Medical Apps in Otorhinolaryngology

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ABSTRACT

The implementation of mobile information and communication technology in the field of health services, e. g. in the form of apps, is becoming increasingly important. Unfortunately, the necessary quality criteria are often missing. Thus, it seems important, that in addition to an app controlling authority highly qualified health care professionals participate in the development of these applications. For reasons of liability, however, the physician must exercise great caution in the selection and recommendation of medical apps, especially considering, that only a few apps are certified as medical devices. There is a large number of medical apps on the market, with only a small proportion being assigned to the field of otorhinolaryngology. The areas of audiology, sleep medicine and allergology are most frequently represented. Although there is increasing scientific work on this topic in the field of otorhinolaryngology, there is a lack of scientific evidence of contents and results, as is generally the case of medical apps. However, there are other possibilities for users to rate medical apps regarding defined quality criteria such as functionality, scientific integrity, but also data privacy. None of the apps assessed by such an evaluation tool met all the required quality criteria, but the applied instrument helped to better assess the application. However, it was possible to consider the quality criteria in the developmental process of a medical app for the field of otorhinolaryngology. In summary, the present work provides a comprehensive insight into the topic "Apps in Otorhinolaryngology" with the aim to use these modern aids in a beneficial way.

Inhaltsverzeichnis

1. Introduction

Since several years, the use of smartphones and tablet PCs is continuously increasing. 81 % of the German population over 14 years of age currently use this technology that provides always more functions besides mobile phone calls [1]. The internet opens the possibility of using mobile information and communication technology. Its use for medical and healthcare-related services, so-called "mobile health" (mHealth) becomes increasingly important. Similar to many other fields, a specific form of application software was established for the devices and their operating systems in the medical sector, so-called medical or healthcare apps.

These applications provide a large variety of comparably simple fitness and wellness apps up to more sophisticated programs for diagnostics and therapy. In the field of otorhinolaryngology, too, an increasing number of apps were developed in the last years that include many aspects of this discipline.

The present article will give an overview about apps in Otorhinolaryngology. One limiting factor, however, is that it is impossible to assess all existing apps already due to the fast-moving market development and the unsatisfactory information politics of store operators and mobile platforms so that especially scientific research and evaluation is significantly restricted. Nonetheless, the investigation of possibly many areas aims at imparting broad knowledge about the current status, in particular with regard to the chances and risks of such applications in the field of Otorhinolaryngology.

The following chapter will introduce the topic of mobile health and medical apps and critically discuss their effectiveness and benefit. Furthermore, the various quality levels of the application software will be described and the criteria of "good apps" will be defined. This includes aspects such as "app as medical product" and liability issues as well as the significance of active contribution to new processes for the patients' benefit. In addition, the development of the number and the quality of apps in otorhinolaryngology will be elucidated based on the example of a specific app store.

Chapter 4 will emphasize and elaborate the results of a literature research with regard to published data on Otorhinolaryngology -related apps.

Chapter 5 deals with the evaluation of the survey on Otorhinolaryngology -related apps that was conducted specifically for this article. Hereby, selected users assessed the apps by means of an evaluation form containing special items that show if an app actually fulfills the requirements to be implemented in patients' healthcare.

The last chapter will describe how new apps may be conceived and programmed in a suitable and reliable way. Regarding the first steps of development, the focus is placed on necessary details so that a new app may be reliably used in healthcare.

The summary of the different focuses of the single chapters allows a critical discussion of these apps for the discipline of Otorhinolaryngology. The authors try to avoid mentioning brand names and companies throughout the entire manuscript in order not to influence the user's selection of specific apps. Instead, it is rather the objective to answer the question of how we as otolaryngologists may assess if medical apps can be suitably implemented. Considering the described aspects, it should not be difficult to find an appropriate app after critical assessment of the features and to recommend it for use.

2. Introduction into the Field of Mobile Health and Medical Apps

2.1. Mobile health

"Mobile health" (in the following "mHealth") is synonymous for the implementation of mobile information and communication technology in the context of medical or healthcare-related services. Healthcare apps that are installed on smartphones, tablet PCs, and other mobile devices are the best known and widest-spread expression of mHealth. The topic includes the medical areas of prevention, diagnostics, and therapy as well as other areas of healthcare provision like fitness and nutrition with the aim of increasing the physical and psychic well-being. The characteristics of this technology led to the success of this mobile concept in other areas and they are supposed to support healthcare provision in the future. They include among others the direct availability of information directly on site, independently from opening hours or cash transactions. This high flexibility allows comfortable use that may be integrated in daily routine. However, this concept also bears several risks. The privacy may be impaired by the nearly always required data collection, storage, sending, and processing. mHealth influences the doctor-patient relationship since both sides have already implemented the technology and use it for their purposes. Still a suitable interface has to be found that connects both aspects in the best way possible. Several options already exist; the future development will reveal which ones will prevail.

2.2. Medical apps in otorhinolaryngology

An uncountable number of medical apps can be found on the market. It is impossible to give exact data because the store operators of the large mobile platforms remain silent and counting is possible only to a limited extent. Beside apps that operate in the fields of fitness or prevention, also some others are provided – to a lesser extent – that cover medical issues, and some even include the discipline of Otorhinolaryngology. An exemplary review by means of the retrospective semi-automated app store analysis (SARASA) [2, 3] and evaluation of the store category of "Medicine" within the Apple App Store (retrieved on April 14, 2018), the following situation could be displayed after searching for German apps with ENT-specific keywords (▶ **Table 1**): Only 97 German apps with reference to Otorhinolaryngology could be identified in the German Apple App Store under the category of "Medicine" (▶ **Table 2**). With a total of 5,045 German apps, this means a percentage of 1.9 %. Comparably often, apps were identified that dealt with hearing, for example allowing hearing care professionals or even hearing aid users to configure their hearing aids in an app-supported way and to adapt them to particular needs or to counsel in cases of tinnitus. Furthermore, apps are found that inform medical staff or patients about ENT-related issues in the sense of dictionary, serve as diaries for allergic patients, or support on the way to healthy sleep (▶ **Fig. 1**). However, for medical apps it is always difficult to find a cost bearer. Assumption of the costs by the statutory health insurances is only performed for two ENT-related apps. Those are "Tinnitracks" and "Audimatch" by the Sonormed Company.

Based on the available metadata of the selected apps, some statements can be made. The developers of "ENT apps" seem to be fully aware of their responsibility regarding current contents and provide

updates in very narrow intervals (median: 4.76 months; IQR: 13.35) compared to other German (median: 11.07; IQR: 22.51) or language-independent apps in the field of medicine (median: 12.98; IQR: 22.32). In addition, the readiness to provide the ENT app users with extensive information seems to be higher. The length of the store descriptions with 1,467 (IQR 1,736) exceeds the usual number or characters of German medical apps (median: 921 characters; IQR: 1,502) (▶ **Table 2**).

It is also eye-catching that German ENT apps need more storage space: the size of the files amounts to a median of 42.59 MB (IQR: 65.74) compared to 24.65 MB (IQR: 30.37) regarding all German apps. Since many of them concern the application of hearing, this fact may be due to the multimedia functions (e. g. audio files) integrated in the apps. With regard to the user feedback on ENT apps, users are more often incited to express their opinions – in a positive as well as negative way. In the median, the ratings only marginally vary (median: 4 stars each; differences exist with regard to the interquartile interval), however, the percentage of apps where ratings are given only amounts to 52.6 % (51/97), which is significantly higher than for most other German apps in the category of medicine with 33.3 % (1681/5054).

About every fifth ENT app is fee-based (21.6 %; 21/97) while this applies only for less than 17 % (16.7 %; 846/5,045) of all German medical apps. This fact is surprising because a lower percentage could be expected since a high number of apps that serve for configuration of hearing aids cannot be used without them.

2.3. Effect and benefit of medical apps

Many approaches appear to be very promising but currently sufficient scientific evidence is missing that would confirm a positive effect of medical apps on the individual health condition. Such a benefit has to be required as sound basis for refinancing, in particular in the context of reimbursement by the statutory health insurances that have to refer to proven benefit in the context of legal conditions [4].

In the scientific literature, numerous publications can be found on "mobile health", however, only few of them can be transferred to the situation in Germany or they focus on very specific application fields that transfer to the entire sector and general conclusions would not meet scientific requirements. On the other hand, there is a high variability regarding the methods. Traditional study designs are based on investigation periods that can only be applied to a limited extent because of the short development cycles in the context of smartphone applications [4].

