

APPENDIX II:

Methods:

Legal and Regulatory References for User Feedback Categories in DTx/ DiGA Evaluation

Category	Associated DiGA Criteria	Legal Basis (Original German Reference)	Legal Basis (English Reference Version) <i>Translated from the original German using ChatGPT-5</i>
Content	Content quality, evidence base, up-to-dateness, scientific soundness, readability	§ 139e Abs. 2 SGB V: "Voraussetzung für die Aufnahme in das Verzeichnis [...] ist, dass [...] die digitale Gesundheitsanwendung [...] den Anforderungen an Sicherheit, Funktionstauglichkeit, Qualität, Datenschutz und Datensicherheit entspricht." DiGAV § 5 Abs. 8 Satz 2: "Sofern die digitale Gesundheitsanwendung die Versicherten mit Gesundheitsinformationen unterstützt, müssen die Gesundheitsinformationen ebenfalls dem allgemein anerkannten fachlichen Standard entsprechen und zielgruppengerecht aufbereitet sein." DiGAV § 5 Abs. 8: "(8) Die von digitalen Gesundheitsanwendungen verwendeten medizinischen Inhalte müssen dem allgemein anerkannten Stand der medizinischen Erkenntnisse entsprechen. Sofern die digitale Gesundheitsanwendung die Versicherten mit Gesundheitsinformationen unterstützt, müssen die Gesundheitsinformationen ebenfalls dem allgemein anerkannten fachlichen Standard entsprechen und zielgruppengerecht aufbereitet sein."	§ 139e (2) SGB V: "A prerequisite for inclusion in the directory [...] is that [...] the digital health application [...] complies with the requirements for safety, functional capability, quality, data protection, and data security." § 5 (8) sentence 2 DiGAV: "If the digital health application provides insured persons with health information, this information must also comply with generally accepted professional standards and be prepared in a way that is appropriate for the target group." § 5 (8) DiGAV: "(8) The medical content used by digital health applications must comply with the generally accepted state of medical knowledge. If the digital health application provides insured persons with health information, this information must also comply with generally accepted professional standards and be prepared in a way that is appropriate for the target group."
Technology	Technical stability, system compatibility, update frequency, bug handling	§ 139e Abs. 2 SGB V: "Voraussetzung für die Aufnahme in das Verzeichnis [...] ist, dass [...] die digitale Gesundheitsanwendung [...] den Anforderungen an	§ 139e (2) SGB V: "A prerequisite for inclusion in the directory [...] is that [...] the digital health application [...] meets the requirements for safety, functionality, quality, data protection, and data security."

		Sicherheit, Funktionstauglichkeit, Qualität, Datenschutz und Datensicherheit entspricht." DiGAV §5 Abs. 2: "(2) Digitale Gesundheitsanwendungen sind so zu gestalten, dass sie robust gegen Störungen und Fehlbedienungen sind." Leitfaden BfArM (2023), Abschnitt 3.3.2: "Technische Stabilität, Kompatibilität mit Endgeräten und regelmäßige Updates sind sicherzustellen."	§ 5 (2) DiGAV: "(2) Digital health applications must be designed to be robust against malfunctions and incorrect use." BfArM Guideline (2023), Section 3.3.2: "Technical stability, compatibility with end devices, and regular updates must be ensured."
Cost/Reimbursement	Perceived cost, issues with reimbursement by health insurance	§ 134 Abs. 1 SGB V: "Die Vergütung erfolgt [...] auf der Grundlage einer Vereinbarung mit dem GKV-Spitzenverband."	§ 134 (1) SGB V: "Remuneration shall be based [...] on an agreement with the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband)."
Login/Registration	Initial access, ease of login or registration	DiGAV § 5 Abs. 5: "(5) Digitale Gesundheitsanwendungen sind so zu gestalten, dass die Versicherten diese leicht und intuitiv bedienen können."	§ 5 (5) DiGAV: "(5) Digital health applications must be designed in such a way that insured persons can use them easily and intuitively."
Prescription/Approval	Problems with prescription, approval by health insurance, diagnosis requirements	Leitfaden BfArM (2023), Abschnitt 3.2.2: "Der Zugang zu DiGAs über Krankenkassen und digitale Rezepte muss gewährleistet sein." Leitfaden BfArM (2023), Abschnitt 2.1.2.2: "Versicherte können sich auch ohne ärztliche Verordnung eine gelistete DiGA durch die Krankenkasse genehmigen lassen."	BfArM Guideline (2023), Section 3.2.2: "Access to DiGAs via health insurance funds and digital prescriptions must be ensured." BfArM Guideline (2023), Section 2.1.2.2: "Insured persons may also obtain approval for a listed DiGA from their health insurance fund without a medical prescription."
UX/Design	User interface, usability, visual and design aspects	DiGAV § 5 Abs. 5: "(5) Digitale Gesundheitsanwendungen sind so zu gestalten, dass die Versicherten diese leicht und intuitiv bedienen können."	§ 5 (5) DiGAV: "(5) Digital health applications must be designed in such a way that insured persons can use them easily and intuitively."
Support	Availability, friendliness, and quality of customer support	Leitfaden BfArM (2023), Abschnitt 3.6.2.5: „Die DiGAV fordert, dass der Hersteller innerhalb von 24 Stunden auf Anfragen reagiert.“	BfArM Guideline (2023), Section 3.6.2.5: "The DiGAV requires that the manufacturer responds to inquiries within 24 hours."
Tracking/Documentation	Documentation of symptoms, nutrition, activities, or behaviors	* § 139e Abs. 13 SGB V: "Zu den Ergebnissen der anwendungsbegleitenden Erfolgsmessung nach Satz 1 zählen insbesondere [...] der patientenberichtete	* § 139e (13) SGB V: "The results of the accompanying evaluation of effectiveness pursuant to sentence 1 shall

