

Randomized controlled clinical pilot study to evaluate the feasibility and acceptability of a telemedicine approach for HIV prevention with HIV Pre-Exposure Prophylaxis versus standard of care in Germany

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PURPOSE

HIV Pre-Exposure Prophylaxis (PrEP) is an effective prevention measure for individuals at increased risk of HIV acquisition. Uptake remains limited in rural populations due to access barriers and stigma. Pilot studies have shown telemedical PrEP services to be effective and well accepted internationally. This study evaluated the technical feasibility and acceptability of a telemedicine-based PrEP model in Germany.

METHODS

Prospective, single-center, randomized controlled, parallel two-arm study (Figure 1). One hundred participants (≥18 years) were enrolled at the study center and randomized to a telemedicine group (TMG, n=50) or a standard-of-care group (SOC, n=50). Both groups received PrEP care every three months over a total period of 12 months. The TMG followed a fully telemedical approach, including at-home biomaterial self-sampling (swabs/urine and 600 µL capillary blood), app-based result delivery, and virtual counseling, while the SOC attended in-person outpatient visits. Satisfaction, outcomes and PrEP preference were assessed by using standardized questionnaires at baseline and month 12. χ^2 tests were used for group comparisons.

RESULTS

The median age was 41.5 years (IQR 31.3–45.9) in the SOC group and 38.5 years (IQR 33.5–44.3) in the TMG group (Table 1). Study retention at month 12 was 96% in both groups. Visit adherence was high and comparable (SOC: 92.1%, TMG: 94.6%; $p = 0.35$). Blood sampling and STI testing were more consistently completed in the TMG across all follow-up visits (mean blood sampling performed: TMG: 91.6% vs. SOC: 86.0%; mean STI testing performed: TMG: 91.6% vs. SOC: 71.6%) (Table 2, Figure 2).

Acceptance of the telemedical approach was high: among TMG participants, the majority strongly agreed that they felt confident about performing self-sampling and expressed willingness to use it again (median Likert ratings 1–2) (Figure 3). Net Promoter Scores for the study app and telemedical PrEP care were 28.2 and 43.6, respectively, which indicates high satisfaction (Figure 4). At the end of the study, most TMG participants preferred a telemedical or hybrid PrEP care model, while most SOC participants preferred a hybrid model (Figure 5).