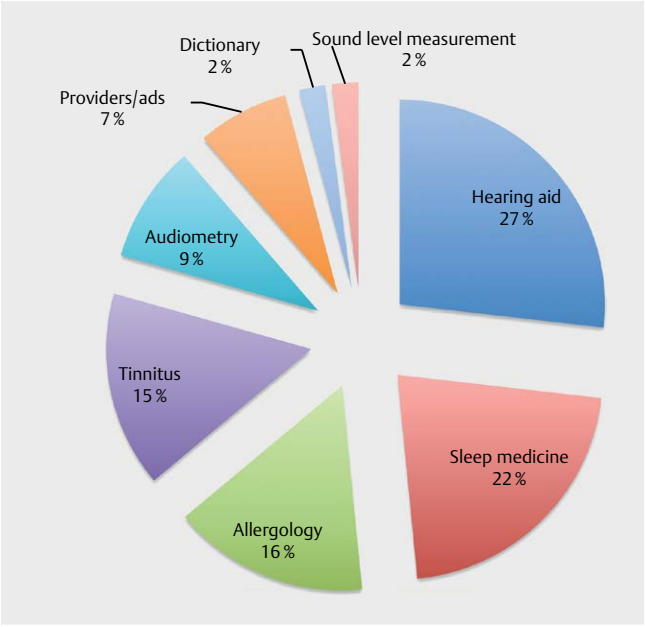
Concluding trials are still expected. But it can already be stated that apps aiming at initiating or increasing fitness activities are mostly rated positively. One reason seems to be the independence from

▶ **Table 1** Keywords used for research and hits in the store category of "medicine".

Keywords (regular expression, perl syntax):	hörtest|hörprüfung|dezibel|tinnitus|ohrgeräusch|otoskop|schlaf|[ge] * schnarch[ent]|(?<!ge)schwindel[ig]|dysphag|schluck[ge] * stör[unget] + |hörgerät|allergie|allergisch
Initially retrieved apps in the category of "medicine"	39,427 apps on April 14, 2018
Among them, with German description	5,045 apps
Manually validated	97 apps

▶ **Table 2** Descriptive comparison of ENT-specific apps in German and the total numbers in the store category "medicine" (Apple App Store for iOS-based apps, retrieved on April 14, 2018).

	All apps in the category of medicine (N = 39,427)	**Description in German (N = 5,045)**	**Selection of ENT, in German (N = 375)**	**Selection of ENT, in Germany, manually validated (N = 97)**
Age in months (overall)				
Median (IQR)	28.22 / 34.89	32.58 / 33.35	37.61 / 39.65	30.11 / 28.74
Age in months (current version)				
Median (IQR)	12.98 / 22.32	11.07 / 22.51	7.63 / 19.37	4.76 / 13.35
File size in MB				
Median (IQR)	22.56 / 36.08	24.65 / 30.37	38.27 / 57.60	42.59 / 65.74
Prize in €				
Min:	0.49	0.49	0.49	1.09
Median (IQR)	n = 6,838; 3.99 / 7.70	n = 846; 3.49 / 3.20	n = 110; 3.49 / 2.93	n = 21; 3.49 / 3.20
Max:	1099.99	499.99	59.99	42.99
Length of the description (signs)				
Median (IQR)	757/1,048.50	921/ 1,502.00	1,757 /1,673.50	1,467 / 1,736.00
Rating/stars (all versions)				
Median (IQR)	n = 2,581; 4.00 / 2.00	n = 1,681; 4.00 / 2.00	n = 214; 4.00 / 1.50	n = 51; 3.50 / 2.00



▶ **Fig. 1** Percentile distribution of the apps identified in the search regarding areas of otorhinolaryngology (Apple App Store for iOS-based apps, retrieved on April 14, 2018).

group pressure that facilitates the start for certain target groups. However, the adherence to such programs is questioned [5]. Many apps provide a reminder function and in particular those that incite their use in a playful way, give individual feedback on the progress, or allow competition with friends and like-minded people in a limited context, are rated as very positive. Hereby it is important that they do not make the users feel bad in cases of failure [6]. In this way it is possible to improve participation in healthcare processes for which apps are considered a chance, and patients can contribute themselves to improve their health by using their smartphones [7].

2.4. Apps as medical devices

Comparable to tongue spatulas or otoscopes, medical apps may be considered as medical device. This circumstance is important especially for professional users if damage or any other harm occurs that may be due to the use of the app. The user must not have the impression that the app in front of his/her eyes is a medical device – even if it may be applied for medical purposes. Often, it is not obvious, what the use of an app is and the users have to decide where and how they use the app. This aspect is completely different for medical devices. Throughout the course of the product development, the app developer defines if the product is a medical device, for example by assigning a medical purpose to an app in accordance to the medical device regulation [8]. This mainly means that the developers stipulate a purpose for their apps in the fields of diagnostics, therapy, or prevention (corresponding to § 3 of the German *Medizinproduktegesetz* (Medical Device Law)). This decision has far-reaching and cost-intensive consequences because the developers have to work their way through a more or less extensive process until the product achieves the conformity approval. This final step confirms that the "general requirements" of the according EU directive (Medical Device Directive, MDD [9]) are fulfilled. Only after this declaration of conformity, the CE label may be added and the product can be introduced into the market and sold to third parties. Depending on the risk class of the medical device (I, Im, Is, IIa, IIb, and III), the so-called "Notified Body" has to be contacted so that for example the validity of measurement functions of the app (as of risk class Im) may be certified. Apps representing a medical product have to meet the basic requirements of documentation, software development, tests, validation, usability, risk management, and version management in accordance to the applicable laws. Developers of apps that are no medical devices do not have any obligation in this context. For more details, the authors indicate the CHARISMHA trial and further literature [10, 11]. It is well understandable that numerous developers decide against the category of medical product for their app because of the intensive efforts that have to be undertaken. An even higher number of developers are probably not even aware of the problems because they come from other areas of software development. The consequences for the users, in particular professional ones, however, are far-reaching.

2.5. Liability prevention

Based to the German Civil Code, the physicians owe to their patients a treatment that is accepted according to the generally applied medical standard unless other agreements have been made. Accordingly, compensation claims may be pursued if the physician applies unsuitable instruments or methods that cause harm. Because of the only poorly standardized development practice and the lack of state supervision, apps bear an increased liability risk for the users and not for the developers [12]. The developer cannot be obligatorily held responsible. It becomes particularly difficult when they have not assigned a medical purpose to the app (see above) and this app has been applied in a medical context. But even if the app is considered as medical product according to the medical products law, it still depends on the intended application by the user. It turns out to be problematic when the app was applied apart from its intended use leading to harm for the patient. Generally, the developer will decline any responsibility. In the sense of liability prevention, physicians should be well informed about the app before introducing and applying it with the patient. This aspect includes the intended use, functionality, application scope, risk potential etc. [12]. It is strongly recommended to thoroughly go through the contents of the app description and the instructions for use (in particular for medical products). Furthermore, the app should be tested previously by performing test calculations, test measurements, and comparisons with standard methods in order to check the plausibility and to get an impression about the validity of the app [12]. Additionally, possible or at least probable user errors should be anticipated and their consequences on the application of the app should be considered. Finally, the app has to convince the user regarding its suitability – in cases of inconsistencies, the decision has to be made against the use of the app in order to act in a liability preventive way.

2.6. "Good" medical apps

The percentage of apps to which the developer has assigned an intended medical use, i. e. that have to be considered as medical products, and that are found in the app store as such is rather low. For apps in the German Apple App Store provided with German descriptions under the category of "Medicine", "Healthcare", and "Fitness",

a recent investigation could identify such a hint in the description in only 34 out of 8,767 apps [2]. For other "quality labels", the result was even poorer with 5 of 8,767 apps although 13 initiatives could be revealed that provide quality seals so that the spectrum may be considered as good. The CE marking is no quality label in the proper sense but it is obligatorily required for medical products. The low number of apps certified with this marking indicates that no security regarding the quality is given for the users in the majority of the apps. Only one single medical app in the ENT context with therapeutic approach ("Tinnitracks") meets those legal requirements ("CE marking"). It is offered by numerous statutory health insurances. Only after diagnostics it may be prescribed by the treating ENT specialist. In this constellation, the interaction of all contributing parties within the healthcare system seems to lead to an appropriate use of the app. Other apps of the same developer will or shall follow in a similar setting in cooperation with the statutory health insurances, e. g. an app for screening of the hearing ability or one in the context of tinnitus counseling [13].

