




## Abstract

# A Step-by-Step Harmonization Process for Nutritional Epidemiology Purposes: A Methodological Work of the Collaborative PROMED-COG Pooled Cohorts Study <sup>†</sup>

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**Abstract:** Background and objectives: Pooling datasets for nutritional epidemiological purposes are becoming more common because of their several advantages. Here, we described our step-by-step dietary data harmonization process applied within the PROMED-COG pooled cohorts study aiming to evaluate the effect of nutrition on neurocognitive ageing. Methods: This is a collaborative project that includes data from four Italian population studies recruited during the 1992–2023 period: BEST; Pro.V.A; ILSA; and NutBrain. Retrospective nutritional data harmonization was performed considering three main nutritional exposures such as body composition (weight and circumference), undernutrition (by combining phenotypic and etiologic criteria), and dietary habits (through food frequency questionnaires). In particular, the challenge was the harmonization procedure for dietary habits that required several steps: (i) access to documentation from the original studies, (ii) discussion with the researchers responsible for each dataset; (iii) exploration of each dataset before the final harmonization; (iv) agreement on portion size and food frequency standardization, and food classification for healthy dietary pattern computation; (v) name, definition, and categorization of the harmonized common variable and the original variables, for each study; (vi) development and application of the algorithm to obtain the harmonized variables from the original ones; and (vii) final pooled dataset preparation. Results: The pooled sample included 9326 adults aged 40–101 years, of which 52% were women. The main issues encountered were due to the heterogeneity of dietary assessment methods across studies: type of instrument (unstructured dietary questionnaires for ILSA and Pro.V.A. vs. structured FFQ for the BEST and NutBrain); data collection time frame (1992–1997 in ILSA, Pro.V.A., and BEST and 2019–2023 in NutBrain); and the period used for diet reporting (last week for ILSA and Pro.V.A., last 12 months for BEST and NutBrain). On the other hand, there were similar characteristics regarding the administration method of data collection (by trained interviewers), comparability of the food composition database used for nutrient profiling, community-dwelling setting, and geographical area (Italy), fostering the comparison across studies. Conclusion: the pooled dataset represents a harmonization standard procedure that may be useful to advance future epidemiologic research with different applications and, specifically within the PROMED-COG, to draw valid and solid conclusions about the nutrition–neurocognitive ageing relation in the general population.

**Keywords:** retrospective data harmonisation; pooled datasets; dietary data; observational studies; population-based studies



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**Institutional Review Board Statement:** The study protocols were implemented in compliance with the guidelines outlined in the Declaration of Helsinki. The responsible Ethics Committees approved all procedures; for the ILSA study, it was approved by the institutional review board of the eight participating municipalities; while for the Pro.V.A. study, it was approved by the local Ethics Committee. The BEST-FU study was approved by the Ethics Review Board of the CNR of Segrate (MI); and the NutBrain study was approved by the Medical Ethics Committee of Pavia.

**Informed Consent Statement:** For original studies conducted by ILSA and Pro.V.A., written informed consent was obtained from all participants. For the BEST-FU study, verbal informed consent was witnessed and formally recorded by all participants. In the case of the NutBrain study, all participants provided formal written informed consent.

**Data Availability Statement:** Data are available under request.

**Conflicts of Interest:** The authors declare no conflict of interest.

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