		Gesundheitszustand während der Nutzung der digitalen Gesundheitsanwendung." <i>* Will become effective on January 1, 2026.</i>	include, in particular, the patient-reported health status during the use of the digital health application." <i>* Will become effective on January 1, 2026.</i>
Effectiveness	Perceived medical benefit, self-management, health literacy, therapy adherence	§ 139e Abs. 13 SGB V: "Zu den Ergebnissen der anwendungsbegleitenden Erfolgsmessung nach Satz 1 zählen insbesondere [...] der patientenberichtete Gesundheitszustand während der Nutzung der digitalen Gesundheitsanwendung." DiGAV § 8 Abs. 2: "Der medizinische Nutzen im Sinne dieser Verordnung ist der patientenrelevante Effekt insbesondere hinsichtlich der Verbesserung des Gesundheitszustands, der Verkürzung der Krankheitsdauer, der Verlängerung des Überlebens oder einer Verbesserung der Lebensqualität." DiGAV § 8 Abs.3: "(3) Die patientenrelevanten Struktur- und Verfahrensverbesserungen in der Versorgung im Sinne dieser Verordnung sind im Rahmen der Erkennung, Überwachung, Behandlung oder Linderung von Krankheiten oder der Erkennung, Behandlung, Linderung oder Kompensierung von Verletzungen oder Behinderungen auf eine Unterstützung des Gesundheitshandelns der Patientinnen und Patienten oder eine Integration der Abläufe zwischen Patientinnen und Patienten und Leistungserbringern ausgerichtet und umfassen insbesondere die Bereiche der [...] 2. Ausrichtung der Behandlung an Leitlinien und anerkannten Standards, 3. Adhärenz, [...] 6. Gesundheitskompetenz, 7. Patientensouveränität, 8. Bewältigung krankheitsbedingter Schwierigkeiten im Alltag, [...]"	§ 139e (13) SGB V: "The results of the accompanying evaluation of effectiveness pursuant to sentence 1 shall include, in particular, the patient-reported health status during the use of the digital health application." DiGAV § 8 (2): "The medical benefit within the meaning of this regulation refers to the patient-relevant effect, particularly with regard to improving health status, shortening the duration of illness, prolonging survival, or improving quality of life." DiGAV § 8 (3): "(3) The patient-relevant structural and procedural improvements in care within the meaning of this regulation are aimed, in the context of the detection, monitoring, treatment, or alleviation of diseases or the detection, treatment, alleviation, or compensation of injuries or disabilities, at supporting patients' health-related actions or at integrating processes between patients and healthcare providers. They particularly include the following areas: 2. alignment of treatment with clinical guidelines and recognized standards, 3. adherence, 6. health literacy, 7. patient empowerment, 8. coping with disease-related challenges in everyday life, [...]"
Overall Impression	Overall subjective rating, perceived utility, user trust	§ 139e Abs. 13 Nr. 2 SGB V "Zu den Ergebnissen der anwendungsbegleitenden Erfolgsmessung [...] zählen insbesondere [...] die Patientenzufriedenheit in Bezug auf die Qualität der digitalen Gesundheitsanwendung."	§ 139e (13) No. 2 SGB V: "The results of the accompanying evaluation of effectiveness [...] shall include, in particular, patient satisfaction with regard to the quality of the digital health application."