For users it is very difficult to identify high-quality apps. Generally, the question is what makes a "good", "high-quality" app. The user has the impression of "good" app when the experience at any time is to work with a thoroughly developed application. Subjectively, this aspect becomes already apparent when individual parameters are retrieved at the time of first use and when those parameters serve as calculation basis throughout the further course so that values or recommendations computed by the app appear comprehensible as well as appropriate for the individual user. The application should be intuitive and each feature should be plausible or at least become available by well accessible and clear explanations. Especially a flexible reaction of the app on changes, for example when the user leaves the ideal setting for application and the app itself indicates it and gives recommendations on how to react on this modified situation, reveals a good design, realistic testing, and careful transfer of test results to the development of updates. In this way, well-designed apps exclude – as far as possible – jeopardizing the user's health. Thus a "good app" may meet its purpose in a complete, efficient, and reliable way and satisfy the users and ideally even surpass their expectations.

If risks can be preventively excluded, they may also be disregarded. "Bad" apps show sequelae of insufficient thoroughness in their development that in the worst case may even endanger the users; at least they lead to frustration. If an app that is supposed to be applied as part of a therapy is "bad" or at least tends in this direction instead of revealing the characteristics of a "good" app, a low adherence has to be expected. Because of the confusingly wide range of apps and the lack of transparency about their quality, the calls of users – in our case patients – but also politics of professional and consumer associations become louder with regard to establishing supervisory authorities that perform competent checkups and evaluation without conflicts of interests. Validation by government authorities is only performed in narrow frames and concerns only a very low percentage of all apps. Test facilities and certification units recognize the high potential in the insecurity about the quality of apps and offer certifications, however, the test procedures are not transparent so that it is not obvious if generally applicable test quality criteria are met and "certified" apps fulfill all quality criteria.

2.7. Challenges

Apps offered in the medical context sometimes reveal an inacceptable lack of quality. On the one hand, the overestimation of the technical possibilities of smartphones is characteristic, for example smartphone-based melanoma screening. Hereby a good idea was implemented in a technology that was still unsuitable [14]. On the other hand, also companies from non-healthcare areas see opportunities to enter this market via apps in the healthcare context, however, because of missing experience and expertise regarding the specific approaches, they neglect customary standards and even statutory regulations. Having a look on all this from a perspective that is less determined by doubts and anxieties, the particularity of the situation becomes apparent: beside the nearly complete availability of the suitable technology, at least in the exactly specified frame, the market of mobile health applications is characterized by a pioneering spirit that provides our healthcare system with many options and a basis for new approaches. In order to experience sustainable success, companies are highly interested in developing high-quality and sophisticated products. Developers have to be incited and sensitized for the necessary thoroughness in the medical sector and the essential observation and further developing "best practice" methods, and ideally be supported.

2.8. Participation in change

As it could be seen at the occasion of the last 2 German Congresses of Physicians, the awareness for the necessity of Digitalization in medicine – and the own contribution – has increased also in the medical profession. In professional organizations, associations, and societies more and more workgroups and task forces are implemented that deal with questions on digitalization and a possible active participation in the development concerning healthcare. Depending on the contributing individuals, the participation varies enormously and also the status of the development is rather different. Some societies for example take care of the issuance of quality markings in the app context. The German Society for Internal Medicine (DGIM) actively supports the development of a tool (SARASA) that is supposed to serve as formal filter of apps that are listed in the stores of large mobile platforms [3].

Efforts may also be considered as helpful to standardize quality criteria on an interdisciplinary level. They include criteria for identification of suitable apps and for their evaluation that have to be defined jointly which have then to be communicated to all involved parties (users as well as providers and developers) [15]. This aspect further ensures transparency. In this way, the preconditions and evaluation parameters that are set by healthcare professionals for the use of an app are obvious for providers and developers. This may be the basis for a quality-assured development in the lifespan of an app [15]. A congruence between the different societies may certainly be achieved on basic aspects such as ethical harmlessness, validity, risk appropriateness, transparency, functionality, and usefulness as well as rather technical features such as for example technical appropriateness, usability, efficiency of resources, and safety issues. The aim is that the single societies are not responsible themselves for the technical testing of the products, which is difficult for them to conduct, but the necessary processes for valid evaluation are coordinated so that they may be performed by suitable partners. Individual (discipline-specific) requirements or focuses of the single societies and professional associations, however, are not concerned by this in-

terdisciplinary coordination [15]; moreover it is the aspect that all stakeholders in this field may contribute to the quality management and that appropriate tools are available.

2.9. Conclusion

Mobile health is a patient-near technology especially for patients who are interested in this field – and their number is increasing. It opens comparably simple options to perform diagnostics in typical situations, to control therapy in narrow intervals, and thus to avoid unnecessary pathways. The same may be aimed at in the field of otorhinolaryngology. For a high adherence, not only the accuracy and a – from a medical point of view – thorough and complete implementation of the features are essential. In this context, high quality also means that the barrier of the patient is kept low by an intuitive and flexibly reacting operating concept. A clear scientific proof for the benefit of applying smartphone apps in the medical context is currently not available. Overall, this may be due to the difficult applicability of established methods in this rapidly developing field.

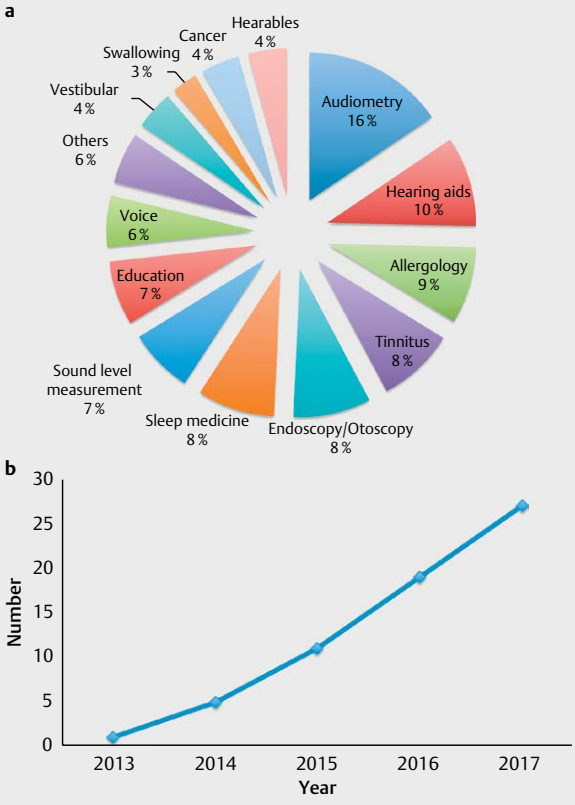
The implementation of healthcare apps often lacks of the observation of quality criteria so that in this context a call is launched to healthcare professionals to actively contribute to the app development for our patients' benefit and well-being. Unfortunately, there is no supervisory authority for standardized evaluation for the large spectrum of apps. The declaration of an app as medical product by the company is a possible option that provides (at least some more) security, however, this way is only pursued by the minority of developing companies. If we as physicians want to count on mobile health, we imperatively have to deal also with liability questions, and so a deep knowledge of the used apps is essential. Based on medical users who implement this technology after thorough training and thus contribute themselves to the quality of mobile health, and based on quality criteria established interdisciplinarily by professional associations and societies, and the observation of these criteria by developers, mobile health represents a benefit for all parties and an easing of the solidary healthcare system. Furthermore it would strengthen the patients' awareness of healthcare issues.

3. Research of the Literature On "Apps in Otorhinolaryngology"

In order to evaluate the scientific discussion around the topic of "apps in otorhinolaryngology" a literature research was performed in the text-based English meta-database Pubmed (https://www.ncbi.nlm.nih.gov/pubmed) at the end of March 2018. For this purpose, the keywords of "app", "mobile app", and "mobile device" were combined with different ENT-specific terms.

3.1. Evaluation of the literature research

A total of 71 publications could be identified, among them 1 study was published in 2013, 5 studies in 2014, 11 studies in 2015, 19 studies in 2016, and 27 in 2017. From January to March 2018, already 8 studies have been published. The identified publication could be assigned to 14 categories of the ENT spectrum. ▶ **Fig. 2** displays an overview of these 14 categories and their percentage distribution (A) as well as the number of trials per year (B). In the following, the single categories with the according studies are described.



