

The Structured Ambulatory Post-Stroke Care Program SANO

Study Design and Results of the Pilot Phase of a Cluster-Randomized Multimodal Post-Stroke Care Interventional Trial

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Background

Previous studies from routine clinical care revealed deficits in cardiovascular risk factor management among ischemic stroke patients and high rates of recurrent cardiovascular events and rehospitalization.

Objectives

The SANO trial investigates whether an evidence-based cross-sectoral post-stroke care program significantly reduces the rate of recurrent stroke, myocardial infarction and death within the first year after ischemic stroke. As secondary endpoints, the rate of stroke complications including depression and falls is assessed.

Methods

Design two-armed parallel cluster-randomized trial in 30 German centers (Fig. 1)

Sample size 2,790

Study period 01.07.2018-01.07.2021

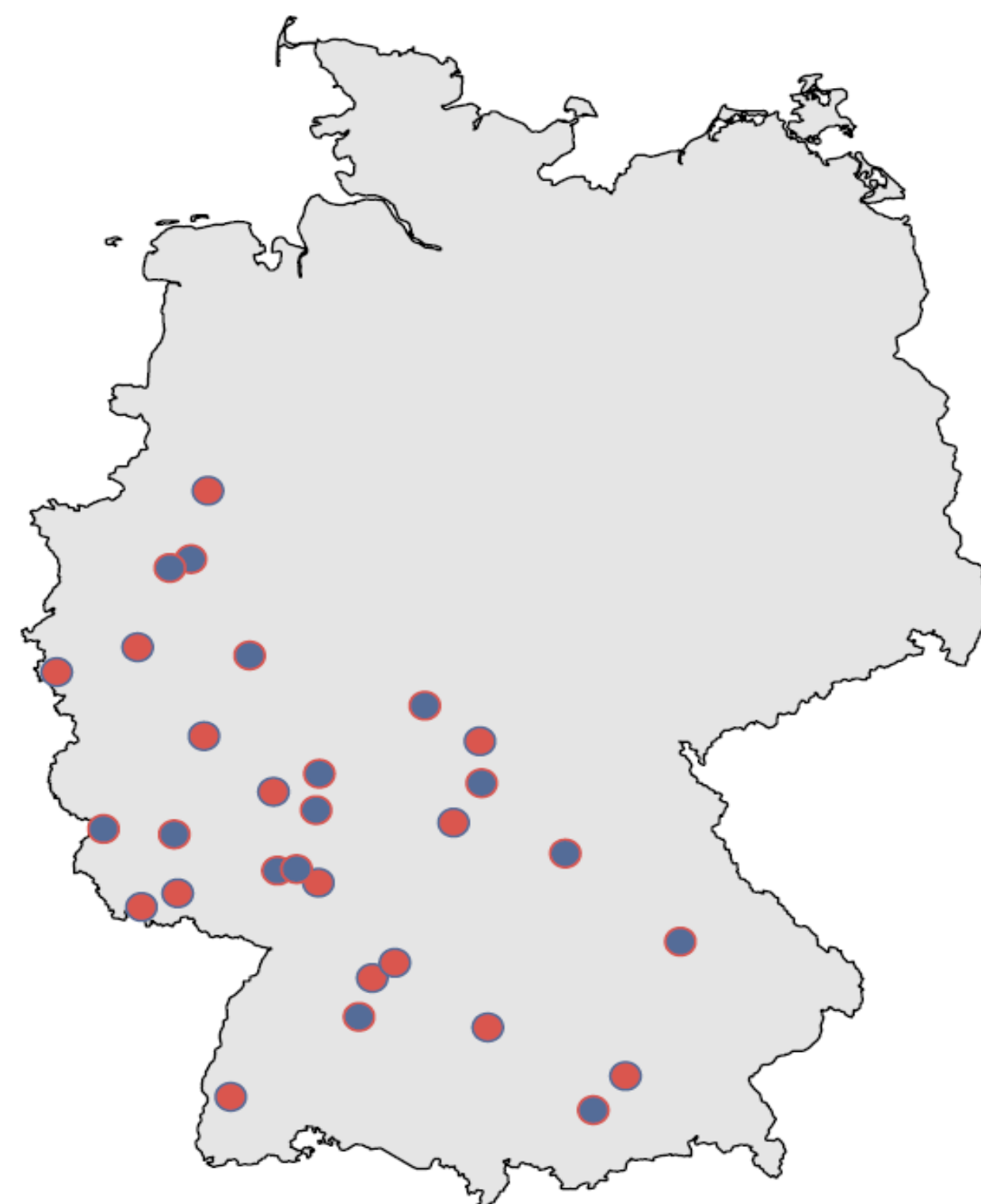


Figure 1: Participating centers in SANO
15 intervention centers (blue) and 15 control centers (red)

