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Costs and clinical outcomes of digital health navigators supporting engagement with prescription digital therapeutics in mental health: feasibility study

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Research Article

Keywords:

Posted Date: November 1st, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11221503/v1

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Additional Declarations: No competing interests reported.

Abstract

Background

Despite growing availability of Germany's Digital Health Applications (DiGA), uptake and sustained engagement remain limited. Barriers include low digital literacy, limited clinician familiarity, and challenges integrating digital tools into clinical workflows. Digital Health Navigators (DHNs) have been proposed to address these barriers, yet little is known about the relationship between DHN-related resource use and clinical outcomes. This study examined this association in routine outpatient care.

Methods

This multicenter feasibility study included adult patients from three psychiatric outpatient clinics and three general practices in Brandenburg, Germany. Participants were prescribed one of 29 approved mental health DiGAs and supported by DHNs over three months. Intervention costs were based on the number of DHN contacts, personnel costs, and DiGA reimbursement. Outcomes included changes in symptom severity, psychosocial functioning, and DiGA engagement. Associations between costs and outcomes were examined using age- and baseline-adjusted linear regression models.

Results

42 participants completed the intervention and were included in the analyses (mean age 43.0 years; 59.5% female). Participants received a mean of 12.9 DHN check-ins. Mean costs per patient were €102.6 (SD 70.1) for DHN support and €229.3 (SD 8.0) for the DiGA. Clinical outcomes improved, with mean GAF scores increasing from 56.5 (SD 15.9) to 64.9 (SD 18.2) and mean CGI scores decreasing from 4.0 (SD 1.2) to 3.2 (SD 1.4). Self-reported engagement fell between occasional and regular use, with typical sessions of 15 to 30 minutes. Higher intervention costs were consistently associated with greater improvements in psychosocial functioning (β = 0.08, 95% CI 0.03 to 0.12) and symptom severity (β = −0.01, 95% CI − 0.02 to − 0.003). These associations persisted in sensitivity analyses excluding DiGA costs, indicating a robust relationship between DHN support intensity and clinical improvement.

Conclusions

DHN-supported use of DiGAs is associated with improved clinical outcomes in routine care. The observed cost–outcome relationship may reflect differences in DHN support intensity and highlights the potential role of DHNs in implementation. Further studies should assess cost-effectiveness and integration into health systems.

Trial registration:

German Clinical Trial Register: DRKS00034327; https://drks.de/search/en/trial/DRKS00034327; Date of registration in DRKS: 2024-08-14; ClinicalTrials.gov: NCT06575582; https://clinicaltrials.gov/study/NCT06575582; Registration Date: 2024-09-03; International Registered Report Identifier (IRRID): DERR1-10.2196/67655

Background

Access to timely and adequate mental health care remains a persistent challenge in many health systems [1–3]. Even in high-income countries, increasing demand for treatment has led to substantial waiting times and unmet needs, reflecting a structural gap between service capacity and population needs [4–7]. This treatment gap has significant clinical and societal implications, as delayed or absent care is associated with chronic disease trajectories, increased comorbidity, and higher healthcare utilization [8, 9].

Digital mental health applications, including digital therapeutics (DTx), have been proposed as a scalable approach to mitigate these access barriers. Importantly, high levels of smartphone ownership and general interest in mental health apps have been reported even among individuals with mental health conditions, suggesting that lack of access to devices is not the primary limiting factor [10, 11]. In this context, digital interventions offer the potential to provide low-threshold, timely, and flexible support, particularly as an adjunct or bridge to traditional care.

In Germany, this potential has been operationalized through the introduction of prescription DTx, known as Digitale Gesundheitsanwendungen (DiGA). Since their regulatory implementation in 2019, DiGAs have enabled reimbursable access to evidence-based digital interventions within statutory health insurance. While prescription numbers have increased, real-world uptake and sustained use remain below expectations [12, 13]. This discrepancy has been attributed to multiple barriers [14], including limited knowledge among healthcare professionals [15, 16], challenges in integrating digital tools into clinical workflows, and low patient engagement and adherence [17]. Finally, evidentiary standards within the DiGA framework have continued to evolve, and the robustness of the underlying evidence differs substantially across applications [14, 18]. This variability complicates clinical recommendation and may weaken the endorsement patients receive when a DiGA is prescribed — a factor closely linked to subsequent engagement [13]. Notably, this gap between availability and effective use is not unique to Germany but has also been observed internationally, where digital tools alone have not translated into sustained engagement or improved outcomes [19].

