Diagnosing metabolic disorder-associated steatotic liver disease (MASLD) in a large MRI-based screening program: gateway to combined lifestyle intervention and weight loss.

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Description of the initiative. Background/context: Metabolic disorder-associated steatotic liver disease (MASLD) is the most frequent cause of chronic liver disease and an independent risk factor for cardiovascular events. Reception of a diagnosis of MASLD may offer a key window of opportunity to stimulate better lifestyle and weight loss. PRESCAN Netherlands commercially offers to subjects without manifest cardiovascular disease, whole body MRI as cancer screening tool (annually >10,000 participants (mean age 57 yrs, 57% male: 56% overweight/obese). MRI-based proton density fat fraction (PDFF) allows accurate liver steatosis quantification. Concomitant investigations in the PRESCAN health check are blood pressure, BMI, glucose and lipid spectrum, echocardiogram and ECG.
Objectives and scope: To explore the potential of PRESCAN as gateway to combined lifestyle intervention (CLI) and weight loss to promote prevention of manifest liver and cardiovascular disease. To identify predictive factors such as concomitant cardiometabolic risk factors for weight loss after one year.

Planned activities & deliverables
Outline the steps to be taken: Inclusion criteria: **1.** BMI>25 kg/m^2, **2.** new MRI-based diagnosis of steatotic liver disease (PDFF>5%), **3.** no current or previous participation in CLI program, **4.** informed consent. In this prospective open randomised controlled study, from November 2024 on, new eligible PRESCAN participants will be will be randomised (1:1 ratio) for **Group A (intervention):** baseline and after 1 year interview by phone. Baseline one-time CLI advise by trained dietician with additional information about further guidance through regular patient care (including CLI coach) and online guidance (https://happiapp.nl) or **Group B (control):** baseline standard PRESCAN participant information, interview by phone after 1 year). Data to be collected at all interviews: BMI and weight, history/medication, cardiometabolic risk factors (i.e. (treated) hypertension and type 2 diabetes: hyperlipidemia). Power calculation: at least 175 participants in earch subgroup need to be included, assuming weight loss difference ≥2 kg between both groups clinically significant (15% loss of FU $\alpha<0.05$: $\beta<0.2$).

What are the deliverables of the project? 1) Proof-of-principle of PRESCAN as gateway to prevention **2.** potential predictive value of concomitant cardiometabolic risk factors for weight loss.
What achievements are possible in the next 12 and 24 months? baseline data of all participants acquired at week 46. 1 yr follow up data in all participants at week 98. Final results including multivariate analysis for predictive factors (following van Diepen Nephrol Dial Transplant 2017; 32:ii1–5) at week 104.

Resources & enablers

- **Describe personnel, financial needs.** Personnel: 0.15 FTE for 2 yrs 29842€ (AvD). Medical Ethical Committee 2500€. Castor database: 2500€.
- **Financial needs:** 34842€
- **Specify how the grant will be spent.** Salary, ethical committee, ICT.
- **What factors will make it successful?** The large nr of participants in PRESCAN

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Results/outcomes & expected impact

- **How will the findings be implemented?** Findings will be shared at (inter)national congresses and published in peer-reviewed journals.
- **How will this project advance patient care / contribute to optimal nutritional care?** first step to avail of PRESCAN for prevention of clinical liver and cardiovascular disease in participants with increased risk. Increased public awareness that liver steatosis is not an innocent bystander.
- **What makes the project innovative?** Large nrs of at risk persons (approx. 0.2% of at risk population in the Netherlands annualy) offers key window of opportunity for prevention.
- **Will the project be likely to influence national nutrition policy?** Yes: major new gateway for prevention of significant overt hepatic and cardiovascular disease in at risk participants
- **Is the project transferable to other settings / countries?** Yes. Also in Belgium and USA similar initiatives as PRESCAN.

☐ **Please tick to confirm the PEN letter of endorsement is attached. Incomplete submissions will not be considered.**