Results:

App and Statement Distribution

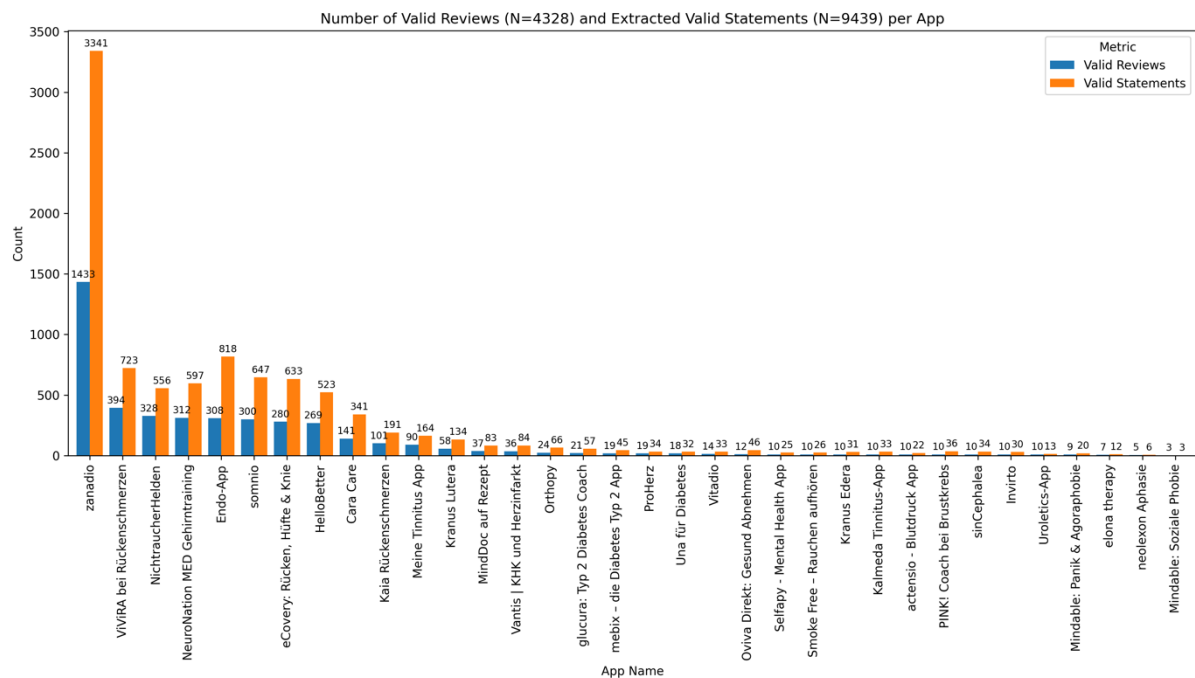


Figure 1: Number of Unique Reviews and Extracted Statements per App

Categories

Cost/Reimbursement

A total of 290 user statements addressed cost-related aspects or the reimbursement process via statutory health insurance. Users explicitly highlighted the positive financial accessibility of reimbursable DTx' through prescriptions. For example, a user commented: *"Works well and helps to exercise regularly. [...] Great that the health insurance covers the cost. Not sure if I would pay for it myself afterwards"* (David F., eCover, Play Store). Another user shared his appreciation by stating: *"It's amazing how easily I can control my diabetes with this app – and I've learned so much about the disease. I can easily contact the Vitadio team for support. Best of all: my doctor prescribed the app, completely free of charge via prescription. Thanks Vitadio"* (Martin, Vitadio, Play Store).

Neutral statements acknowledged the benefit of reimbursement while expressing concerns about the overall price-performance relations, e.g., *"Not much new knowledge about sleep. Presentation is okay. But for 460€, I expected significantly more. Luckily, my health insurance covered most of it"* (Stefan S., somnio, Play Store).