To address these challenges, the role of the Digital Health Navigator (DHN) has emerged as a promising implementation strategy [20, 21]. DHNs are members of healthcare teams who support patients and clinicians in selecting, using, and integrating digital health technologies into routine care. Their core functions include app evaluation and recommendation, technical support and troubleshooting, facilitation of patient engagement, and translation of app-generated data into clinically meaningful information [20]. Early evidence suggests that DHNs can improve digital literacy [22], enhance

engagement [23], and support the integration of digital tools into clinical workflows, thereby addressing key barriers to implementation. However, the role remains heterogeneous and not yet standardized, particularly regarding training, responsibilities, and integration into existing care structures [24, 25]. At the same time, DHNs represent a broader class of solution strategies aimed at addressing competence and knowledge gaps in digital health implementation. A central challenge for their large-scale adoption lies in the constrained human resources of healthcare systems. It remains unclear which professional groups can sustainably and efficiently assume this role without exacerbating existing workforce shortages [20, 26]. Questions regarding task allocation, training requirements [27], and economic feasibility are therefore critical for real-world implementation.

Despite growing interest in DHNs, a key research gap persists. Existing studies have primarily focused on feasibility [28], role definition [20], and preliminary clinical effects [23], whereas the resources required to deliver DHN support have rarely been quantified. A recent scoping review of 78 digital navigator studies found that the availability of staff and funding was among the most frequently discussed determinants of implementation success, yet roughly three quarters of the included studies reported neither whether navigators were compensated nor how their positions were financed, and only one study reported cost as an implementation outcome [29]. Cost may therefore represent the decisive constraint on scaling the role while remaining the dimension on which evidence is most scarce — evidence that is essential to assess the scalability and long-term sustainability of DHN-supported care models.

The present study therefore aimed to examine the relationship between the costs and clinical outcomes of DHN-supported DiGA use. By linking resource utilization to patient-relevant outcomes, this study seeks to provide an empirical basis for evaluating the efficiency and scalability of DHN interventions in routine mental health care.

Methods

Study design

This study is part of the DigiNavi trial (July 2024 to October 2025; “Digital Navigators for Acceptance and Competence Development with Mental Health Apps”), a single-arm, multicenter, observational study conducted to evaluate the feasibility of DHNs supporting the use of DiGAs for mental health conditions in German outpatient care [28, 30].

While the primary outcomes of the DigiNavi trial, including digital health literacy, digital and technical literacy, and readiness to change, are reported elsewhere [23], the present analysis focuses on the economic dimension of the intervention, examining intervention-related costs in relation to clinical outcomes and user engagement.

The study was approved by the Ethics Committee of the Brandenburg Medical School (MHB; reference number: 218062024-BO-E) and registered in the German Clinical Trials Registry (DRKS00034327) and on ClinicalTrials.gov (NCT06575582).

Setting

The study was conducted at six sites in the federal state of Brandenburg, Germany, comprising three general practice clinics and three psychiatric outpatient clinics. These settings were deliberately selected, as both represent key entry points into the health care system where patients with unmet mental health needs frequently present. The study sites were located in the Brandenburg districts of Märkisch-Oderland, Oder-Spree, Barnim, Brandenburg an der Havel, and Dahme-Spreewald.

Intervention: digital health navigator

At each study site, a medical assistant was trained as a DHN. The training covered knowledge of DiGAs for mental health conditions, disorder-specific clinical basics, and principles of motivational interviewing. It was based on the Harvard Digital Navigator Training (HDNT) and further developed and adapted to the German health care context within the scope of this study [31].

During the interventional study phase (December 2024 to April 2025), patients were consecutively enrolled and received a three-month intervention. Based on the respective indication, one of the 29 DiGAs for mental health conditions available at the time was selected. Where several DiGAs covered the same indication, the choice was made individually in a joint discussion between patient and DHN, considering technical accessibility, whether the application offered in-app guidance or standalone self-help, and its integration into ongoing treatment; final prescription remained with the treating physician. DHNs subsequently supported patients and physicians in configuring and using the DiGA and in integrating it into routine care. Patient support was primarily delivered through regular check-ins, conducted either in person or by telephone, focusing on organizational, technical, motivational, and application-related aspects.

The primary aim of these check-ins was to ensure smooth initiation and sustained use of the DiGA following activation, while addressing potential barriers such as low motivation or technical difficulties. In addition, DHNs monitored patients' engagement and informed treating physicians in cases of clinical deterioration or emerging safety concerns.

Eligibility criteria for patients

All patients provided written informed consent prior to participation in any study procedures. Eligible participants were adults with a mental health condition requiring treatment, including ICD-10 diagnoses F1, F3–F6 (substance use, affective, neurotic, behavioral, and personality disorders) as well as F06.7 (mild cognitive disorder), and access to a digital device. Exclusion criteria included ongoing psychotherapeutic treatment or recent changes in psychopharmacological medication. A detailed description of all inclusion and exclusion criteria is provided in the study protocol [28].