▶ **Fig. 2** **a** Classification of the studies on medical apps to the areas of otorhinolaryngology and their percentile distribution. **b** Assignment of the studies to the year of publication.

3.1.1. Studies on apps for audiometry

Eleven studies were found on the topic of "apps for audiometry" [16–26]. They mostly evaluated apps comparing the audiometric function of the smartphone with usually performed tone audiometric tests [16–22, 24–26]. Only one publication mentioned an app for a speech audiometric test [23]. Some articles described deviations of 10 dB [26] up to 25 dB [17] regarding the accuracy of audiological examinations performed by means of the smartphone. However, the smartphone was sometimes used in the free field so that the accuracy was limited [17]. Other authors reported a high accuracy of smartphone apps [16, 20], especially when earphones were used [22]. A professional setting for the application of the user software reached a higher degree of accuracy compared to a setting selected by the user [16, 20]. The publication that evaluated speech understanding revealed a high consistency of the speech understanding values ($r = 0.89$) comparing measurements with the smartphone and audiometric examinations [23]. Two studies investigated different audiometric apps with regard to the evaluation of hearing disorder in older patients [17, 18] and the possible detection of sudden hearing loss [20]. Despite the high correlation of the measured values with those of certified devices, the conclusion was drawn that a clinical decision with regard to therapy should still be based on reliable and verified clinical parameters. A review article on "apps for audiometry" from 2016 identified 30 apps with audiometric function,

but only 6 had been previously tested in trials. The authors came to the conclusion that this type of app may be a good assistive tool, but because of non-existing or varying study results and sometimes incorrect function still only clinically tested and certified devices should be applied for diagnostics [27].

3.1.2. Studies on apps for sound level measurement

Five authors investigated the measurement of sound levels by means of apps installed in smartphones [28–32]. In one publication, also the use of an Apple iPod was described [32]. In the different studies, the accuracy of the measurements was rated with "satisfactory" [13, 14] down to "significant deviations" [15, 16]. One publication could show that the additional use of a microphone leads to a higher measurement accuracy [30]. Compared to other devices, the iPod was also suitable to measure the average sound level during the day. However, the results of conventional measurements of the sound level were more accurate [32].

3.1.3. Studies on apps with regard to the complex of education

In this category, 5 studies could be identified focusing on different aspects [33–37]. Two publications dealt with apps aiming at the improvement of teaching for ENT residents. One app had been developed to share specific contents with other users and to ask questions to them [34]. This app was mostly used by young staff members spending their internship in ENT departments. After one year, the participants showed a better teaching status compared to the beginning, but the paper did not make a comparison to a control group. Again without control group, another trial investigated the use of a quiz app with figures of different pathologies of the tympanic membrane [37]. After implementation of the app, a better understanding of tympanic pathologies was described compared to the situation before using the quiz app. Another article was based on a survey of US American otolaryngologists asking for the need of a homepage and/or app optimized for smartphones with regard to information and literature research. Based on these data, a website was created that shall be available also as app in the near future [33]. One publication evaluated the use of smartphones for healthcare information referring to the application of hearing protectors for farm workers [35]. A superiority of the app-based information and training could not be found compared to the classic personal training. A summary about the use of apps in the category of "hearing" including previous years up to 2015, can be found in a review article published this year [36]. It describes apps for healthcare providers as well as those intended for patients.

3.1.4. Studies on apps referring to tinnitus

In this category, a total of 6 publications were found [38–43]. On one hand, apps have been evaluated that may be applied for tinnitus retraining therapy. The use of those apps had a positive effect because the burden caused by the tinnitus could be reduced [39, 43]. On the other hand, apps have been investigated that assess the presence as well as the stress caused by tinnitus. Regarding the longitudinal description of symptoms, the apps proved to be well-applicable [41]. The use of the app also improved the coping strategy in the context of tinnitus [38]. Other articles examined if tinnitus pitch masking may be simplified and improved by using apps, which could actually be confirmed by these studies [40, 43]. Another publication investigated if the recruiting of tinnitus patients for participation in studies may be performed via apps. This was generally possible but the classic recruiting strategies achieved more homogenous patient cohorts [42].

3.1.5. Studies on apps regarding "endoscopic" and "otoscopic" imaging

Because of the meanwhile highly sophisticated smartphones cameras, they may be used as substitution or addition to classic endoscopy. For this purpose, however, always a special adapter to be fixed to the usual endoscope or otoscope has to be applied. A total of 5 studies could be identified that described the use of smartphones for imaging in otorhinolaryngology [44–48]. Two papers compared the quality of the images with classic procedures. In both studies, a high quality of the app-based imaging could be revealed which fosters the use of smartphones for endoscopic examinations in clinical routine [47, 48]. Another publication described the possible application of the devices by non-experts, e. g. parents, for telemedical findings [45]. However, a clearly lower significance was found for the images made by non-professional compared to professional users [46]. Another publication contains data on the development of smartphone-assisted imaging. It also gives an overview of the systems available on the market [44].

3.1.6. Studies on apps regarding sleep medicine

In this category, a total of 6 articles could be identified [49–54]. A pilot study could show the effective measurement of snoring and other symptoms of obstructive sleep apnea by means of an app used during the sleep-medical examination. The application at home, however, was described as problematic, because it may be associated with significant disturbing factors [51]. Another article investigated if the sleep duration can be improved by applying a training and monitoring app, which was possible in some subjects [55]. The improvement of the obstructive sleep apnea syndrome (OSAS) by app-controlled weight reduction was also examined. The app users achieved a weight loss; however, it had no impact on the OSAS [50]. The four review articles on apps regarding "sleep and snoring" [49, 52–54] criticized the intransparent management of the assessed data in addition to the fact that often no scientifically confirmed evidence was mentioned or found referring to the analyses and statements of the apps.

3.1.7. Studies on apps regarding the voice

Four publications elaborated apps for the category of voice [56–59]. Two of them showed that a multidimensional voice profile can be created by means of such an app. The authors came to the conclusion that the apps may provide results comparable to conventional devices and may be well implemented in a clinical setup [56, 58]. Another study could show that the quality of microphone recordings with smartphones can be compared to those of microphones that are usually applied in studies on the voice quality [59]. Another trial assessed if the voice quality of students who had to give a presentation can be measured and controlled with such an app. At the time of publication, the study had not been completed but first results showed that the app may be applied successfully to assess the voice quality [57]

3.1.8. Studies on apps regarding balance

Three articles could be found on this topic [60–62]. One study rated an app that may assess and evaluate Unterberger stepping test [62].

The smartphone held by the subject was able to measure the angular deviation as exactly as it is recommended for clinical routine. Another app is considered as positive that measures the visual vertical line in pediatric patients [60]. Another publication deals with the repositioning maneuver in cases of positional vertigo. The authors drew the conclusion that the respective app may be helpful in the learning process of performing those maneuvers [61].

3.1.9. Studies on apps regarding swallowing

Two studies describe the development [63] and the verification [64] of apps aiming at reducing dysphagia after tumor therapy. In the 1st article, important functions of an app for therapy of dysphagia were identified that were based on structured interviews with the affected individuals [63]. They contained biofeedback, a clear description of the pathologies, and instructions for exercises. The second publication showed that the use of an app for therapy support in the context of dysphagia is rated very positively which could be confirmed by a positive data logging [64].

3.1.10. Studies on apps regarding hearing aids

A total of 7 publications were found on this topic [65–71]. Five studies investigated if the microphone technology of the smartphone may be used to improve speech understanding [69, 70]. Two trials examined the use of specific apps with noise suppression algorithms to improve speech understanding [68, 71]. All these studies revealed an improvement of the speech understanding in the experiment, in some of them this effect could be confirmed in test subjects. However, it was not described if these technologies have already been included in current hearing aids. In another study, the impact of the implementation of new technologies concerning hearing aids and smartphones on the relationship between the treating physician and the patient was evaluated [67]. For this purpose, cases were established and structured interviews were made with physicians and patients. The implementation of new technologies may have a positive impact on the relationship. Furthermore, an article was published describing the theoretical basis for a future study. Here, the patients' acceptance of new mobile technologies in hearing aids shall be investigated systematically. Up to now, only criteria for the literature research as well as inclusion and exclusion criteria have been defined and published [66]. Unfortunately, no further data or results were available at the time of manuscript submission.