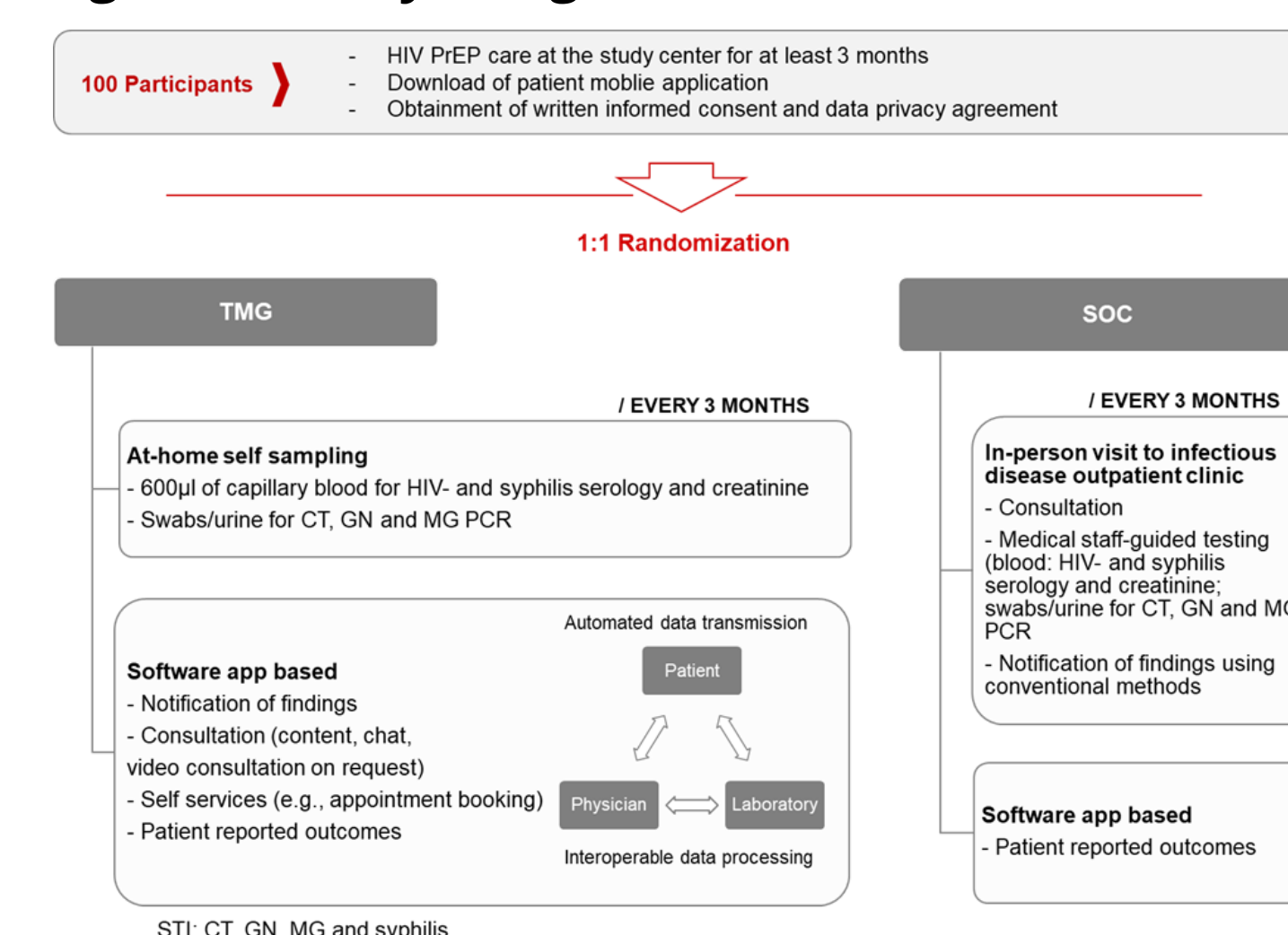
CONCLUSIONS

A telemedicine-based HIV PrEP service is technically feasible, well accepted, and may offer a promising alternative or complement to conventional care.

ACKNOWLEDGEMENTS

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Figure 1: Study design and intervention overview



HIV, human immunodeficiency virus; PrEP, pre-exposure prophylaxis; SOC, standard of care group; TMG, telemedicine group; STI, sexually transmitted infections.

