-to-face) and regional effects. Because data collection will include both online and face-to-face administration, potential mode effects—differences in responses attributable to the survey mode rather than true population differences—will be explicitly assessed. First, descriptive comparisons will be conducted between respondents recruited online and those surveyed face-to-face across key sociodemographic variables (age, sex, education, region, urban–rural residence) to evaluate selection differences.

Next, we will test for measurement equivalence across modes using a multi-group confirmatory factor analysis (CFA) with mode (online vs. face-to-face) as the grouping variable. Configural, metric, and scalar invariance will be examined sequentially under the WLSMV estimator for categorical indicators, applying ΔCFI ≤ .010 and ΔRMSEA ≤ .015 as invariance thresholds. If partial invariance is achieved, latent means will be compared to identify systematic score differences by mode.

Additionally, as a robustness check, we will fit a MIMIC (Multiple Indicators–Multiple Causes) model, adding a binary mode covariate (0 = face-to-face, 1 = online) to test for direct effects of mode on individual items while controlling for the latent HL factor and sociodemographic covariates (Tekwe et al., 2014). Significant mode effects ($p < .05$ after FDR correction) will be reported and, if substantial, corrected using multiple-group or MIMIC-adjusted estimates in the main analyses. Weighted regression analyses will also be repeated within each mode subgroup to assess whether associations between covariates and HL differ across collection modes.

Analyses will be performed using SPSS v.28 for descriptive and regression models, and Mplus v.8 (Muthen & Muthen, 2010) for CFA and structural equation modeling.

Measurement model

We conceptualize stroke-related HL as a latent construct reflected by items covering three knowledge/action domains: (i) recognition of stroke symptoms; (ii) knowledge of risk factors; and (iii) intended action/response in time-critical situations. Items contributing to these domains are drawn from the Stroke Knowledge Test (SKT), the Awareness of Stroke Symptoms and Risk Factors Questionnaire, and the Stroke Risk Factor Knowledge and Perception Questionnaire

(SRFKPQ). Open-ended items will be coded by two independent raters into dichotomous or ordered categories (0 = incorrect/omitted; 1 = partially correct; 2 = fully correct where applicable); disagreements will be resolved by consensus (κ reported).

We will test three theoretically-plausible structures in a confirmatory framework: a) Unidimensional model: all items load on a single HL factor (g-HL); b) Multidimensional correlated-factors model: three first-order factors—Symptoms, Risk Factors, Action/ Response—allowed to correlate; c) Bifactor model: a general HL factor (g-HL) plus the three orthogonal domain-specific factors capturing residual domain variance (van Zyl & Ten Klooster, 2021).

Model comparison will be based on fit indices and interpretability. If the bifactor model is retained, we will report ωH (omega-hierarchical) for the general factor and explained common variance to quantify the prominence of g-HL (Flora, 2022). The integration of items from different questionnaires will be carried out using two methodologies, as the items are harmonized into categorical indicators (binary/ordinal) and mapped to the above domains regardless of the source instrument. To address potential method variance due to instrument origin or item stems, we will (a) use local residual correlations only when strongly warranted by modification indices and content (Bandalos, 2021), or (b) add instrument method factors (orthogonal to substantive factors) as a sensitivity analysis (Ellis, 2017). No parcels will be used; all items are modeled directly to preserve diagnostic information.

Depending on the retained structure, the primary outcome will be (a) the g-HL factor score (unidimensional/bifactor), or (b) a composite latent HL score derived from the correlated-factors solution (and, secondarily, domain-specific scores). This replaces the previous generic description of a single CFA-derived HL score and aligns scoring to the empirically supported structure.

Ethical consideration

This study was reviewed and approved by the Ethics Committee of the Catholic University "Our Lady of Good Counsel," Tirana, Albania (Approval No. Pr.362/2021). The protocol adheres to the principles of the Declaration of Helsinki (2013 revision) and the European Union General Data Protection Regulation (GDPR 2016/679).

In accordance with the EU General Data Protection Regulation (GDPR 2016/679) and national privacy laws in Italy and Albania, data processing will be based on explicit informed consent obtained from all participants prior to participation (Article 6(1)(a), GDPR).

Each participant's identifying information (name, contact details) will be stored separately from survey responses and linked only via a randomly generated numeric code. The linkage key will be securely stored in an encrypted, access-restricted file and will be destroyed within six months after data collection is completed. De-identified data will be retained for five years for secondary analyses and quality assurance, after which they will be permanently deleted.

The data controller for the study is the Catholic University "Our Lady of Good Counsel," Tirana, Albania, represented by the Principal Investigator (GP), who can be contacted for any data protection-related inquiries at his institutional email address.

All data transfers between research partners will occur through encrypted channels, and only aggregated, anonymized data will be shared for analysis.

Expected Results

We anticipate observing heterogeneity in stroke-related HL across and within countries, with lower average HL in Albania than in Italy, consistent with differences in health-system resources, health information access, and prior public health campaigns described in the introduction.

Primary outcomes (population survey)

Descriptive analyses will likely show right-skewed distributions of HL-related knowledge, with gaps in the recognition of early stroke symptoms and time-critical actions, and incomplete knowledge of modifiable risk factors (e.g., hypertension, atrial fibrillation, smoking, physical inactivity). We expect faster intended response behaviors (e.g., calling emergency services) to be more frequently reported in Italy than in Albania. Urban residence and previous exposure to stroke (self or family) are expected to correlate with higher knowledge scores.

