

# Study protocol and statistical analysis plan

Act in Time -Implementation of Health Promotive Work-way in Primary Care Setting  
(Acti) ID: 275301

Date: 2025-12-09

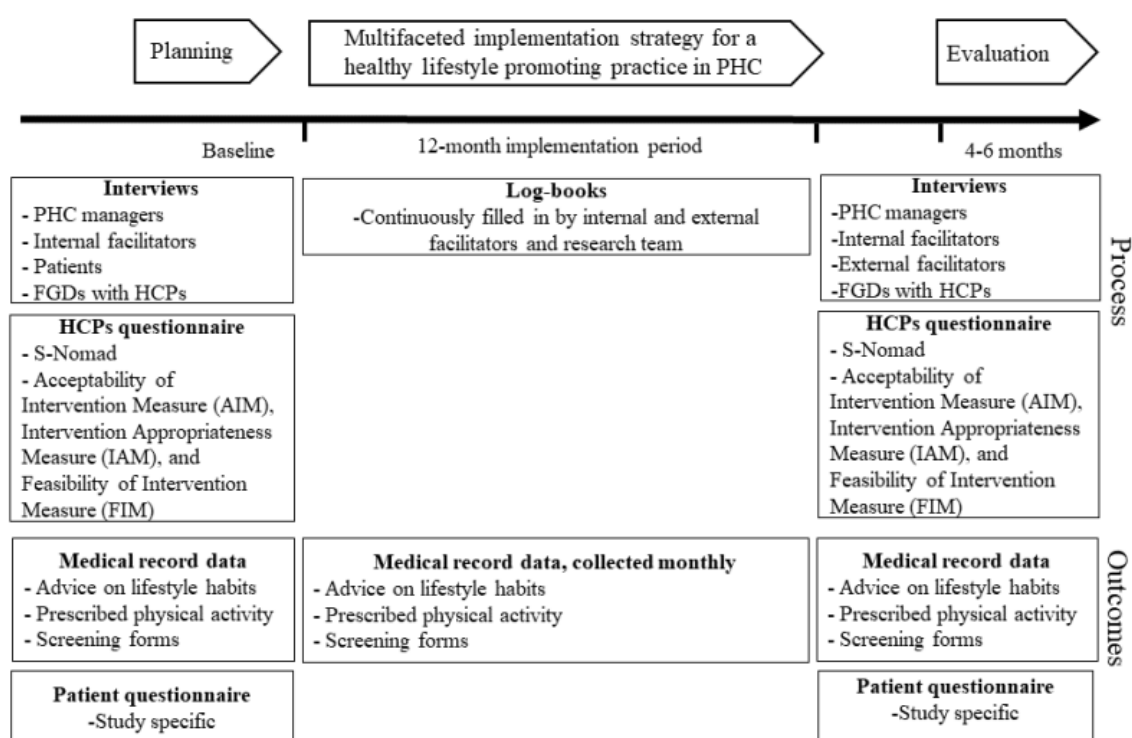
There is growing evidence that noncommunicable diseases (NCDs) can be attributable to unhealthy lifestyle habits. However, there has been little application of this knowledge in primary health care (PHC). This study aims to evaluate the process and outcomes of a multifaceted implementation strategy for a healthy lifestyle-promoting practice in a PHC setting. This practice is based on national guidelines targeting unhealthy lifestyle habits with a potential risk for NCDs.

A pre-post implementation study design with a control group is used in a PHC setting in central Sweden. The implementation process and outcomes will be assessed using a mix of qualitative and quantitative methods. Core components in the implementation strategy are external and internal facilitators in line with the integrated-Promoting Action on Research Implementation in Health Services (i-PARIHS) framework and the Astrakan change leadership model. The implementation strategies will be prioritized and adapted through discussions with the involved stakeholders.

A strategic sample of up to 6 PHC centers will be included as intervention centers, which will receive a 12-month multifaceted implementation strategy. Up to 6 matched PHC centers will serve as controls.

Data will be collected at baseline, during the implementation phase, and up to 18 months after ending of the implementation intervention. Questionnaires will be sent to roughly 500 patients in every PHC center and 200 health care professionals before and after implementation. In addition, purposeful sampling will be used for interviews and focus group discussions with managers at different levels, health care professionals, patient representatives, and internal and external facilitators. Use of data from medical records and activity logs will be an additional data source. For rigorous process evaluations, data will be collected before, during, and after accomplishing the implementation strategy.

An overview of data collection including the timeline, target group, and methodology.



Quantitative data will be analyzed using SPSS Statistics for Windows (version 27.0, IBM Corp). Data from patients' questionnaires and medical records and HCPs' questionnaires will be analyzed using generalized linear mixed models. Fixed effects will include intervention, month, and sex, whereas random effects will include nested patients at PHC intervention centers. Model checking will involve the inspection of residual and autocorrelation plots. To determine statistical significance, a P value of value of 0.05 will be considered. CIs will be adjusted for simultaneous inference where several contrasts are presented.

All qualitative data will be audio-recorded and transcribed verbatim. Qualitative content analysis will be used, both inductively and deductively.