Figure 2: Blood sampling and STI testing adherence over study period

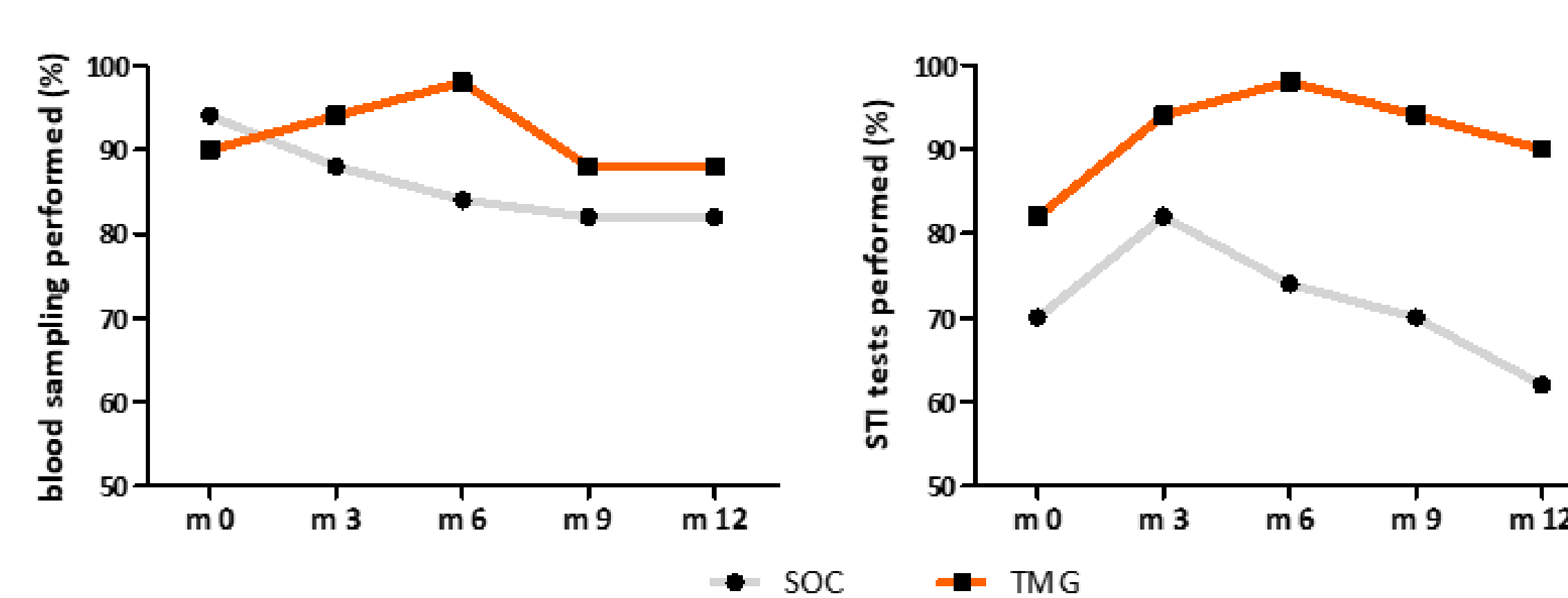


Figure 3: Confidence and willingness to perform at home self-sampling

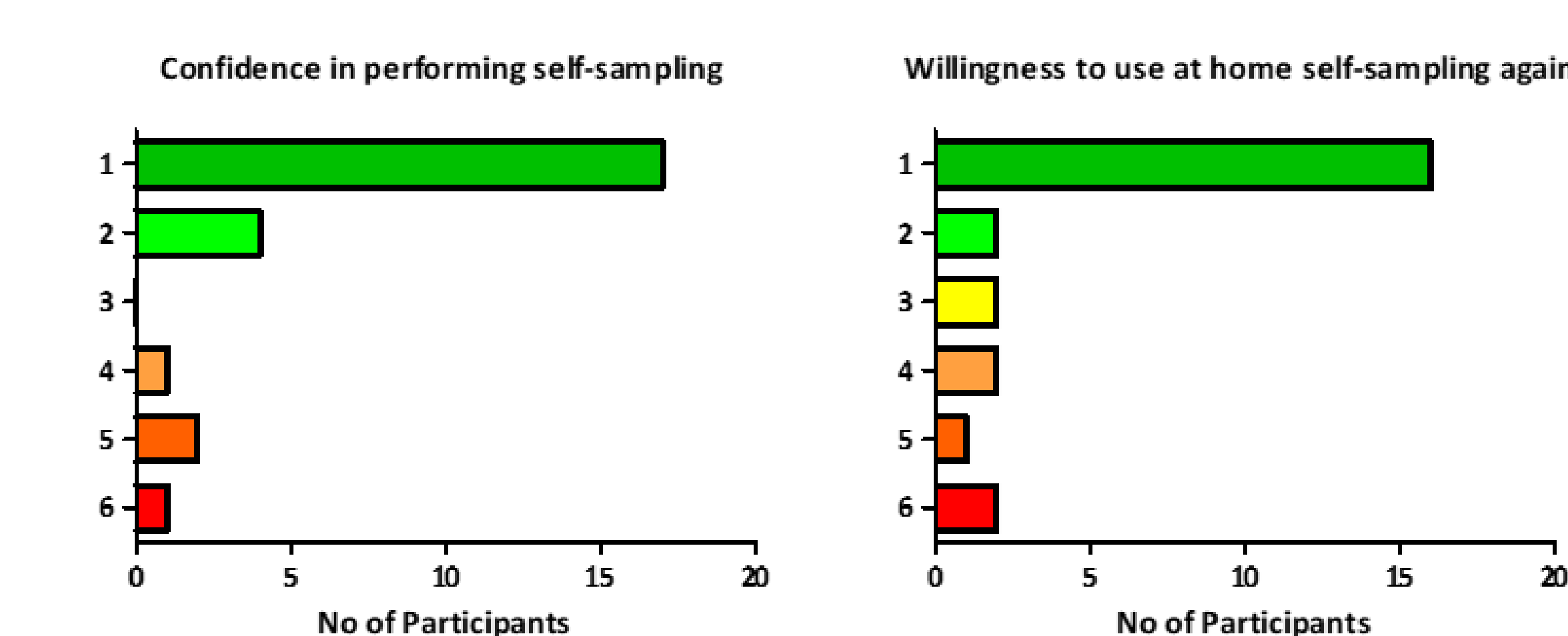


Table 1: Baseline characteristics of participants

Variable	SOC	TMG
Median age (years)	41.5 (IQR: 31.3–45.9)	38.5 (IQR: 33.5–44.3)
Male Gender (n, %)	50 (100%)	50 (100%)
Duration of PrEP use (years)	3 (IQR 1-4)	3 (IQR 1.5-5)