3.1.11. Studies on apps regarding head and neck cancer

Three studies dealing with apps in teh context of head and neck cancer could be retrieved [72–74]. In one article, a patient cohort that also included head and neck cancer patients was asked by means of a questionnaire if they could imagine that cancer therapy and also the quality of life could be monitored and probably even controlled by an app [72]. According to the evaluation, predominantly younger patients considered it useful to implement data via an app and to benefit from processing. Critical aspects, however, were mentioned with regard to data security and the complex user interface. In another trial, an app was used that is supposed to monitor the individual quality of life of head and neck cancer patients and to improve it by giving specific recommendations [74]. According to the authors, the participants of the study were satisfied with the product. Thus, the app will be further improved in order to achieve a sustainable increase of the quality of life. The early detection of head and neck cancer as well as its improvement by means of an app were discussed in another study [73]. In this app, a questionnaire is filled out regarding risk factors for the development of head and neck cancer, such as for example noxae or unprotected oral sex. The app also allows including images of the affected mucosa and to have them assessed by experienced physicians. It has been tested for high-risk patients for developing head and neck tumors. The specificity and the sensitivity were not as high as by the evaluation of the clinical history and the direct examination. However, the authors are convinced that such an app may be helpful to early detect head and neck malignancies.

3.1.12. Studies on apps regarding allergology

In this context, a total of 6 articles could be identified [75–80]. One publication described the theoretical basis and the possible development of an app in the field of allergic rhinitis [79]. Affected individuals can perform a screening procedure for detecting allergic rhinitis. For physicians, further tools are available, for example the digital assessment of symptoms via a visual analogue scale. In a position paper to which the german society of Oto-Rhino-Laryngology contributed, the digital assessment of symptoms of allergic rhinitis via app was described as useful [75]. Accordingly, this issue was validated in a follow-up study [76]. Another publication could show that the complaints assessed by means of such an app correlated with the subjects' absence from work which confirms the function and accuracy of the app [78]. By means of this app, the allergic symptoms under medication could be controlled in a patient cohort [77]. A case report described a targeted desensitation in 2 patients with allergic rhinitis who had overlapping sensitization of allergens. The symptoms recorded by the app in daily intervals were correlated with the pollen calendar; then the allergens with the highest sensitivity were assessed and the patients were hyposensitized against them [80].

3.1.13. Studies on apps regarding "hearables"

Hearables are earphones that are equipped with additional functions such as for example wireless connection to a smartphone or sensors for medical monitoring. Three studies could be found in this regard [81–83]. One publication investigated the possibility to measure neuronal auditory evoked potentials in the auditory canal by means of such a system [81] with the objective to improve the adaptation of hearing aids in particular in complex hearing situations. Hearables with several electrodes have been developed that were able to measure reproducible potentials via direct contact with the skin of the auditory canal. According to the authors, the sensitivity depends on the position of the contacts. Two other studies measured physiological parameters such as for example the heart rate, EEG, and speech synchronous respiratory movements, with specifically developed hearables [82, 83]. However, very complex signal processing strategies were necessary to identify the signals.

3.1.14. Studies on apps regarding miscellaneous areas

"Miscellaneous areas" summarize fields for which only one trial could be found [84–87]. One of them dealt with an app that allows planning of rhinoplasty [87]. The function of the app and its applicability were evaluated by experienced surgeons and compared to the gold standard, i.e. surgery planning based on imaging. The app facilitated the preoperative planning and the patient information about the surgery could be simplified. Another app contained predefined signs and videos in sign language [84]. One publication gave an overview about 9 apps that may be

used in the context of gastro-esophageal reflux disease [85]. According to the authors, most of these apps have significant deficiencies with regard to their function and/or user-friendliness. In the context of cochlear implantations, a publication is available describing an app that enables the user to modify the implant setting [86]. First evaluations revealed that the CI users were able to modify the setting of their devices. Even if the individual program created by the user differed significantly from the previous settings, comparable speech understanding could be achieved.

3.2. Conclusion

In the context of a literature research, many trials could be found that dealt with apps regarding Oto-Rhino-Laryngology. Since 2013, when the first study on this topic had been published, the number of publications has grown significantly. This makes clear that the discipline of Oto-Rhino-Laryngology works increasingly on this topic also on a scientific level. Most studies, however, were descriptive and/or did not include control groups so that reliable statements on the advantages of app-based approaches can hardly be made. This fact emphasizes the necessity to generate standards how apps may be assessed and evaluated scientifically in the future. Those standards might then be a precondition for further certification in order to use apps in patient care, research, and even administration without legal concerns.

4. Survey on "Apps in Oto-Rhino-Laryngology"

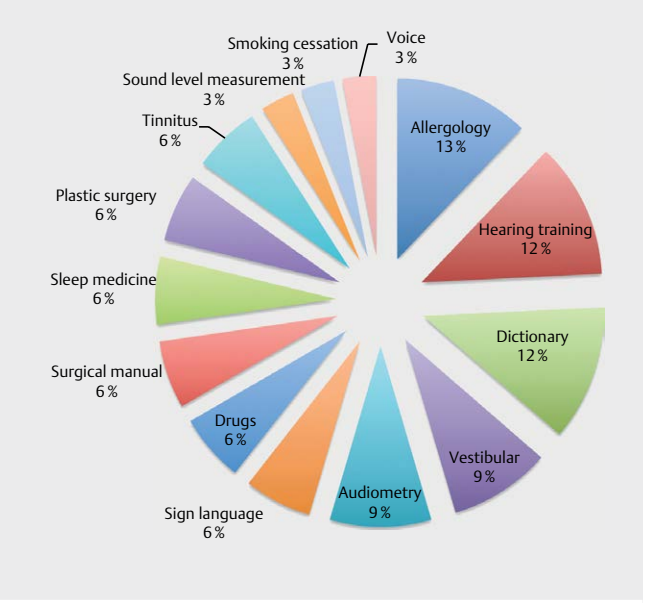
The assessment of an app, in particular for the use in clinical routine, is rather complex because standards are not available and many parameters have to be observed. Developers praise their apps without mentioning the risks. Without performing objective and standardized evaluation, the application in healthcare and the use in clinical studies may lead to significant, even legal issues. Thus, apps should be evaluated based on a standardized assessment catalogue. In this way, it would be possible, at least to some extent, to have an objective evaluation if the product might be used in clinical routine. Such a catalogue was published in 2013 entitled "App Synopsis" [88]. The aim was to transparently assess mobile medical apps. The evaluation according to the "App Synopsis" should then be published in the stores as additional description of the available apps [88]. In this context, data have to be provided in the categories of "imprint", "rationale", "functionality", "validity and reliability" as well as "Retrieving information and administration". In addition, there are several subcategories such as for example questions on the developer and sponsoring, but also on data processing and storage [89]. As an example, the authors want to mention the publicly available assessment for the app "iSignIT" based on the "App Synopsis" [84]. Furthermore, also an "App Synopsis for Users" was developed allowing users to evaluate medical apps based on defined criteria [90]. This users' checklist encompasses 39 items that have to be answered with "yes", "no", or "unclear". The questions are categorized into "medical product", "purpose", "functionality", "scientific character", "limitations and limits", "risks", "reliability and contents", "data protection", and "imprint". The possible answers are displayed in the three traffic light colors so that the user is able to already assess the risk of application when ticking the items (red = high risk/green = low risk).

4.1. Concept of the survey

In order to give an overview which apps may be used in clinical routine in the field of otorhinolaryngology, an own trial has been initiated at the Department of Oto-Rhino-Laryngology of the University Hospital of Würzburg, Germany. For this purpose, all colleagues of the department were invited at the beginning of May 2018 to evaluate a freely selectable app according to the above-mentioned "App Synopsis for Users". An question, if the app is related to the sub specialization "Ear", "Nose", "Throat", or "Others" were added to the questionnaire. In addition, the question was asked if the app was used in clinics or in research and a short description as free text was requested. An online questionnaire was developed and the access link was sent to the participants via e-mail. The answers were collected until June 30, 2018.