Assessment of costs

The present analysis focused on direct intervention-related costs related to DHN support and DiGA use. These consisted of two components.

Personnel costs for DHNs were estimated based on the recorded number of contacts per patient. Because check-in durations were not recorded reliably, a standardized duration of 10 minutes per check-in was assumed for cost estimation, corresponding to the mean of the available duration estimates, and applied uniformly across all contacts. Costs were calculated using an employer gross hourly wage of approximately €48 for medical assistants, based on pay grade E 6, step 5 of the German public sector collective agreement (TVöD-K/VKA), including employer social insurance contributions, levies and occupational pension, divided by annual productive working hours [32].

In addition, the costs of the prescribed DiGAs were included. The exact prices of the DiGAs used during the intervention were retrieved from the directory of the German Federal Institute for Drugs and Medical Devices (BfArM; https://diga.bfarm.de/) on April 7, 2026 (Table 2). Total costs per patient were calculated as the sum of personnel costs and DiGA costs. Both components were additionally analyzed separately in a sensitivity analysis (see Statistical analysis), as DHN support is not tied to DiGAs and may also be deployed alongside less costly digital interventions.

Outcomes

User engagement with DiGAs was assessed as a composite measure combining self-reported frequency and intensity of use. Frequency was rated on a 5-point scale ranging from 0 (never) to 4 (very regularly/continuously), and intensity on a 5-point scale reflecting typical session duration (1 = < 15 minutes, 2 = 15–30 minutes, 3 = 30–45 minutes, 4 = 45–60 minutes, 5 = > 60 minutes).

Clinical outcomes were defined as changes from baseline to three-month follow-up and represent secondary outcomes of the study. These included clinician-rated measures capturing complementary dimensions of mental health: global clinical severity assessed with the Clinical Global Impression (CGI) scale [33] (range 1–7, with higher scores indicating greater severity; a score of 4 corresponds to moderately ill and 3 to mildly ill) and psychosocial functioning assessed with the Global Assessment of Functioning (GAF) scale [34] (range 0–100, with higher scores indicating better functioning; scores of 51–60 denote moderate symptoms or moderate difficulties in social or occupational functioning, and 61–70 mild symptoms with some difficulty but generally adequate functioning). Change scores were calculated as the difference between follow-up and baseline values, with reductions in CGI and increases in GAF indicating clinical improvement.

Statistical analysis

Descriptive statistics were used to summarize sample characteristics, intervention exposure, and cost distributions. Continuous variables are reported as means and standard deviations. To examine the association between intervention costs and clinical outcomes, linear regression models were fitted with

change scores in CGI and GAF from baseline to three-month follow-up as dependent variables. Total intervention costs per patient were entered as the main independent variable.

All models were adjusted for age and baseline values of the respective outcome measure. Regression coefficients therefore represent the expected change in outcome associated with increasing intervention costs, conditional on baseline severity and age. Inference was based on heteroskedasticity-consistent robust standard errors. Model-based predictions were derived to illustrate the relationship between costs and changes in clinical outcomes across the observed cost range. To assess the robustness of the findings, a sensitivity analysis was conducted using an alternative cost specification including only personnel costs, excluding DiGA costs. Effect estimates and confidence intervals were compared with the main analysis. All analyses were performed using standard statistical software, and statistical significance was defined as a two-sided α level of 0.05.

Results

A total of 53 participants were enrolled and completed the baseline assessment. Of these, 42 participants completed the intervention and the follow-up assessment and were included in the analyses. Most participants were diagnosed with mood disorders (ICD-10 F3; 42.9%) or neurotic, stress-related and somatoform disorders (ICD-10 F4; 35.7%), the latter comprising anxiety, stress-related and somatoform presentations. Mean self-reported engagement was 2.6 on the frequency scale (range 0–4, where 2 corresponds to occasional and 3 to regular use) and 2.3 on the intensity scale (range 1–5), indicating that most participants used their DiGA between occasionally and regularly, with typical sessions lasting approximately 15 to 30 minutes. At baseline, participants showed moderate symptom severity and moderate impairment in psychosocial functioning (CGI 4.0, GAF 56.5), consistent with a clinically relevant outpatient population rather than a subclinical or preventive sample. Clinical measures indicated an improvement over the course of the intervention, reflected by increased psychosocial functioning and reduced clinical severity from baseline to follow-up (Table 1). The mean improvement of 8.5 points on the GAF exceeded the minimal important difference for this instrument, whereas the mean CGI improvement of 0.8 points remained below the proposed threshold. Mean costs per patient were €102.6 (SD 70.1) for DHN support and €229.3 (SD 8.0) for the prescribed DiGA (Fig. 1). While DiGA costs varied little across applications, DHN costs varied considerably between patients, reflecting differences in the number of check-ins.