Number of anal sex partners last 3 months (n, %)	4 (IQR 1-7)	4 (IQR 2-8)
≥1 Documented Mpox vaccination (n, %)	32 (67%)	32 (65%)
Stigma regarding PrEP (shortened PrEP Stigma Scale, median, IQR, min. 11, max. 55)	21 (18-27)	24 (19.3-30)

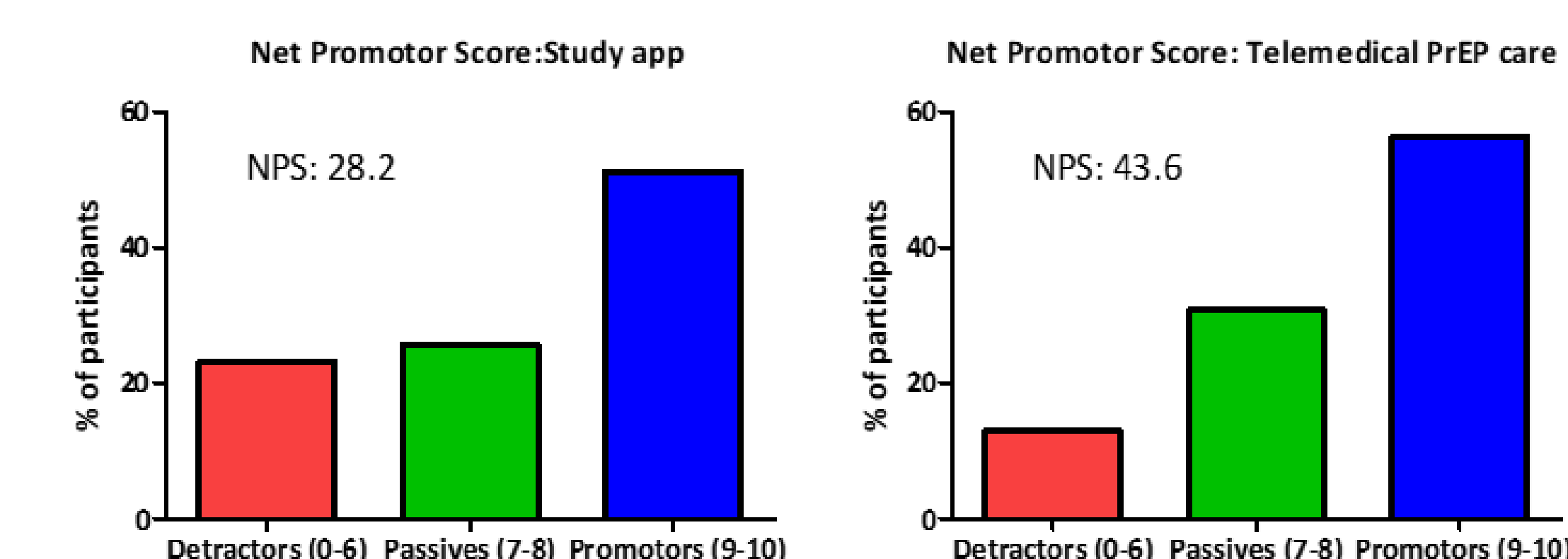
IQR, interquartile range; Mpox, monkeypox; PrEP, pre-exposure prophylaxis; SOC, standard of care group; TMG, telemedicine group.