Critical statements often referred to high prices or complicated reimbursement procedures, e.g., *"I'm very satisfied with the app, but the price is way too high. Also, I really miss an offline mode"* (Martin Wi, Kaia Rückenschmerzen, Play Store). Another user criticized pricing policies as follows: *"This app is great. But the pricing is questionable. NeuroNation and NeuroNation MED are exactly the same. As a private user, the annual subscription is 72€. The NeuroNation MED subscription costs my health insurance 499€ for 90 days. Makes you wonder: 'What's wrong with you?'"* (Alexander B., NeuroNation MED, Play Store). A user of Endo-App expressed dissatisfaction with recurring bureaucracy: *"The app itself is great, the features are super helpful to track health. But requesting a new code every 30 days is annoying. After the current period, I won't use it anymore. Too complicated. I believe health insurance funds could spend the money better"* (Maren F., Endo-App, Play Store). Similarly, another user questioned the cost-benefit ratio: *"[...] The design is not very appealing, and the exercises are the same"*

ones I've done before – or am still doing- using a book that cost me a one-time 20€, compared to the hefty price the health insurance pays for this strange app.” (Mietzi M., ViViRA bei Rückenschmerzen, Play Store).

Content

The category Content received a total of 2,565 user statements. A large share of this feedback referred to the informational content as well as educational and therapeutic resources provided by the DTx's. Many users appreciated the diversity and practical value of the content, as well as the integration of scientifically based information. For example, a user commented: *“clear, crisp and no-nonsense. The videos are a big plus, and the daily feedback gives you a good feeling of support. I'm looking forward to new exercises. Keep it up!”* (A google user, ViViRA bei Rückenschmerzen, Play Store). Another user described his DTx as: *“very good, scientifically sound concepts”* (Marc A., somnio, Play Store). Similarly, a user reported: *“Varied support for successful therapy, without a raised finger. Explained through magazines on different topics (exercise, food, medication, relaxation, smoking) – helpful and supportive. In short, a helpful therapy I'm very convinced of”* (Klaus B., Vantis KHK und Herzinfarkt, Play Store).

Neutral feedback highlighted positive aspects but also pointed to limitations. For example, a user commented: *“The app is very helpful and conveys extensive knowledge to improve health. Great that it's covered by my health insurance. But I would prefer more audio content instead of reading”* (Karin H., HelloBetter, Play Store).

In contrast, some reviews were explicitly critical regarding the app content. A user wrote: *“I didn't learn anything new, basically I'm as smart as before. Pretty naive to believe that an app providing just a few pieces of information will actually help to change behaviour and break the cycle.”* (Daniela B., Meine Tinnitus App, Play Store). Another user expressed dissatisfaction with limited functionality and missing information: *“The app expires, and your own data gets completely deleted without regular prescriptions from the doctor. I didn't benefit from the symptom diary. The exercises didn't help, and there's no information or help that I hadn't already learned myself. The app gives me nothing... shame”* (faye.faronia (Faye), Endo-App, Play Store).

UX/Design

For the UX/Design category, 606 positive, 83 neutral and 340 negative statements in the dataset were allocated. Positive feedback highlighted the intuitive structure, visual presentation or accessibility of the evaluated DTx. For example, one user reported: *“The exercises are specifically tailored to the condition. They are clearly explained via video and very varied. The app is intuitive to use”* (Rudolf P., eCover: Rücken, Hüfte & Knie, Play Store). Another review highlighted the clear structure: *“The app is very easy to understand and helps to see tinnitus in a more positive light. It is interesting and fun to work with”* (Rosina S., Meine Tinnitus App, Play Store). Similar positive feedback was expressed regarding user-friendliness: *“The modules are explained very well and understandably. Very user-friendly”* (Karin K., somnio, Play Store). Neutral statements often included suggestions for improvement without entirely negative sentiment, e.g., one reviewer commented: *“Good and helpful information and guidance. I would appreciate an option to have the text read aloud. Therefore, one star deduction.”* (Moe001!!!, Meine Tinnitus App, Apple Store).