Table 1
Sociodemographic and Clinical Characteristics of the Sample (N = 42)

Parameter	***Value***
Age in years (M, SD)	43.02 (14.77)
Female (n, %)	25 (59.5)
ICD-10 Diagnosis (n, %)	
F3: Mood Disorders	18 (42.9)
F4: Neurotic, Stress-Related and Somatoform Disorders	15 (35.7)
Other	9 (21.4)
GAF at admission (M, SD)	56.48 (15.92)
GAF at discharge (M, SD)	64.93 (18.15)
CGI at admission (M, SD)	4.02 (1.20)
CGI at discharge (M, SD)	3.22 (1.42)
Check-Ins per Patient (M, SD)	12.86 (8.75)

CGI: Clinical Global Impression; GAF: Global Assessment of Functioning; ICD-10: International Classification of Diseases, 10th Revision; M: Mean; SD: Standard deviation

A range of DiGAs targeting mood, anxiety, and related disorders was prescribed during the study period. Applications addressing depressive and stress-related conditions were used most frequently, while others targeted anxiety, sleep disturbances, and somatic symptom-related disorders. The distribution of prescriptions and associated costs varied across applications (Table 2).

Table 2
Overview of Prescribed Digital Health Applications (DiGAs), Indications, Prices, and Frequencies

Name of the DiGA	***ICD-Approved Diagnoses***	***Price in €[x]***	***n***
deprexis	F32.0, F32.1, F32.2, F33.0, F33.1, F33.2	228.00	10
HelloBetter Stress and Burnout	Z73	235.00	6
Selfapys Online-Course for depression	F32.0, F32.1, F33.0, F33.1	217.18	6
Selfapys Online-Course for generalized anxiety disorder	F41.1	228.50	4
Somnio	F51.0, G47.0	224.99	4
HelloBetter Panic	F40.01, F41.0	230.00	3
NeuroNation MED	F06.7	229.00	3
Mindable: Panic & Agoraphobia	F40.0, F41.0	245.50	2
velibra	F40.01, F40.1, F41.0, F41.1	230.00	2
HelloBetter Chronic Pain	F45.40, F45.41, M79.7	235.00	1
My Tinnitus App - Digital Tinnitus Counseling	H93.1	260.00	1

x: Data retrieved on April 7, 2026 from the website of the federal institute for drugs and medical devices; DiGA: Digital Health Application; ICD: International Classification of Diseases

Model-based predictions indicated a broadly linear trend between intervention costs and changes in clinical outcomes across the observed cost range. Higher costs were associated with greater improvements, as reflected by decreases in clinical severity (CGI) and increases in psychosocial functioning (GAF). This pattern was consistent across outcomes and remained stable after adjustment for age and baseline values (Fig. 3).

To assess the robustness of these findings, a sensitivity analysis was conducted using an alternative cost variable excluding DiGA costs. The overall effect structure remained largely unchanged. Higher costs continued to be associated with improvements in both outcomes (GAF and CGI), and both the magnitude of the effects and the confidence intervals were comparable to the main analysis, indicating consistent results across cost specifications (Fig. 2).

CGI: Clinical Global Impression; GAF: Global Assessment of Functioning

Discussion

In this feasibility study, higher intervention costs, which reflected differences in DHN support intensity rather than DiGA prices, were consistently associated with greater improvements in clinical severity and

psychosocial functioning. These findings suggest that more intensive DHN-supported DiGA implementation may be associated with measurable clinical improvements. Importantly, the observed associations remained stable after adjustment for age and baseline severity and persisted in sensitivity analyses excluding DiGA costs, supporting the robustness of the findings.

The reported association between intervention costs and clinical improvements may be compatible with a dose–response–like relationship, whereby greater DHN involvement may contribute to increased clinical benefit. Notably, these effects emerged at relatively low additional costs, primarily driven by a modest DHN time investment of about two hours per patient over three months and fixed DiGA prices. From an implementation perspective, this pattern suggests that even modest investments in structured support may enhance the real-world use and potential effectiveness of digital interventions.

These findings align with international evidence showing that guided digital interventions achieve higher adherence and better clinical outcomes compared to unguided approaches [35]. The present study extends this literature by suggesting that implementation support may not only improve outcomes but may represent a potentially resource-conscious implementation strategy.

The clinical relevance of the findings should be interpreted cautiously. Improvements in CGI and GAF, while statistically significant, were of moderate magnitude (approximately 0.8 points on the CGI and 8.5 points on the GAF). The CGI improvement was slightly below a proposed 1-point minimal clinically important difference derived from treatment-resistant depression samples [36], but may still reflect clinically meaningful change in the context of a low-intensity adjunctive intervention. In contrast, the observed GAF improvement clearly exceeds the 4-point minimal important difference reported for psychological therapies, albeit derived from a different clinical population [37]. The magnitude of change further aligns with studies on low-intensity psychological interventions, including internet-based CBT and guided self-help approaches, which have reported moderate improvements in symptoms and functioning [38–40]. At the same time, the observed effects remain smaller than the large within-group effects described for more intensive short-term outpatient psychotherapy [41].