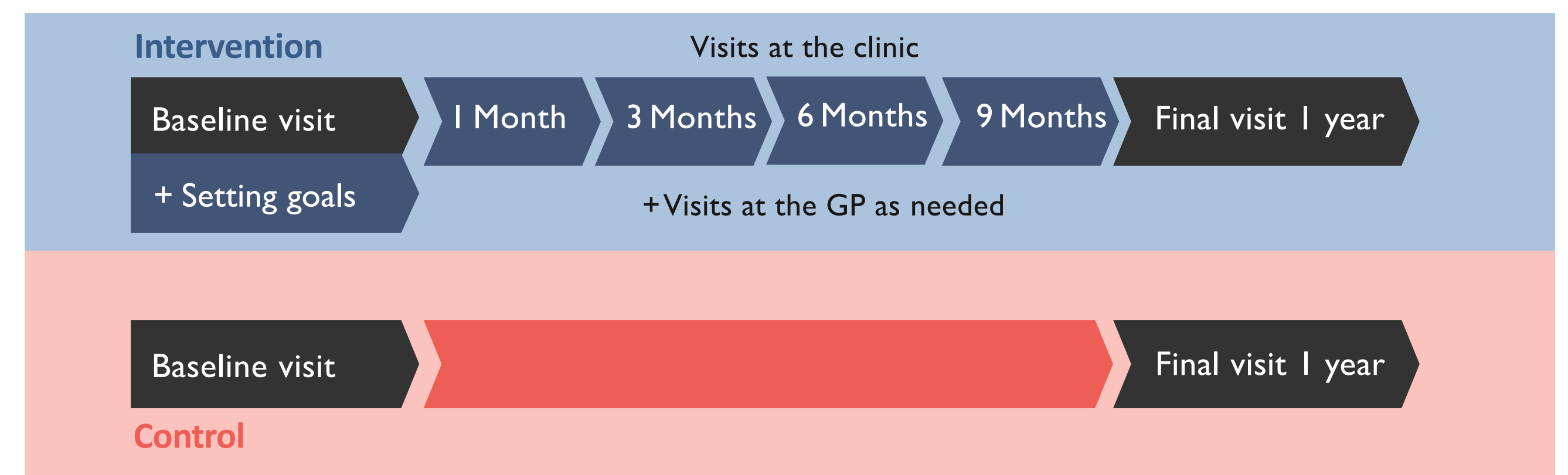


Figure 3: Trial course of control and intervention group

Results 2: pilot phase

Variable	
Total N	18
Women, N (%)	5 (28)
Age, mean (SD)	66 (± 12)
Duration Informed consent, mean (SD) [min]	15 (± 7)
Duration Baseline assessment, mean (SD) [min]	120 (± 48)

- Pilot phase from July to Dec 2018
- Two centers (Würzburg and Ludwigshafen)
- Assessment of
 - recruitment rates
 - conduct and duration of baseline assessment
 - willingness to participate among patients and general practitioners

Results 1: development of the intervention

The standardized intervention follows the recommendations of the Medical Research Council Framework for complex interventions. The intervention consists of various elements:

(1) Patient education

- Information on individual risk factors
- Optimal approaches to adjust risk factors

(2) Clinical staff education

- Training on current high-qualitative secondary prevention guidelines
- Technique of motivational interviewing

(3) Multidisciplinary post-stroke networks

- Establishment of local multidisciplinary networks including general practitioners (GP), specialists, therapists and lifestyle supporting groups (Fig. 2)