Predictors of HL

In multivariable linear regression, we expect lower HL scores to be independently associated with older age, lower educational attainment, lower socioeconomic position, rural residence, and absence of prior stroke exposure, whereas higher HL should be associated with younger age, higher education, urban residence, and prior exposure to stroke. We also anticipate health-behavior correlates: higher HL co-occurring with more frequent physical activity, healthier diet patterns, nonsmoking status, and lower hazardous alcohol intake on the SRFKPQ lifestyle items. Effect directions should be stable across countries, though magnitudes may differ.

Secondary outcomes: Instrument performance (validation phase)

For the SKT, Awareness of Stroke Symptoms and Risk Factors Questionnaire, and SRFKPQ, we expect acceptable internal consistency (Cronbach's α and McDonald's ω ≥ 0.70) and adequate CFA fit under the planned estimation (e.g., RMSEA ≤ 0.08; SRMR ≤ 0.08), supporting linguistic and cultural appropriateness of the Italian and Albanian versions. Item performance is expected to reveal a small subset of easier items with ceiling effects (basic symptom recognition) and several discriminating items (time-to-action, atrial fibrillation, and lifestyle risk factors), aligning with the knowledge gaps described above. Where individual items show weak loadings or misfit, minor wording refinements will be proposed without altering the substantive constructs.

Discussion

Our multidimensional survey is based on a recent European study (Sorensen & Bredahl Kristensen, 2023), which states that Europe has a large and fragmented picture of cardiovascular disease mortality and incidence, specifically noting that inequalities in cardiovascular disease mortality are massive in Central and Eastern Europe. Hence, our survey includes two countries from this region, Italy and Albania. A potential limitation of this study is his convenience sample which may not be representative of the population.

However, cognitive survey of the state of knowledge of lifestyles and preventive behaviors implemented by these two populations could make aware of the public health of the two nations, defining new pathways to make aware and implementable primary prevention pathways on stroke. Public health interventions, particularly on primary prevention, has shown great effectiveness in increasing population awareness of symptoms, which means fewer hospital delays, morbidity, and mortality (Mszar et al., 2020). In addition, these studies aim to show how the burden of stroke can be reduced by identifying and reducing stroke risk factors. However, only a few studies have demonstrated a causal relationship between HL and health outcomes in cardiovascular disease (Albus, 2018; Visscher et al., 2018; Walters et al., 2020). These studies could identify key predictors of stroke, for new preventive health policies in Central and Eastern European countries.

The cognitive survey expressed as a goal in the first study will bring new data and help future research create appropriate health interventions. By recruiting participants from the general population of all ages, our study will reflect the actual situation of stroke knowledge. Regarding the recognition of predictors in these two countries, it is crucial, as expressed by Kur et al. (Kaur et al., 2022), as it allows focusing precisely on the population under investigation, facilitating the acquisition of predictors of poor HL and the right notions about stroke, which are fundamental criteria for primary prevention in public health. Studying stroke in a particular area is important for several reasons. First, it helps identify knowledge, causes, gaps, symptoms, and outcomes in a particular region (Han & Jang, 2021). To our knowledge, this will be the first study in Albania that attempts to assess HL; unlike Italy, where a survey on general elements of knowledge related to stroke has already been investigated but goes back 9 years and investigates knowledge only in adults (Baldereschi et al., 2015). The proposed research will examine HL as a cause of disability and death. We believe that it is critical to study the population of a particular region to learn about its culture and education level, which can help identify factors that promote HL. For this reason, we will also include questions about education level, socioeconomic status, HL vascular risk factors, and treatment options, which can expand our ability to explore additional factors that might be associated with a lack of understanding of stroke.

Regarding the second validation study of the cognitive survey instrument, it would be important to uniquely investigate knowledge and risk factors for stroke. In Italy, we have an instrument that investigates the readiness for stroke identification by the population (Denti et al., 2015), but there are no questionnaire that give a picture of knowledge related to stroke prevention. As for the Albanian population to our knowledge, it does not have questionnaire that investigate knowledge about stroke to prevent it. Finally, providing questionnaire such as questionnaires to target the level of stroke knowledge (Hou et al., 2017) can make health professionals aware of the population to be indoctrinated, with the goal of targeting the right educational interventions in the target population.

In the literature, several guidelines are provided on how to structure primary prevention interventions in the population (Feigin et al., 2016; Sullivan et al., 2008; Yan et al., 2016); but in our case, given the cognitive survey and psychometric inquiry, we may be able to develop a usable program specific to the populations under investigation. Indeed, in a recent scoping review (Movsisyan et al., 2021), we define how important it is to investigate the knowledge levels of a population about a particular object of study, so as to make an intervention adaptable to the entire population previously investigated. Indeed, this is precisely the motivation for developing the program at the end of the two antecedent studies. It is extremely engaging to link the three surveys that could develop new interventions, tailored to the needs that emerged from the two populations.

Implications

Collectively, these results are expected to: map HL deficits most strongly associated with suboptimal intended response and preventable risk profiles; and identify high-risk subgroups (by age, education, residence, and prior exposure) for tailored messaging; and support the feasibility and reliability of the adapted questionnaire for routine population surveillance and for evaluating future educational interventions in both countries.

Conclusions

These studies provide researchers with a solid foundation to revise and adapt existing interventions, aligning them more closely with the specific needs of diverse populations. By doing so, interventions become more usable, equitable, and scalable across varying levels of public health need. As the most comprehensive domain of public health, primary prevention plays a critical role in averting diseases with significant socioeconomic consequences. Effective primary prevention strategies can help reduce the incidence of conditions such as stroke, ultimately mitigating the long-term health and social burdens associated with disability.

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