Finally, the approximately linear cost–outcome relationship identified in the regression models should be interpreted with caution. While consistent with a dose–response pattern, it remains unclear whether this relationship persists at higher levels of resource use or whether a threshold or saturation effect emerges beyond which additional investment yields diminishing returns.

From a health system perspective, the cost level of DHN-supported digital interventions appears notably low when compared to established treatment options. In the present study, DHN support amounted to approximately €100 per patient over three months, complemented by DiGA costs of around €230 per quarter. Although not directly comparable, the direct intervention costs observed in this study were lower than those typically associated with short-term outpatient psychotherapy, exceeding €1,062 in Germany and often being considerably higher in the US over a comparable period [42, 43]. This suggests that the combination of DiGA and DHN support may represent a comparatively resource-conscious complement to conventional care, particularly in settings characterized by limited psychotherapy capacity and long

waiting times. At the same time, face-to-face cognitive behavioral therapy has demonstrated durable long-term effects and comparatively low relapse rates, whereas comparable long-term outcome data for DiGAs remain largely lacking [18, 44]. DHN support may, however, help consolidate what patients learn through the application, which could plausibly contribute to more durable effects — a hypothesis that warrants long-term follow-up.

At the same time, the scalability of this model depends critically on workforce considerations. Medical assistants, who assumed the DHN role in this study, offer several practical advantages in routine care, including established relationships with patients, familiarity with care processes, and involvement in appointment coordination. These factors may facilitate integration of digital interventions into existing workflows. Qualitative findings further highlight the importance of a trusted and familiar person serving as the DHN [27]. Beyond ongoing support, DHNs also contributed to the initial matching of patients to applications, taking into account technical accessibility, the degree of in-app support, and integration into ongoing treatment — a task that requires familiarity with the available applications and is not captured by contact frequency alone. In contrast, some DiGAs provide built-in remote guidance by previously unknown health care professionals (HCP), raising the question of whether familiarity and continuity within the DHN relationship contribute to the effectiveness of guidance interventions. Evidence further suggests that non-clinician–delivered interventions are not less effective than clinician-led approaches (Hedges g = 0.08; 95% CI − 0.01 to 0.17), supporting the use of medical assistants in such roles [26]. In addition, DHN training required only a few hours and could be implemented alongside routine duties, supporting feasibility in real-world settings.

However, medical assistants themselves represent a constrained workforce in many health care systems [45], including Germany, and the availability of personnel may vary across settings. Alternative models, such as the use of more highly qualified staff (e.g., psychologists), as proposed in other implementations [20], may offer advantages in terms of clinical expertise but could likely increase costs substantially. This raises questions about whether the comparatively low direct intervention costs of DHN-supported DiGA use can be maintained under different staffing models while highlighting the need to balance scalability, qualification level, and economic efficiency in future implementations [26].

Implications for research, policy, and practice

From a research perspective, future randomized controlled trials with more comprehensive economic evaluations are needed to validate the findings and examine long-term economic effects. Integrating patient-reported outcomes and a broader cost perspective, including indirect costs, would further strengthen the economic evidence base. A promising avenue for future investigation concerns the potential role of AI-based DHNs, which could further reduce personnel costs and increase scalability [24, 46]. At the policy level, the results support the case for formally recognizing and reimbursing the DHN role within the statutory health insurance system, as the current absence of a dedicated billing code may represent a barrier to broader implementation. The use of medical assistants as DHNs - a professional group already embedded in outpatient care - offers a scalable and resource-efficient pathway that does

not require additional specialist capacity. For clinical practice, the findings suggest that even modest investment in DHN support may yield clinically relevant improvements. Integrating this role into existing outpatient workflows, particularly in settings where patients face prolonged waiting times for psychotherapy, may represent a feasible and potentially impactful strategy to enhance the real-world value of prescription DTx.

Strengths and Limitations

To our knowledge, this study is the first to examine the relationship between costs and clinical outcomes of DHN support for mental health apps in routine care, providing an initial basis for evaluating the economic relevance of this emerging role.

