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Pocket Profile for BioPersMed (Biomarkers of Personalized Medicine) Graz: a mono-center, long-term, observational, prospective cohort study to evaluate novel biomarkers for the assessment of cardiovascular and metabolic diseases and related complications

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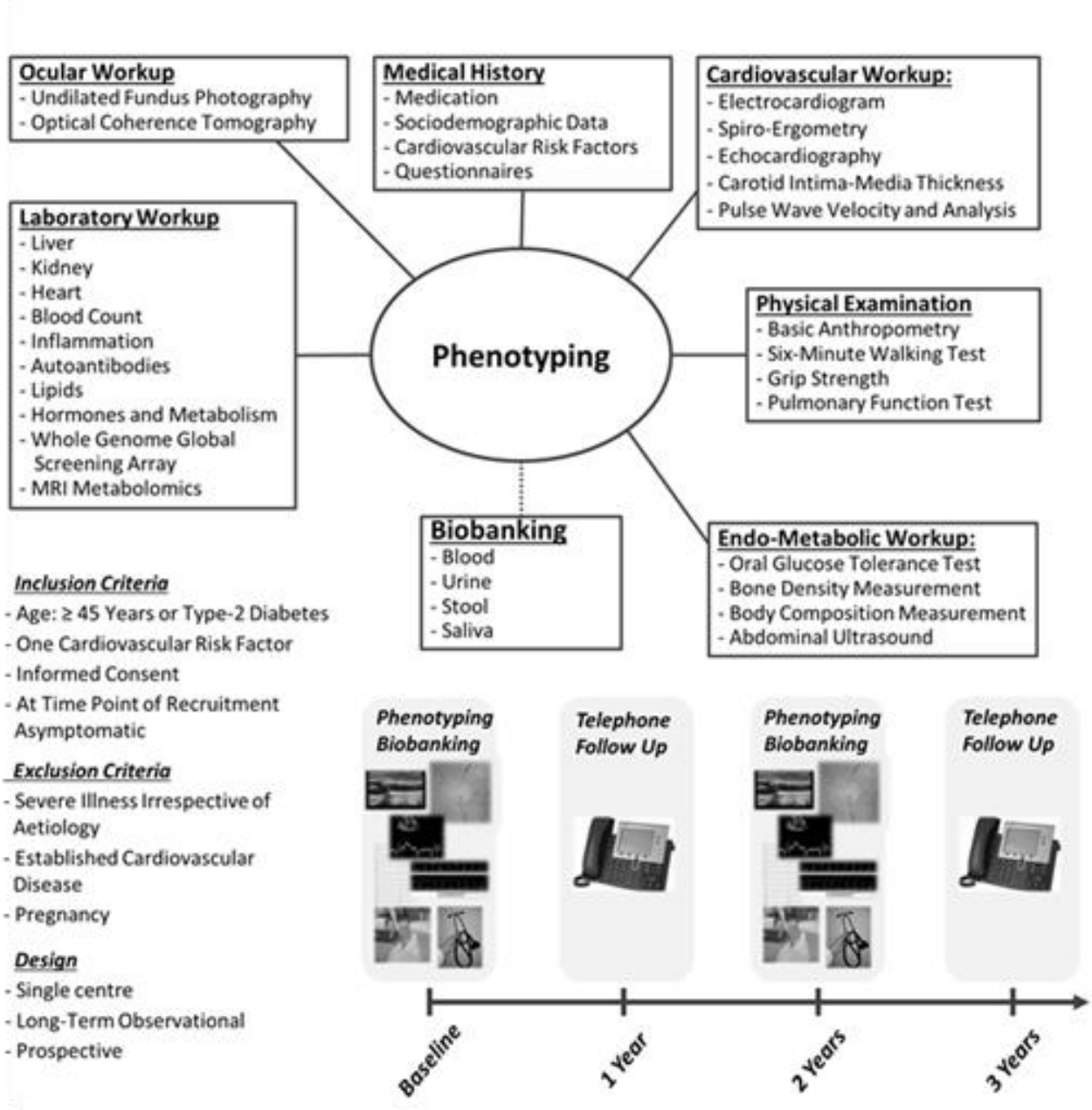
Cohort Purpose: In the BioPersMed Study (Biomarkers of Personalized Medicine), we enrolled community dwelling and asymptomatic patients at risk for cardiovascular disease in order to evaluate the predictive value of various biomarkers reflecting different pathways of cardiovascular and metabolic disease development. The aim is to evaluate large-scale screening tools for the improvement of cardiovascular and metabolic risk stratification, early diagnosis, prediction of clinical outcomes, and long-term clinical monitoring of patients at cardiovascular risk.

Cohort Basics: Centred at the city of Graz (Styria, Austria), baseline data collection between 2010 and 2016 resulted in the initial recruitment of 1024 patients at the age of 45 years or oder presenting with at least one classic cardiovascular risk factor or manifest diabetes mellitus type 2 at the age of 18 years or older.

Follow-up and Attrition: Follow-up includes a telefone visit every odd year after enrollment and a full clinical phentyping every even year after enrollment. Until now, 799 patients completed the first clinical follow-up and 595 patients have attended the second clinical follow-up. A few patients skipped either the first or second clinical follow-up but are continuing the study. So far (1st March 2020), 169 probands will not be available for future follow-ups (drop-outs).

Design and Measures: The BioPersMed project is designed as a single-centre, prospective, observational study. At baseline and at regular 2 years-follow-ups, an in-depth diagnostic work-up is carried out including: questionnaires (for health, past medical history, psychosocial and sleep issues), physical examination, ECG, lab/blood sampling with biobanking (including a broad hormonal and metabolic characterisation), exercise testing (6min walking test, grip strength, spiroergometry), echocardiography, pulmonary function testing, carotid intima/media-thickness measurement, pulse-wave analysis, ophthalmologic examinations, body composition assessment, bone density quantification and oral glucose tolerance tests.



Unique Features: The variety of assessed biomarkers allow a comprehensive phenotyping of patients at cardiovascular risk, thereby opening up the possibility to reveal connections between different biomarkers of different organ systems and diseases. This information may serve as a basis for a multi-disciplinary in-depth analysis and cooperation with other prospective cohorts (e.g. with an interventional design).

Reasons to be Cautious: Firstly, a potential weakness of this study is the time range of a rather slow recruitment due to logistic reasons between 2010 and 2016. This results in a prolonged follow-up period of study participants between 4 and 10 years. Secondly, after a thorough standardized baseline phenotyping, the characterization of the BioPersMed cohort has been expanded by additional diagnostic tools at later timepoints (e.g.non-mydriatic funduscopy). Although some of these biomarkers are not available for the complete duration of the entire cohort, cross-sectional analysis of a considerable number of probands can already be performed with these data sets and will be available for longitudinal comparison of follow-up visits thereafter.

Collaboration and Data Access: The design of the BioPersMed study, data management, biobanking and data analyses are compliant to the STROBE, STROBE-ME and STREGA recommendations. Collaboration in data analysis and publications will be welcome through specific research proposals sent to the BioPersMed investigators listed as corresponding authors.

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