Negative user statements focused on missing functionalities or technical limitation affecting their experience. For instance, a user remarked: *“The video display is much too small, no full-screen option, no streaming to TV. The video stops after a few seconds”* (Hu K., eCover: Rücken, Hüfte & Knie, Play Store). Criticism also addressed missing features: *“It's a shame that the health insurance pays for this. The app doesn't even offer a dark mode. A timer is also missing”* (Android Nutzer, somnio, Play Store). Another user mentioned design related

inconsistencies: *“After initial problems, the app works quiet well. Some animations still don’t work and most of the information was already known to me. But the app is still helpful”* (Dethora B., somnio, Play Store).

Tracking/ Documentation

For the Tracking/Documentation category, 230 positive, 43 neutral, and 195 negative statements in the dataset address the tracking and documentation functionalities of the analyzed applications. Positive feedback frequently highlighted the ability to gain structured insights into patient’s health status and progression. For example, one user stated: *“By entering what you eat every day, you always have an overview – I personally find that very important and good”* (Marion N., zanadio, Play Store). Another reviewer appreciated the integrated tracking features in the mobile version: *“I’m still new here, but so far I really like it. All content is now available in the app, I previously only used the web version, and I like the app better because you can also track your mood here”* (dennis1977_123, Selfapy – Mental Health App, Apple Store).

Neutral reviews often suggested improvements, especially regarding the scope of tracking options. For instance: *“Very good app. Motivates and helps. Only the recipe ideas are hard to implement for working people. It would be also be nice to track additional values”* (M. Pape, glucura: Typ 2 Diabetes Coach, Play Store).

Negative feedback mainly criticized technical shortcomings or usability barriers related to tracking functionalities. One user reported: *“Unfortunately, I’m not satisfied. When tracking, the app constantly interrupts with notifications. I tried to enter a meal with more than five ingredients several times – without success. Pity.”* (Raphaela B., Cara Care, Play Store). Another review criticized unreliable data integration: *“Sleep data based on subjective perception? Data synchronization with Fitbit doesn’t work. Nothing more to say.”* (Jean R., somnio, Play Store).

Technology

A total of 668 user statements in the dataset address the technical performance and stability of the analyzed applications. Positive feedback emphasized smooth functionality and reliable operation. For example, one user stated: *“The app runs flawlessly 👍 good explanations, exercises easy to understand. Usable even when short on time”* (Silvia H., ViViRA bei Rückenschmerzen, Play Store). Another reviewer confirmed: *“The app runs very stable for me, and the courses are very helpful”* (Marc L., HelloBetter, Play Store).

Neutral feedback acknowledged minor technical issues: *“Very good app. Extremely helpful. I’m finally making progress with my diet! Small things, like occasional glitches, are not worth mentioning.”* (Raven1246, Cara Care, Play Store).

Negative user feedback mainly criticized crashes, slow performance, or severe malfunctions. One user reported: *“At first, I was very satisfied. Since the spring update, the app has become sluggish but still worked. Now, since the latest update, I’m logged out several times a day, and all entries disappear. The app shows the last entries from March. It’s barely usable anymore”* (Ibrahim U. Cara Care, Play Store). Another user experienced more fundamental issues: *“I installed the app but unfortunately cannot open it. The start screen appears briefly, and then it closes again. Reinstalling didn’t help either.”* (Bianca J, Endo-App, Play Store).

Support

In total, 865 user statements were assigned to the category Support, addressing user experiences with both technical assistance and supportive features such as guided sessions or communication with healthcare professionals. Many users expressed satisfaction with the availability and quality of support services. For example, one user of actensio – Blutdruck App praised the overall user experience and highlighted that the: *“customer support is excellent”*

(Dr.Nuk3s, actensio – Blutdruck App, Apple Store). Similarly, another user appreciated the helpfulness of both the app and the support team: *“It is so helpful to document everything in one app. Also, great support!”* (Hanna A., Endo-App, Play Store).

However, technical issues and delayed responses were also reported. One user noted ongoing login problems and app crashes despite multiple attempts to resolve the issue with customer service, stating *“I already informed support, they have been working on the problem for weeks. [...] The chat support is always friendly and responds quickly”* (Sonja L., zanadio, Play Store). Negative experiences often related to unresolved technical problems or insufficient assistance. A reviewer stated: *“Several features don’t work properly [...] support could not help. At this price, it should work!”* (Evi R. mebix, Play Store). Similarly, another user criticized the lack of response: *“A great app that really challenges you, but one point deduction because I’ve been waiting for an answer to my question for three months”* (Uwe M., NeuroNation MED, Play Store).