Several limitations should be considered. The observational design precludes causal inference, and residual confounding cannot be excluded despite adjustment for baseline values and age. Patients receiving more intensive DHN support may also have differed in motivation, engagement, or clinical complexity in ways not fully captured by baseline adjustment. Personnel costs were based on a standardized contact duration, as individual durations were not reliably recorded. Because intervention costs were closely linked to the frequency of DHN contacts, the observed associations likely reflect a broader combination of support intensity, patient engagement, and implementation success rather than economic effects alone. Moreover, DHN time invested in the initial selection of an appropriate application was not separately recorded, meaning that total DHN resource use may be underestimated. It is also possible that patients who engaged more successfully with the intervention received more frequent DHN contact over time, resulting in bidirectional associations between support intensity and outcomes. In addition, the three-month follow-up limits conclusions regarding long-term sustainability. Generalizability may be limited by the single-state setting, although the inclusion of multiple outpatient sites supports ecological validity. Outcomes were based on clinician-rated measures, and the economic evaluation was restricted to direct costs, excluding indirect costs and potential savings through reduced health care utilization.

Overall, the findings should be interpreted cautiously but provide an important first step toward evaluating the scalability of DHN-supported care.

Conclusions

DHN-supported use of DiGAs was associated with improved clinical outcomes in routine outpatient mental health care. The findings suggest that even modest investments in structured implementation support may enhance the real-world effectiveness of digital interventions while maintaining comparatively low direct intervention costs. DHNs, particularly when integrated into existing outpatient workflows, may represent a promising and potentially scalable strategy to support engagement with prescription digital therapeutics more broadly.

Abbreviations

DHN
Digital health navigator
DTx
Digital therapeutics
DiGA
Digitale Gesundheitsanwendungen
BfArM
German Federal Institute for Drugs and Medical Devices
CGI
Clinical Global Impression
GAF
Global Assessment of Functioning
HCP
health care professional
HDNT
Harvard Digital Navigator Training
ICD-10
International Classification of Diseases and Related Health Problems, 10th Revision

Declarations

Ethics approval and consent to participate

The study was approved by the ethics committee of the Brandenburg Medical School (reference number: 218062024-BO-E) and conducted in accordance with the Declaration of Helsinki. In addition, it was registered with the German Clinical Trials Register (DRKS00034327) and on ClinicalTrials.gov (NCT06575582).

Consent for publication

All participants were informed about the content and benefits of this study and the data collected from them. The prerequisite for the study was the signing of a detailed declaration of consent.

Competing interests

The authors declare no competing interests.

Funding

Open Access funding enabled and organized by Projekt DEAL.

Author Contribution

JT, JS, and JW designed the study and secured funding. Data was collected by the DigiNavi study team. JW analyzed the data. JS drafted the manuscript. All authors (JW, JT, MG, JH, AK, LH, JS and FM) critically revised successive drafts and approved the final version. All authors agree to be accountable for their contributions and to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated, resolved, and documented.

Acknowledgement

This study was funded by the German Federal Ministry of Health (BMG) as a pilot project for the implementation and consolidation of digital health approaches in health care, rehabilitation, and nursing (funding reference: 2524FEP10A). This funding source played no role in the design of the study, its execution, analysis, interpretation of the data, or decision to submit results. The open access publication of this study was funded by the Brandenburg Medical School Theodor Fontane publication fund supported by the Ministry of Science, Research, and Culture of the State of Brandenburg. JH is funded by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) - Project number 558130994.

Data Availability

The datasets generated and/or analyzed during this study are not publicly available but are available from the corresponding author upon reasonable request. Information on DiGA pricing is publicly available via the German Federal Institute for Drugs and Medical Devices directory (https://diga.bfarm.de/de/verzeichnis).