4.2. Overview about the evaluated apps

A total of 33 apps were included. Twenty three apps were tested on the operating system of Apple iOS, and 10 apps on Google Android. Fifteen apps were assigned to the field "Ear", 6 apps to the field "Nose", 10 apps to the field "Others" and 1 app to the field "Throat". The evaluated apps could be summarized in 14 groups. Four apps were examined that allowed a digital forecast of pollen in the field of allergology. Two apps were investigated that provide support for communication in sign language. In the field of neuro-otology, 3 apps were tested that dealt with instructions for diagnostics and/or therapy of balance disorders. Furthermore, 3 apps on hearing tests and 4 on hearing training after cochlear implantation were evaluated as well as a system on sound level measurement by means of a smartphone. Two apps comprised the correct dosage of drugs. Four apps included different dictionary functions for the discipline of otorhinolaryngology and 2 apps contained digital surgery manuals. In addition, one app was found on smoking cessation, two apps were analyzed from the field of sleep medicine with sleep monitoring, one app in the field of phoniatrics/voice, and 2 apps on tinnitus therapy. ▶ **Fig. 3** depicts the



▶ **Fig. 3** Percentile distribution of ENT-specific apps assessed based on the "App Synopsis for Users".

distribution of the single categories, ▶ **Table 3** contains a detailed description of the functions of the evaluated apps.

4.3. Evaluation of the questionnaire

The detection of possible risks when using an app was an important factor for the assessment of the survey. Thus, primarily questions and answers were evaluated that led to marking a red field when ticking "No". Already this should serve as a signal for the user that the application software has a clear deficiency in this item. The first question leading to red marking when ticking "No" was "Is the described purpose of the app easy to understand?". In 4 apps, this question was answered negatively. The question "Is the description of the functions and performance features clear and understandable?" was answered with "No" for 3 apps. The question "Does the explanation make clear that the development is based on the current status of science and technology?" was negatively answered in 13 cases. Also the question "Can information be retrieved about the authors of the contents, including their names and qualifications?" was answered with "No" in 13 cases. In 17 cases, "No" was the answer to the question "Are the sources of the contents mentioned and are they reliable?"; the question "Can you use the desired functions of the app even without inserting your personal data? Is the data entry optional?" was answered with "No" in 6 cases. The question "Is there an option to control data collection or data transmission and are you informed about how you may modify the settings?" was answered negatively for 14 apps.

According to the above-mentioned rules, the positive answer to all the questions is associated with high application safety. The evaluation, however, showed that only 4 apps (12 %) reached this result. Tolerating one additional "No", which then includes 2 further apps (6 %), only 18 % of the apps provide sufficient safety for use. The questionnaire contains two other questions that are particularly relevant since their positive answer leads to marking with green, i. e. a recommendation for use. The first one is the question "Is the app a medical product (is it CE certified or FDA approved)?" Only in two cases, this question was answered with "Yes". Also the question "Is the app based on scientific trials, and are they reliable?" was only answered positively in 2 cases. The evaluation revealed that only one of the evaluated apps achieved "Yes" for both questions. Considering the combination of positive and negative questions, it became obvious that none of the evaluated apps received a rating with "Yes" for positive questions and no rating with "No" for negative questions.

4.4. Conclusion

Overall, the assessment of the apps based on the "App Synopsis for Users" revealed that none of the investigated apps can be recommended unlimitedly for use. Unfortunately, the possibilities to certify apps (as medical product or CE marking) are only rarely used in the discipline of otorhinolaryngology, as in other medical fields as well. Often the data on the current status of science and technology are not sufficient, which should, however, be the standard for medical apps. But also the missing transparency with regard to limitations and limits as well as a lack of information on data protection and risks in the context of using the app has been complained. Anyhow, the application of the structured and systematic assessment catalogue on the evaluation of medical apps leads to the fact that such applications may be evaluated with a rather low time effort. In this way, the user may retrieve the necessary information about the weaknesses as well as the positive aspects of the software. Every user should check after evaluation of the benefit if the benefit of using the app outweighs the risks.

5. Development of an App for Training of the Mimic Muscles in Cases of Facial Nerve Palsy

After investigating intensively the apps on the market with regard to otorhinolaryngology, it was the objective to develop a flmpeccable and transparent app for the user in terms of functionality and reliability of the content. Restrictions and limitations as well as risks should be taken into account in the development process. Thus, an application should be developed meeting the criteria of a good and high-quality app (chapter 3). This includes all legal requirements concerning data processing and storage; furthermore, the essential aspects of certification as a medical product should be included.

5.1. Conception

In the conceptual design, several topics and forms of implementation were initially taken into consideration. Of course, the app should be innovative, realizable with manageable efforts, easy to use, and clinically useful. Generally it is important in the development process to clarify whether a native, hybrid, or web-based app architecture should be chosen. In this context, an app is said to be native when it is produced for a specific operating system of the particular mobile device with a corresponding programming language and development environment. In contrast, a web-based app is a website that is optimized for being displayed on mobile devices, but can also be equipped with complex functionalities. The main advantages of this approach are the relatively fast and cost-efficient implementation as well as the platform independence. Thus, web-based apps can easily made available e. g. for iOS as well as Android devices, ultimately without having to take the "detour" via the Apple AppStore or Google Play Store for distribution. Disadvantages of web-based applications are the sometimes significantly limited usages of hard- and software of the devices, such as e. g. camera, microphone, location services and security features. Furthermore, the user is usually dependent on an internet connection. Similar to websites, hybrid apps are based on simple scripting languages (HTML, CSS, and JavaScript) and are implemented through a respective framework as a kind of container in a specific mobile architecture (e. g. iOS or Android). Externally, a hybrid app appears like a native app, is able to access many hard- and software features of the devices and can be used offline. However, among other aspects, the low performance is a disadvantage.

5.2. Selection of the topic

Since the website of the ENT Department of the University Hospital of Würzburg is already designed for optimum display on desktop computers, tablet PCs and smartphones, the idea of developing a (hybrid) app for external presentation of the clinic was rejected. A clinical topic emerged as a suitable task for a new app: we decided to focus on specific instructions for targeted training of the mimic muscles for patients suffering from facial nerve palsy. In the clinical context, the need for optimization became obvious. Facial training

▶ **Table 3** List of all app functions mentioned in the survey.

Area (in alphabetical order)	Short description of the apps
Allergology	App to identify the daily pollen forecast with therapy recommendations. Spatial distribution is possible.
	App to depict the pollen flight in a certain place (by given the ZIP code). Forecast for 7 days, including allergenic potency for 15 frequent allergens.
	App for pollen forecast. Inclusion of own locations and plants is possible, individualized warning messages, information on allergy-triggering plants.
	App provides local pollen forecast. Day, location, and type of pollen may be set. Current warnings and manifestation of the pollen flight.
Sign language	Single signings may be selected and are displayed in a short video clip.
	Dictionary of the German sign language for iPhone with more than 19,000 items and video clips. For targeted learning, lists may be created and played in a test mode with elimination of the subtitles.
Balance	App with training instructions and video clips for patients for therapy of vertigo complaints.
	App for depiction of the activity of the semicircular canals when moving the head; normal and pathological findings, demonstration of the vestibular-ocular reflex (VOR).
	App for monitoring for patients with vertigo disorders. Data on symptoms, medical consultations, and drug intake are stored.
Audiometry	The app allows performing separate hearing tests for both ears by earphones (6 min). The results are intended to give an orientation for healthy and hearing-impaired subjects as well as provide health care related preventive information. Combined with another app, the hearing experience for music can be optimized. In addition, further techniques (hearing test with background noise: "test the cocktail party effect"), surveys, recommendations for hearing protection as well as a printout of the tone audiogram are available. The app should support medical consultation regarding hearing aids.
	App to perform hearing tests for both ears separately. Graphical display of the results as tone audiogram. Comparison of the results within the age group.
	App with digital hearing test.
Hearing training after cochlear implantation	Hearing training for CI patients to get used to new hearing impressions and to foster speech understanding.
	Hearing training with 11 exercises with 10 items each for hearing training after CI implantation. Differentiation and identification of vowels and consonants (3 exercises), differentiation and identification of real words (8 exercises).
	The app provides a structured training program for CI hearing training on three different difficulty levels (easy, moderate, difficult). The items are classified according to the training literature. The subject has the possibility to listen to a hearing example (flashing loudspeaker icon) and to choose an answer from a fourfold table.
	App for hearing training after cochlear implantation provided by the manufacturer.
Sound level measurement tool	The app measures the current sound level in dB and indicates consequences for hearing.
Drugs	App for application recommendations regarding medication during pregnancy and breastfeeding.
	Drug dictionary for use in clinical routine.
Dictionaries	The app provides basic anatomical as well as clinical knowledge about organ systems of otorhinolaryngology and their diseases for medical staff. The contents are classified based on different anatomic organs. Further, an overview about typical diagnostic findings (CT scan, audiometry), TNM classification, and ENT-specific anti-infective drugs is given.
	The app provides an overview of all common audiological examinations, their basics, and possible therapies.
	The app provides the possibility to download literature from a certain publisher.
	Visualization of the human anatomy in a 3D picture. Learning of muscle and bone names with size, location, and labelling.
Surgery manual	Digital surgery manual for otorhinolaryngology.
	App-based surgery manual, written by experienced surgeons.
Plastic surgery	App explaining plastic surgeries of the face with descriptions and videos as well as pre- and postoperative pictures. Surgeries such as facelift, blepharoplasty, lid lift, facial implants, rhinoplasty, otoplasty, liposuction of the neck and botox injections are listed.
	Additional option to use a simulator for visualization of modifications of the nose or face (e. g. lifting).
	App with tools so that the user may visualize the result of plastic surgeries. Two options of "zoom" and "reshape" are available. In this way, the results of interventions such as rhinoplasty, liposuction, or plastic face and breast modifications can be simulated. If the user is interested in surgery, he may request professional consultation via the app.
Smoking cessation	App with a scoring system for smoking cessation (savings of money, hour counter, health check, target definition).
Sleep medicine	App for determination of the depth, duration, and quality of sleep, also depending from physical activity, moon phase, and the heart rate. Possibility of waking up in a time window of 30 min during lightest phase of sleep.
	App for assessment of the sleep phases, sleep efficiency, sleep diary, dream diary, sleep phase alarm.
Voice	App for rapid diagnostics and documentation of the voice quality. Two questionnaires with possible selection: questionnaire to assess the vocal self-conception and voice handicap index 12 with printout of the protocol, text example with recording function, sound holding period with "best of 3" in seconds. Additionally, there is a visual analogue scale for documentation of further questions.
Tinnitus	The app allows assembling an individual sound plan from an integrated or own music library. The sounds are supposed to attract the individual's attention in order to distract from tinnitus.
	App offering different sounds for tinnitus therapy.