Prescription/ Approval

A total of 234 user statements were assigned to the category Prescription/ Approval, reflecting user experiences with obtaining or redeeming access codes for the DTx. Positive Feedback emphasized the convenience and accessibility of the prescription process. One user reported: *“Quick and reliable access to prescriptions for sleep disorders. Great solution, makes life much easier!”* (Terminator Arnold, somnio, Play Store). Similarly, another user appreciated the combination of medical support and accessibility: *“[...] Where else can you get a personal coach by prescription? Absolutely recommendable, extensive, informative, personal and motivating”* (Ronny H., zanadio, Play Store).

Neutral feedback highlighted mixed experiences, particularly regarding bureaucratic hurdles. For example, a user described the app as helpful but noted: *“Unfortunately, the process of obtaining and renewing the access code is complicated [...] prescription from doctor, send to health insurance, receive code, forward to app support...”* (jimbo, NeuroNation MED, Play Store).

Other users criticized the lack of information about the prescription requirement, stating: *“Pity, you need a prescription code, otherwise the app is useless – and my doctor doesn’t even know about this app 😞”* (AnKa Dar, zanadio, Play Store) and *“Not usable, requires some ‘prescription code’. Nonsense if you can’t test the app before dealing with all the paperwork”* (Chibi S., zanadio, Play Store).

Comparison of Ratings

Beyond the sentiment and category analyses, a comparison was conducted between the average star ratings of reviews containing written feedback and the overall average star ratings for each app (including reviews with and without free-text comments). We performed the analysis separately for the Apple App Store and the Google Play Store to take platform-specific differences into account.

The results reveal discrepancies between the two rating types for several DTx. (For Apple Store see Figure 2 and Play Store see Figure 3). In many cases, the average star-rating among reviews with written feedback was lower than the overall DTx-rating, indicating a more critical tendency among users who provide detailed feedback. For example, in the Apple Store, the DTx *“Mindable – Soziale Phobie”* shows an overall rating of 3.7 stars, while the average rating among written reviews is only 2.33 (Δ -1.37). In contrast, several DTx app received higher average ratings in written reviews compared to the overall DTx rating. For example *“Kalmeda – Tinnitus-App”* shows an overall rating of 3.6 and written review rating of 5 stars (Δ +1.4) in the Apple App Store.

These findings highlight that aggregated star ratings alone may provide an incomplete or potentially biased picture of user satisfaction. Analyzing written feedback offers additional insights that are not always reflected in overall ratings, emphasizing the importance of considering qualitative user comments in the evaluation of DTx products.

