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1. Objectives

The primary aim of this study was to validate the **BIOS-MS** questionnaire, developed to assess **knowledge, attitudes, and informational experiences** related to biosimilar drugs among people with multiple sclerosis (MS). The tool is intended to support patient-centred communication and informed decision-making in clinical practice.

2. Materials

The study involved **99** adult patients with a diagnosis of MS, all receiving biosimilar therapies. The BIOS-MS includes items grouped into three conceptual domains—**Knowledge, Attitude, and Information** about biosimilars. Additional items explored patients' perceived treatment outcomes (effectiveness, side effects, convenience, and overall satisfaction).

3. Methods

Psychometric validation comprised internal consistency analyses (**Cronbach's α** and **McDonald's ω**), **Confirmatory Factor Analysis (CFA)**, and **Exploratory Factor Analysis (EFA)**. **Spearman's rank correlations** assessed relationships among variables. Group differences by gender, age, education, prior biosimilar awareness, and perceived influence of healthcare professionals were tested using **Kruskal–Wallis** and **Mann–Whitney U** tests.

4. Results

The BIOS-MS demonstrated **excellent internal consistency** ($\alpha = 0.872$; $\omega = 0.876$). CFA supported a **three-factor model** with good fit ($\chi^2(24) = 30.5$, $p = .168$; **CFI** = 0.984; **RMSEA** = 0.043), and EFA confirmed the factor structure (**KMO** = 0.864; Bartlett's test $p < .001$). Moderate-to-strong correlations were observed among the three domains ($\phi = 0.459$ – 0.587 , $p < .001$). Patients who had previously heard of biosimilars (**N** = 37; 37.4%) reported **significantly higher BIOS-MS scores** ($p = .002$). The **perceived influence of nurses** was strongly associated with higher BIOS-MS scores ($p < .001$) and with greater perceived treatment effectiveness ($p = .025$). Differences in **convenience** and **satisfaction** were also observed by education level and gender, respectively.

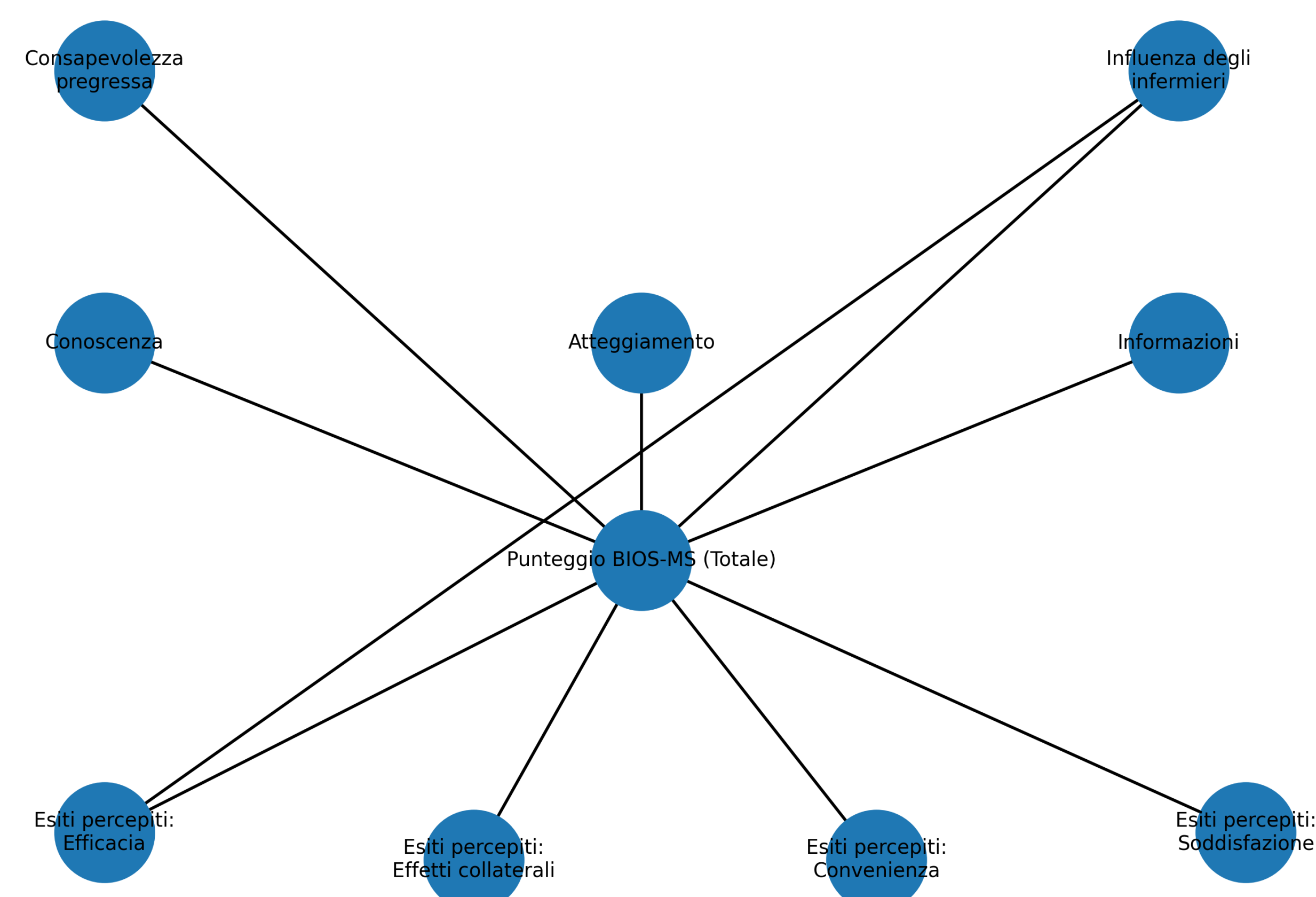


Figure 1. Conceptual model of BIOS-MS domains, total score, and perceived outcomes.

5. Discussion

The BIOS-MS is a valid and reliable instrument for assessing how people with MS perceive biosimilars. Findings underscore the ****key role of healthcare professionals—especially nurses—**** in shaping patient understanding and attitudes toward biosimilars.

6. Conclusions

The validated BIOS-MS questionnaire is a useful tool for evaluating patient perspectives on biosimilars in MS care. Its implementation in clinical settings may enhance communication, guide tailored education, and support broader acceptance of biosimilars in the management of multiple sclerosis.

| Aspect | Key results / statistics |
|---------------------------------|---|
| Sample | N = 99 adults with MS treated with biosimilars |
| Theoretical structure | 3 domains: Knowledge, Attitude, Information |
| Internal consistency | Cronbach's $\alpha = 0.872$; McDonald's $\omega = 0.876$ |
| CFA (3-factor model) | $\chi^2(24) = 30.5$, $p = .168$; CFI = 0.984; RMSEA = 0.043 |
| EFA / Sampling adequacy | KMO = 0.864; Bartlett $p < .001$ |
| Inter-domain correlations | $\phi = 0.459$ – 0.587 , $p < .001$ (moderate–strong) |
| Prior knowledge of biosimilars | Higher BIOS-MS scores if previously informed ($p = .002$) |
| Perceived influence of nurses | Higher BIOS-MS scores ($p < .001$) and greater perceived effectiveness ($p = .025$) |
| Differences by education/gender | Significant differences in convenience (education) and satisfaction (gender) |

Table 1. Psychometric evidence for the BIOS-MS questionnaire (N = 99).