as a non-invasive therapy approach is recommended for patients with facial nerve palsy of various origins and comprises functional motor exercises for the reactivation of the mimic muscles in the sense of a neuromuscular training. The currently available studies show that a well-structured therapy within the framework of an interdisciplinary concept may achieve good therapeutic results contributing to avoid synkinesis or hyperkinesis [91–94]. Currently available instruction forms revealed a high need for improvement, since the visual control by using a mirror is from our experience associated with a low compliance.

From this situation the idea came up to develop an app for structured facial exercises with visual feedback via the front camera of the smartphone. A search in the Apple AppStore and the Google Play Store, as well as a literature research via PubMed revealed that up to now no adequate app exists with the stated objective. Only one paid app in English language provides facial training, but only in the form of a digital exercise sheet without visual feedback [95]. To make the best use of the device hardware, we chose a native iOS app architecture, which may be considered as particularly safe and user-friendly. The implementation for Android devices in the further course is planned.

5.3. Structure of the app

Various basic functions of the app were elaborated. For introduction into the topic, understandable explanations on anatomy and (patho-) physiology of the facial nerve as well as on the functioning of the app should be provided. One central aspect of the app was a training mode with step-by-step instructions for mimic exercises with visual feedback via the front camera. Hereby, the instructions should be offered as text and for better comprehensibility also via an animated "smiley system". A timer should display the training progress. After completing training, a success message should contribute to positive reinforcement. (Optional) training reminders via the iOS Notification Center might increase the long-term compliance. Furthermore, an imprint with respective indications of the liability requirements and data protection according to the Basic Regulations of Data Protection is obligatory. As a future supplement, a determination of the degree of paralysis by the application of a defined score is being considered. Initially, this might be performed manually based on one or several common score systems (Stennert's paralysis index, House-Brackmann score, Facial Grading System), theoretically even the application of the face recognition function via the TrueDepth camera of current or future iPhones would be conceivable. Pourmomeny et al. could show that a software-based grading system provides reliable results in the context of facial nerve paralyses [96]. The score values assessed in this way could be mapped in a history diagram. In order to prevent data abuse, the data should be stored exclusively on the respective terminal device.

5.4. Graphic design and programming of the app

The graphic conception and the layout were done with Adobe Photoshop, Adobe Illustrator and Sketch app. Whereas the mentioned Adobe products are the industry standard for pixel- and vector-based image processing, Sketch app is specifically optimized for the user interface design of mobile devices and thus allows a first simulation of the future app. In the conceptual phase, the requirements of the corporate design of the University Hospital of Würzburg were complied. The aminations of the facial movements for mimic training were created in Adobe After Effects and exported with the Bodymovin Plugin in order to be finally integrated into the Xcode Project via the open source framework Lottie. This as well as other frameworks were integrated into the project with the dependency manager Cocoapods. Programming via Swift and Objective-C and the actual creation of the graphical user interface were performed with the development environment Apple Xcode. This software allows to create the individual pages and link their operating elements with the program code. One helpful feature of Xcode is that the app can be tested on virtual as well as physical terminal devices of several generations during the development process and thus be optimized continuously (▶ **Fig. 4**).

5.5. Further development and validation

After successful development of the app, it is planned to evaluate it in the context of a clinical trial. For this purpose one could use the possibilities of the Apple Research Kit, which offers highly attractive options for rapid and large-scale data collection without media discontinuity and which has already been implemented by internationally leading medical institutions [97]. In addition, the app will also be described according to the objective criteria for medical apps of the "App Synopsis" [88] and also evaluated based on the defined criteria of the "App Synopsis for Users" [90].

5.6. Conclusion

During the development process of the app for training the mimic muscles after facial nerve palsy, it was possible to conceptualize an application software and to program first versions that have the potential to meet the criteria of a good and high-quality app. The further development and validation of the app will reveal if it is of functional value and provides a benefit for the patients. This knowledge will be the basis for the future development, but also for a possible certification of the app as medical product.

6. Summary and Outlook

The use of mobile information and communication technology in medicine, among others also medical apps, is defined as "mobile health". This area gains more and more in importance because it provides new solutions for the healthcare system. The awareness of healthcare providers that digitization has to find its place also in medicine has significantly increased during the last years which led to establishing workgroups or task forces of several professional organizations. The implementation of this technology provides important advantages such as for example the direct availability or the independence of opening hours, which allows a high flexibility in daily routine. However, the new technology also bears risks such as e. g. an unfiltered data storage that may lead to an impairment of privacy. Already today the relationship between the physician and the patient is influenced by these new technologies, which makes clear that a thorough and detailed analysis of the topic is essential.

The number of medical apps that are available on the market is continuously increasing, even those concerning the discipline of otorhinolaryngology. The number of applications in German that may be assigned to this field is rather low with about 2 %. Compared to the whole group of medical apps, ENT-related apps are provided more frequently with updates, their data volume is higher and bet-

ter described. This might be an indication for the higher responsibility of the developers and a better quality of the apps. However, a higher percentage of apps is fee-based and only for a few ones the costs are paid by the health insurance companies.