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Figures

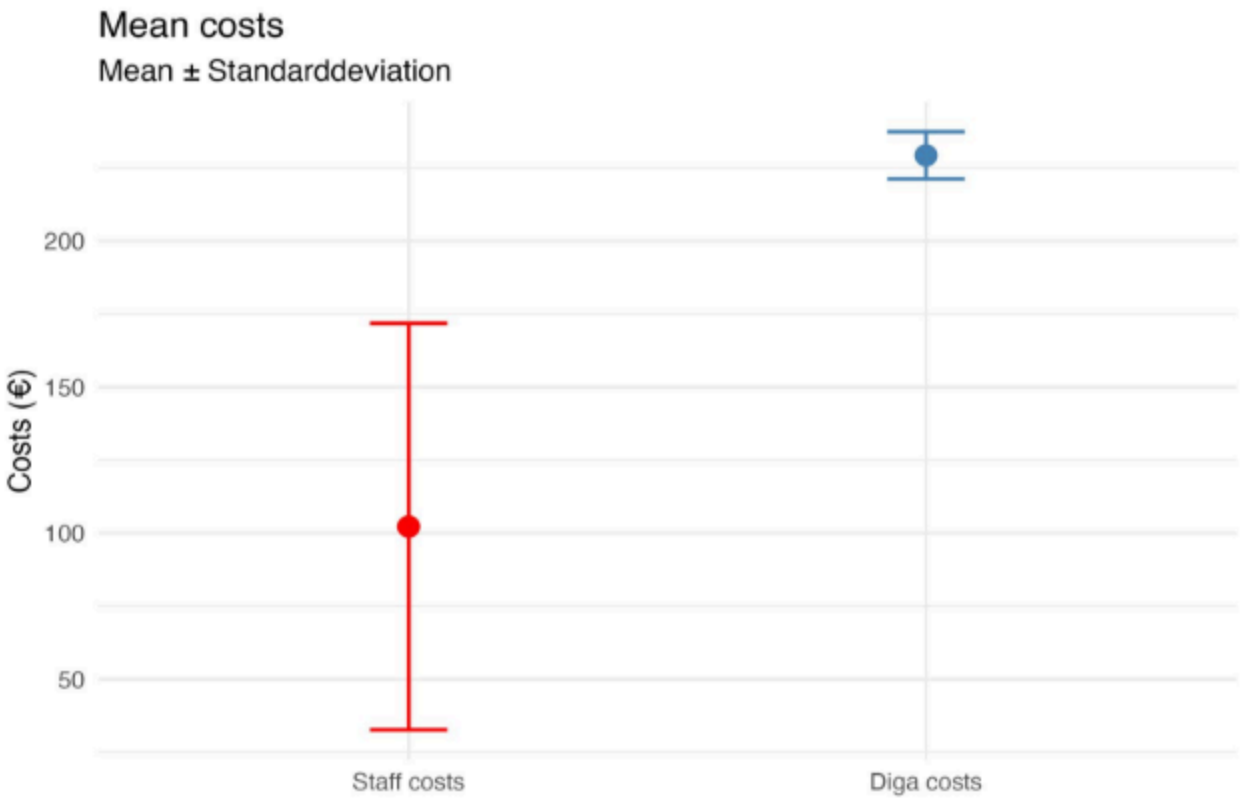
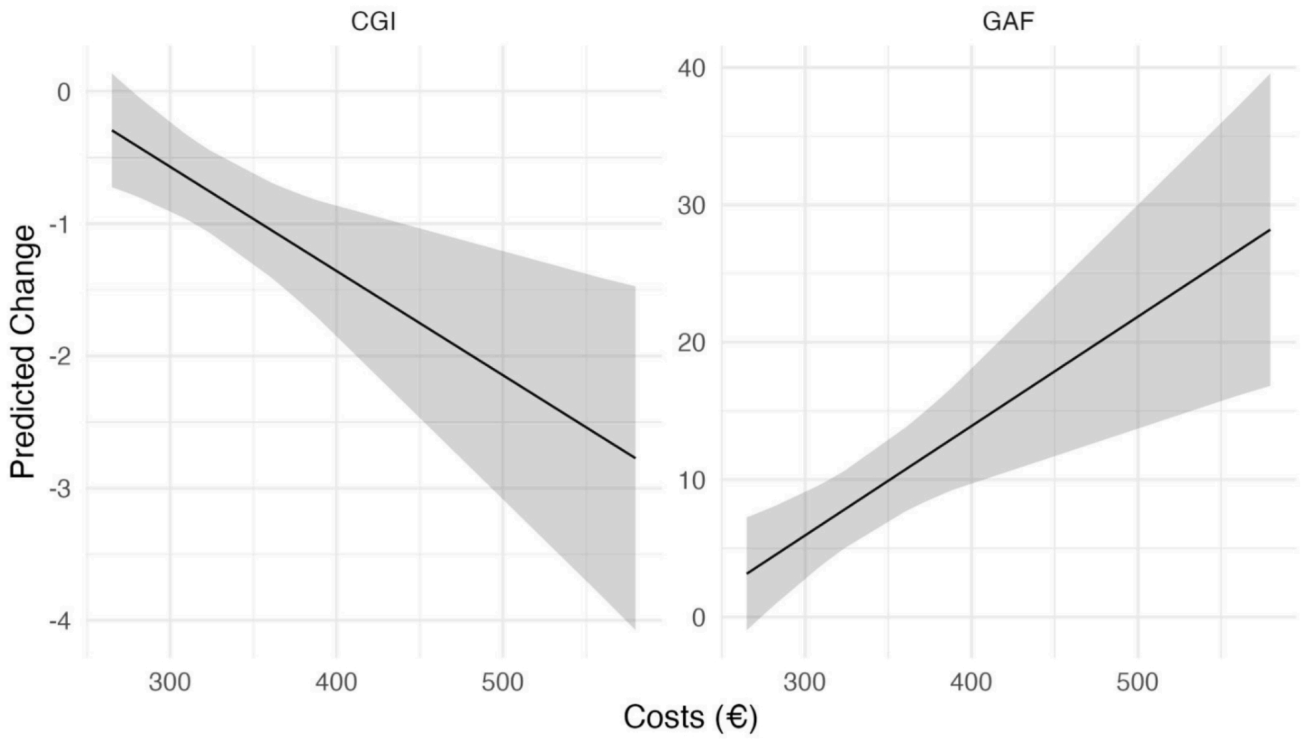