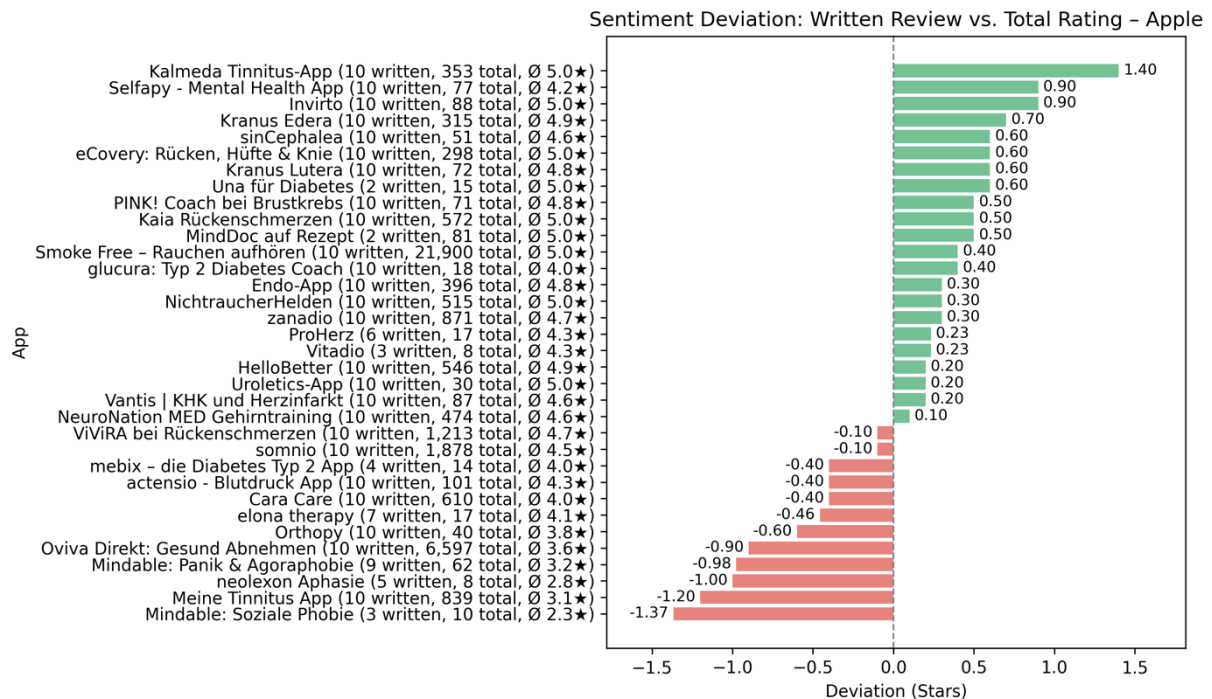


Figure 2: Apple Store: Deviation of Free-text Star Ratings Compared to Overall App Ratings

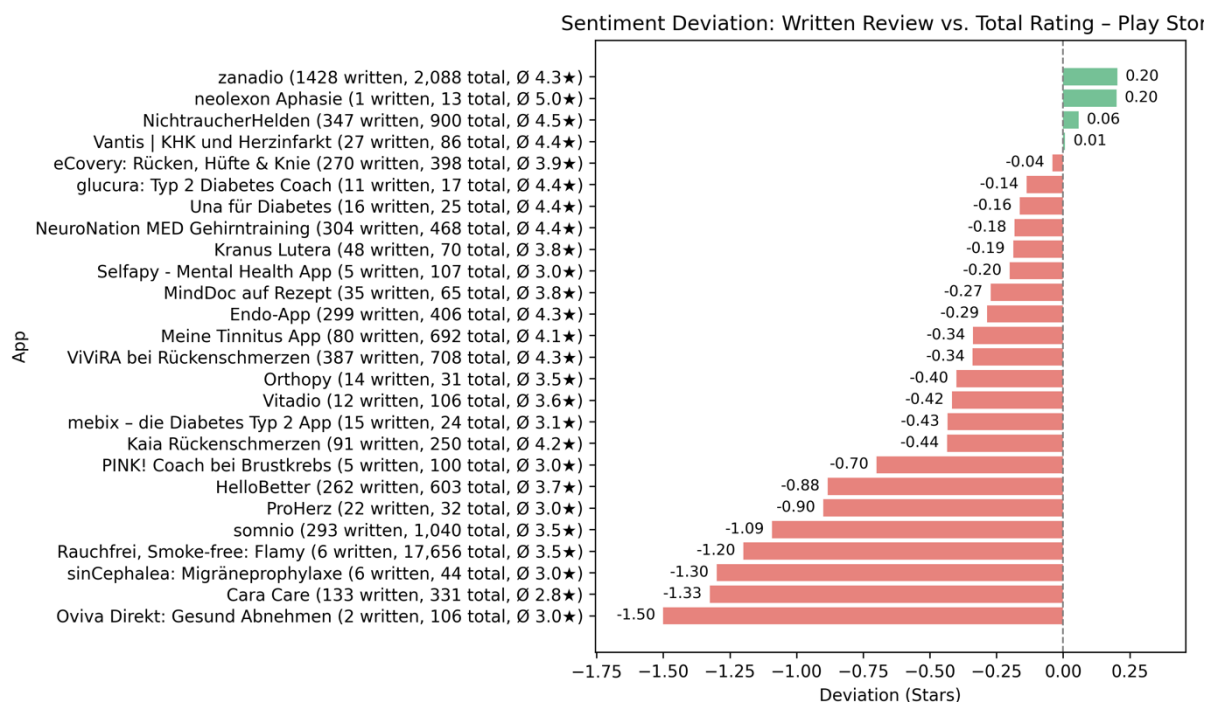


Figure 3: Play Store: Deviation of Free-text Star Ratings Compared to Overall App Ratings