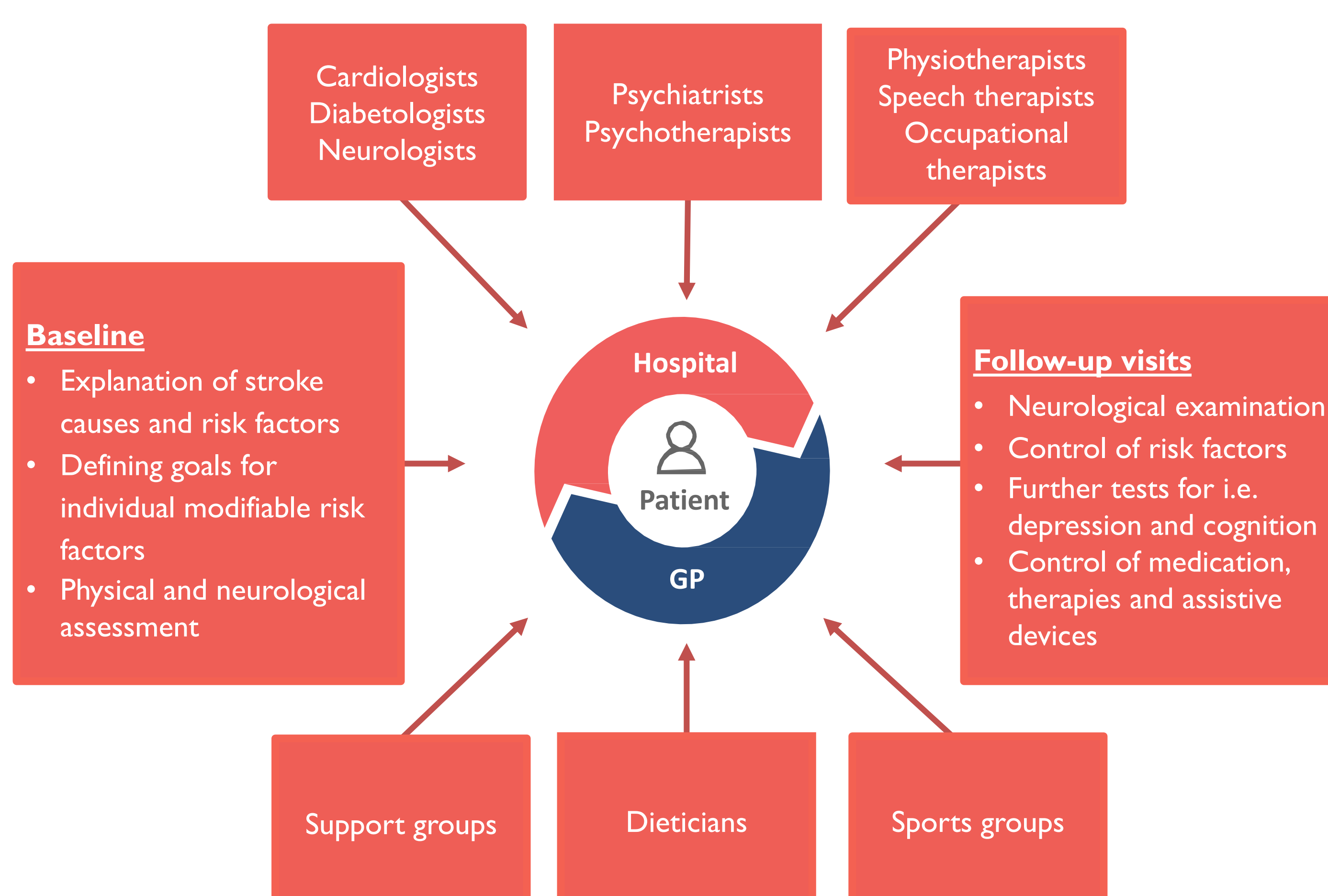
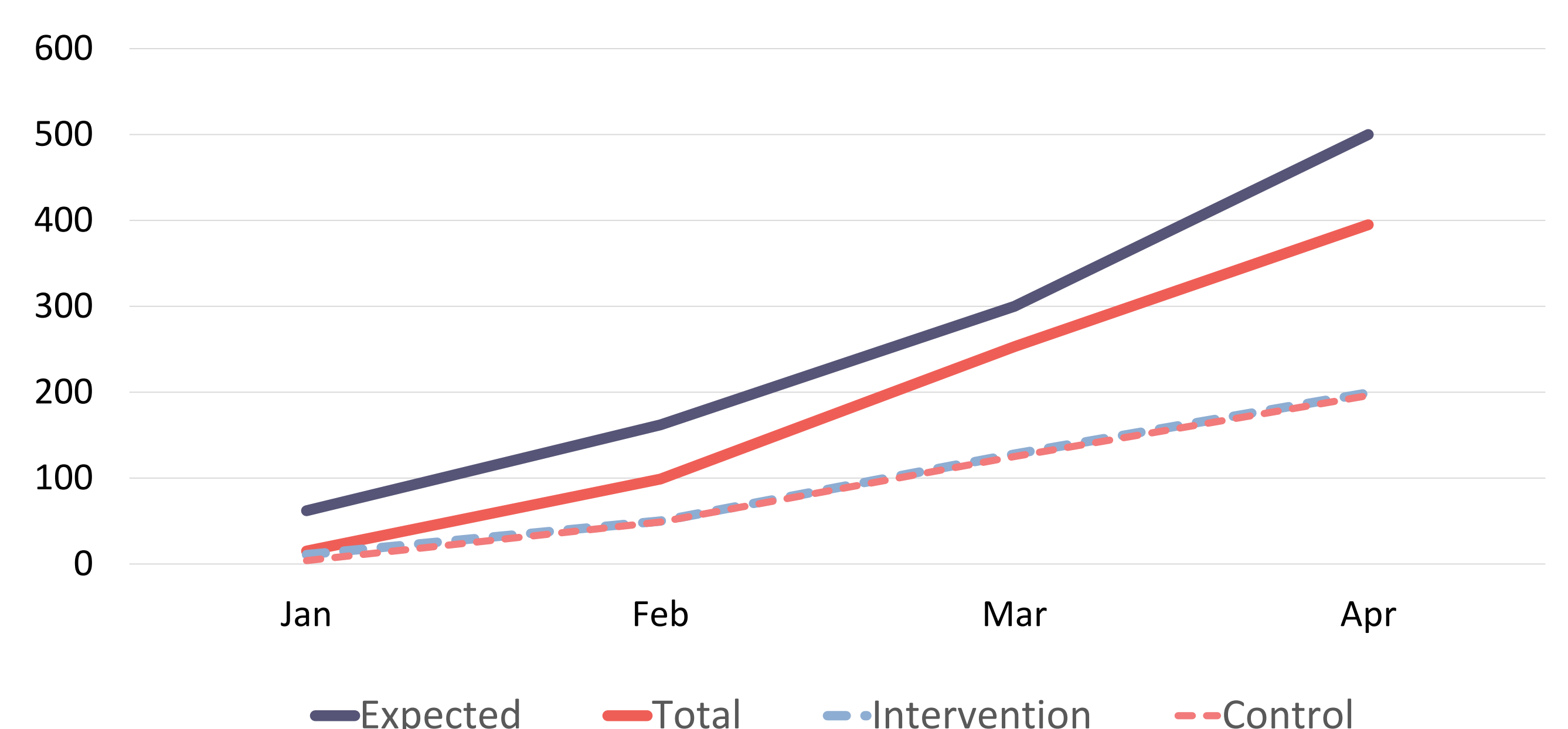


Figure 2: Graphical illustration of the cross-sectoral network supporting recovery and risk factor control of the trial patients

Local composition of the networks can differ and also include other professional groups; regular contact between clinic and GP to coordinate treatment and monitor the patient's progress.

Figure 4: Recruitment status 1st of May 2019



Results 3: trial start

Patient recruitment started as planned on January 1st 2019. Until 1st of May 2019, 395 patients have been enrolled into the study (Fig. 4). All 30 participating centers are currently recruiting.

Conclusion

SANO combines structural and patient-centered elements to adjust individual cardiovascular risk factors and is therefore a promising approach to reduce secondary vascular events and further stroke complications.

Baseline assessment of the intended post-stroke care program was feasible. Enrolment is expected to be finished in January 2020 and primary results of the SANO trial will presumably be reported in mid 2021 (DRKS00015322).

References

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