Table 2: Retention and visit adherence

Variable	SOC	TMG
Retention in care (n, %)	48 (96%)	48 (96%)
Visit adherence m0-m12 (%)	92.1%	94.6%
Blood sampling performed (%)	86.0%	91.6%
STI sampling performed (%)	71.6%	91.6%
Total positive STI tests (n)	41	47

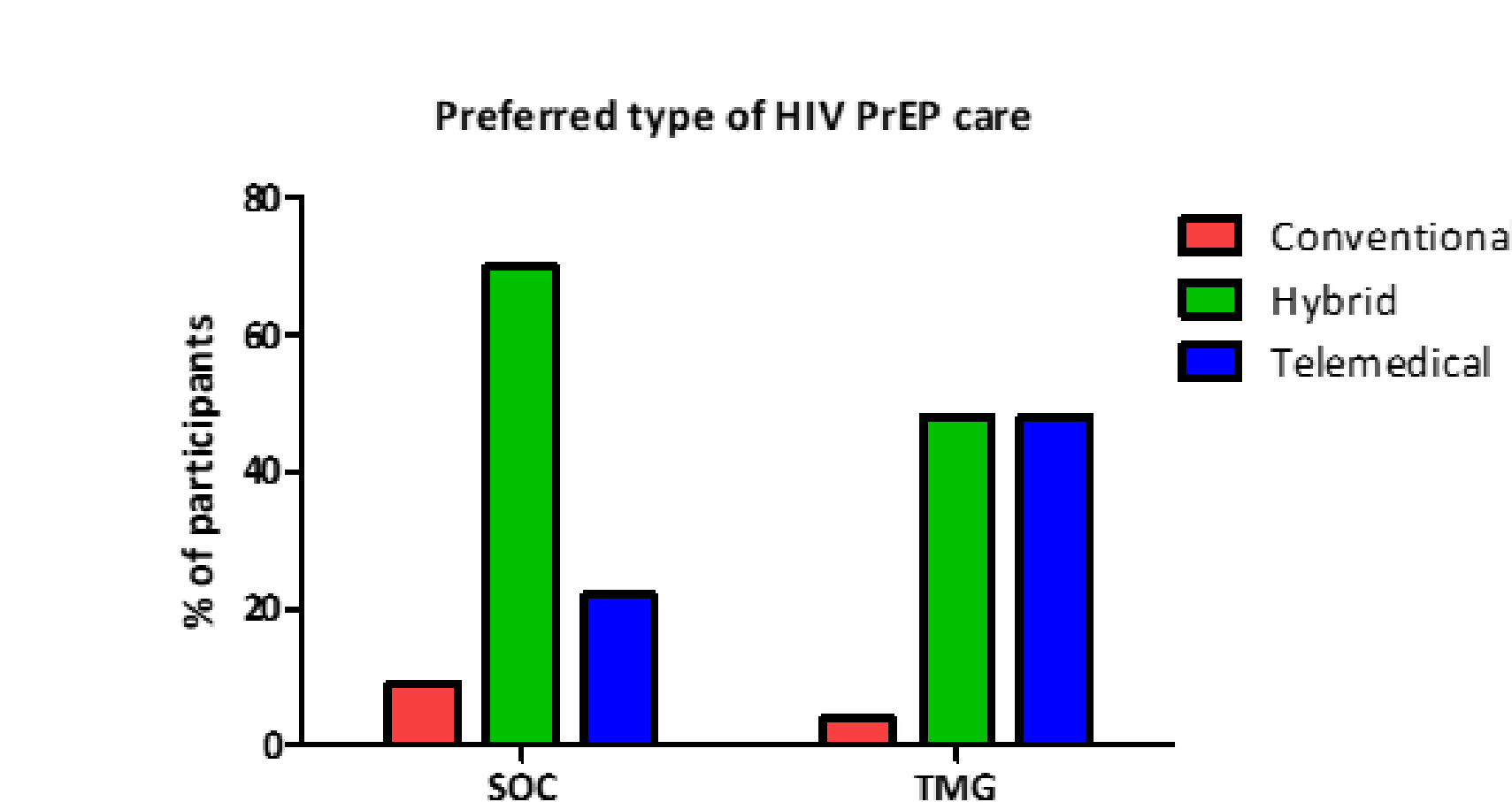
m0, baseline at month 0; m12, end of study at month 12; SOC, standard of care group; STI, sexually transmitted infections; TMG, telemedicine group.

Figure 4: Participant recommendation of app and telemedical PrEP care (Net Promoter Score)



Data from TMG at month 12; NPS = % Promoters – % Detractors; NPS ranges from –100 to +100; scores above 30 are considered strong positive feedback. NPS, Net Promoter Score; PrEP, pre-exposure prophylaxis.

Figure 5: Preferred model of PrEP care at study end



Data from all participants at study end; SOC, standard of care group; TMG, telemedicine group.