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Innovative approaches for personalized cardiovascular disease prevention: preliminary findings from the INNOPREV project in Sicily

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Background. Cardiovascular diseases (CVD) remain a leading cause of global mortality and morbidity. Precision public health aims to integrate novel technologies into primary prevention strategies to improve personalized risk assessment and targeted lifestyle interventions. The INNOPREV project (PNRR MAD-2022-12375795) evaluates the clinical efficacy of combining polygenic risk scores (PRS) and digital tools, such as smartwatches, in enhancing lifestyle behaviours and mitigating cardiovascular risk in adults.

Materials and Methods. A multicentre randomized controlled trial was conducted in three Italian sites: Rome, Palermo, and Catania, enrolling 1,020 individuals aged 40–69 years with a 10-year CVD risk of 2.5–10% assessed by SCORE2. Participants were randomized into four arms: 1) Standard of Care (SoC); 2) Genetic Intervention (SoC + PRS feedback); 3) Digital Intervention (SoC + smartwatch and dedicated app for self-monitoring diet, physical activity, sleep, and smoking); 4) Combined Genetic and Digital Intervention. Lifestyle and biological profiles were assessed at baseline, 6- and 12-months using Life's Essential 8 (LE8) and SCORE2 metrics. Salivary samples were collected for DNA profiling via Illumina Global Screening Array to generate global and trait-specific PRSs.

Results. In the Sicilian cohort (Catania and Palermo), 693 participants were enrolled at baseline (T0), with 551 completing the 12-month follow-up (T3), yielding an overall dropout rate of 20.5%. At baseline, LE8 scores categorized 10.2% of subjects with an unfavourable profile, 83% intermediate, and 6.8% favourable. Significant positive overall improvements in LE8 scores were observed across all intervention arms at 6 and 12 months (+2.3 and +2.6 points, respectively; $p < 0.05$), with no statistically significant differences in total LE8 or SCORE2 changes between individual groups. Trait-specific PRSs (hypercholesterolemia, hypertriglyceridemia, low HDL) demonstrated strong positive correlations with measured lipid profiles, validating the predictive accuracy of genetic testing alongside clinical metrics.

Conclusions. Preliminary data from the INNOPREV trial demonstrate the feasibility of embedding genomics and digital health tools into public health practice. While general lifestyle improvements occurred across all study arms, trait-specific PRSs provide valuable added value for precision risk stratification, laying the groundwork for tailored preventive strategies in Italian healthcare.