Figure 1

Mean intervention costs per patient for DHN support (staff costs) and DiGA. Error bars indicate ± 1 standard deviation



CGI: Clinical Global Impression; GAF: Global Assessment of Functioning

Figure 2

Association between intervention costs and predicted changes in clinical outcomes

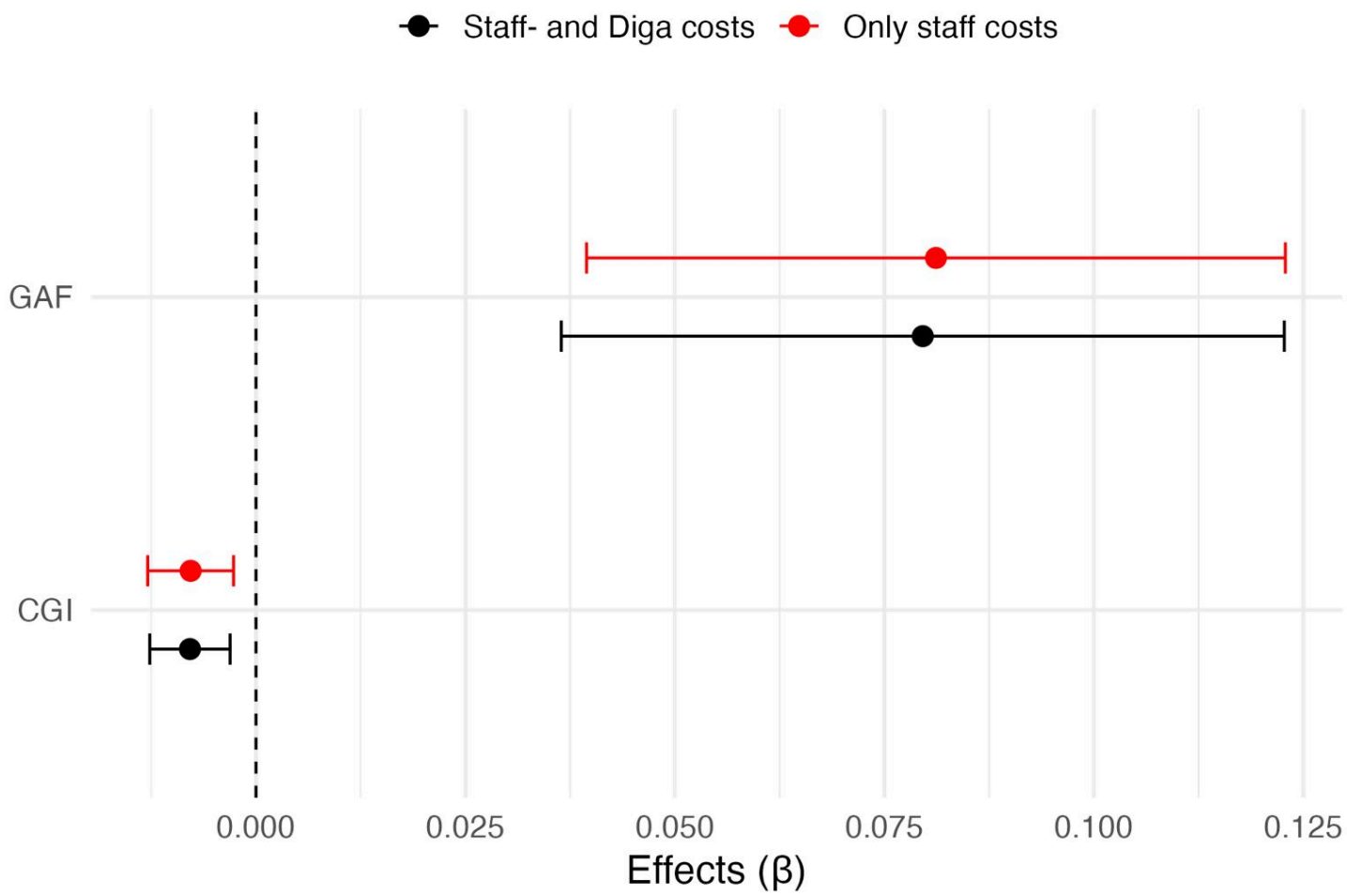


Figure 3

Regression coefficients (β) with 95% confidence intervals for the association between intervention costs and changes in clinical outcomes, shown for total costs and staff costs only