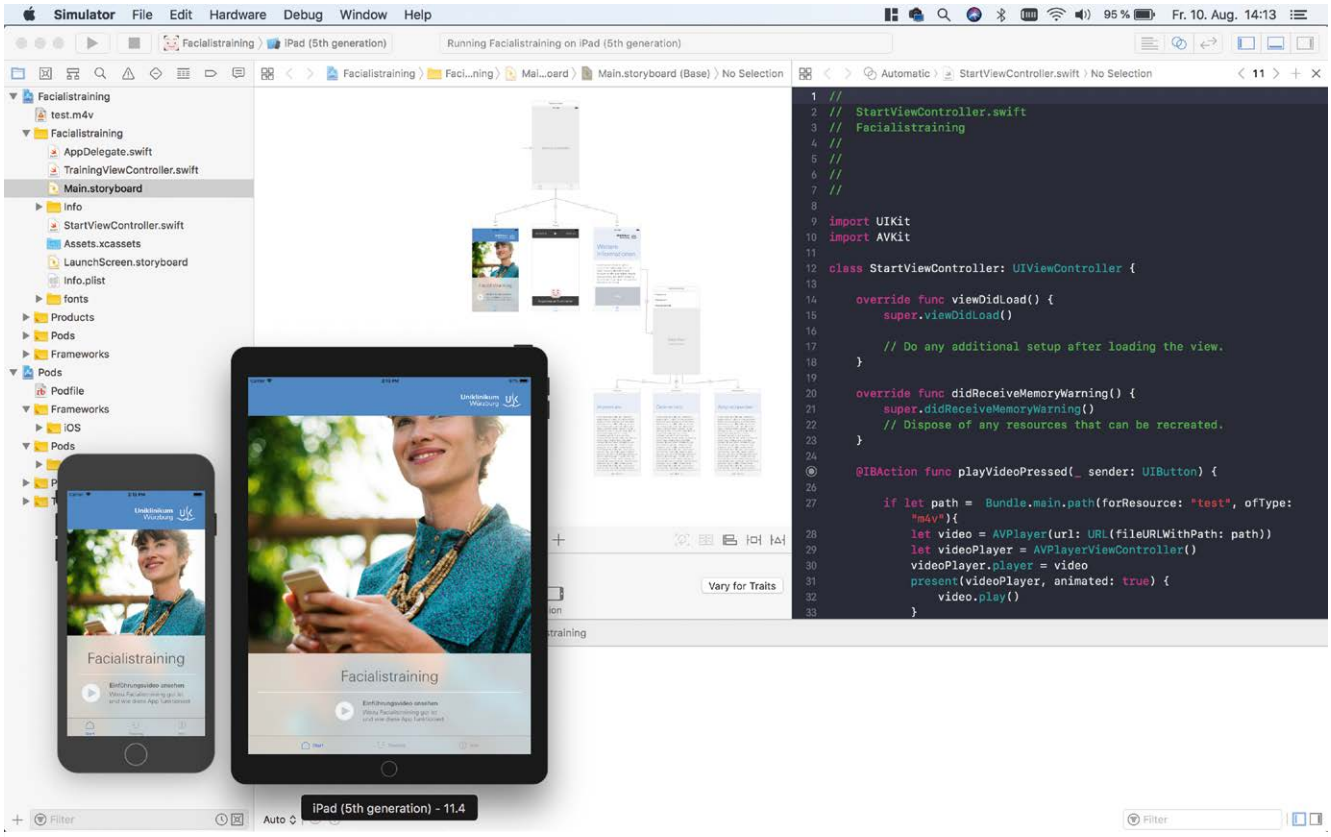
Medical apps can be medical products or assume their functions. This leads to a particular legal aspect, especially in cases of compensation claims. The user may not expect that an app is a medical product even if it may be applied in a medical context. The developers determine if they want to declare the application as medical product which then leads to a very extensive approval procedure. That is why most providers decide against certification as medical product because the apps then have to meet fundamental requirements with regard to documentation, software development, tests, validation, serviceability, risk management, and version management. On the other hand, the providers are not even aware of these problems. For physicians, this means a particular responsibility because they owe a treatment to the patients that is acknowledged according to generally accepted medical standards. So if they recommend an app that is not certified as medical product, they may theoretically be held liable because of the use of unsuitable instruments. This aspect also applies when the app is used apart from its actual objective. So a physician may be expected to show great diligence when selecting and recommending an app in order to act in a liability-preventive way. Other quality labels are rarely found. Already because of the enormous number of apps found in the different stores, it is not possible to conduct nation-wide examinations. Furthermore, due to the missing transparency, it is rarely obvious which evaluation criteria are set by certification providers. Increasingly, also non-medical developers try to take roots in the field of medical apps without having sufficient experience and expertise with regard to medical topics and neglecting respective standards and even regulatory requirements. Sometimes the developers of the apps overestimate the technical features thus giving the users a false sense of security and lead them to a possibly dangerous misinterpretation of their health status.

Regarding the effectiveness of medical apps, scientific evidence is still missing which is also reflected in the low reimbursement by health insurance companies. If the medical app is nonetheless useful, it would be desirable to have a suitable design concerning conception and performance of the application. It would be characterized by the fact that the users always experience the security to work with a thoroughly developed application that clearly excludes risks for health or the social and economic situation as well as risks for their environment. The use of an app designed in this way may lead to high satisfaction and include an appropriate probability of therapy success. In contrast, poorly conceived and designed apps lead to low acceptance without long-lasting success.

In scientific literature, numerous publications are found on medical apps, but most of them focus on a narrow application spectrum so that a transfer to the whole sector and general conclusions would lack of a scientific basis. However, it could be shown that some smartphone functions such as for example the reminder function or the independence concept may lead to a positive assessment of such apps and thus to an improved participation in healthcare processes. A literature research for the present manuscript could identify more than 70 trials that could be assigned to different sectors of otorhinolaryngology. Those were in particular the fields of “audiometry”, “sound level measurement”, “education”, “tinnitus”, “endoscopic and otoscopic imaging”, “sleep medicine”, “voice”, “balance”, “swallowing”, “hearing aids”, “head and neck cancer”, “allergology”, “hearables”, and “miscellaneous”. In the majority of the publications, only the new function or the app itself was described and control experiments were missing so that the scientific quality of the articles has to be considered as clearly limited. Nonetheless, this literature research allowed getting an overview about the existing application spectrum of smartphones and apps in otorhinolaryngology.

The survey conducted for this manuscript at the ENT Department of the University Hospital of Würzburg revealed a broad spectrum of applications in the field of otorhinolaryngology. A total of 33 apps were mentioned that could be assigned to the field of our discipline. They included the areas of “allergology”, “sign language”, “balance”, “hearing test”, “hearing training after cochlear implantation”, “sound level measurement”, “drugs”, “dictionary”, “manual”, “plastic surgery”, “smoking cessation”, “sleep medicine”, “voice”, and “tinnitus”. The apps were evaluated based on a standardized assessment catalogue, the so-called “App Synopsis for Users” allowing a reliable assessment of how safely such an app may be used in healthcare. This checklist contains a total of 39 items that can be answered with “yes”, “no”, or “unclear”. The items are classified into the categories of “medical product”, “description of the purpose”, “functionality”, “scientific aspect”, “limitations and limits”, “risks”, “reliability and contents”, “data protection”, and “imprint”. The answers to some questions are marked in red, yellow, and green so that the user may already assess the risk of the app when ticking the answers (red = high risk, green = low risk). Overall, the evaluation with this assessment tool revealed that none of the apps could be recommended unlimitedly for use. It became particularly obvious that the option of certifying an app (as medical product or CE marking) was only rarely realized. Often, information on the current state of science and technology is missing. But also the lack of transparency with regard to limitations and limits as well as risks concerning data protection and the use of the app were complained. The use of this structured assessment catalogue allowed a precise and clear evaluation of the apps with low time consumption. Thus, a tool is available that is able to simply outweigh risks and benefits of medical apps.

Having analyzed the apps referring to otorhinolaryngology that are available on the market, the idea came up to develop an app on our own that is transparent and well-balanced with regard to its functionality and reliability of the contents. All legal requirements regarding data processing and storage should be met and real chances for certification as medical product should be realized. After careful research, we decided to develop an app for training the mimic muscles for patients suffering from facial nerve palsy because a clear need in this context was apparent. It is well-known that targeted motor exercises for reactivating paralyzed mimic muscles in the sense of neuromuscular training may lead to measurable progress and furthermore contribute to avoid synkinesis and hyperkinesis. This acknowledged and scientifically evaluated rehabilitation concept is also suitable for a mobile application. On the app market, currently no comparable application can be found; only digital training instructions are available. The basic functions of the app contained well-understandable explanations about the anatomy and (patho)physiology of the facial nerve, a training mode with instructions for mimic exercises with visual feedback via the front camera, and a reminder function. In addition, the app should include indications on the lia-



▶ **Fig. 4** Graphic conception, layout, and simulation in the program "Sketch App".

bility requirements and on data protection with regard to the new "Basic Regulations of Data Protection". The conception and the chosen procedure for the new app revealed that it is possible to develop application software having the potential to meet the criteria of a good and high-quality app. Further validation of the app will show if the functions are correctly implemented and also if it is beneficial for the patients. This knowledge will be the basis for the further development but also for a possible certification of the app as medical product.

In the context of the present manuscript, it was possible to show that medical apps gain increasingly in importance despite all associated risks. This also applies for the discipline of otorhinolaryngology because already apps are available for nearly all sections. They include the area of diagnostics, e. g. app-based audiometric examinations, imaging diagnostics by means of an app camera, or the definition of a voice profile. However, apps may also be used as a therapeutic tool as for example for tinnitus retraining, in sleep medicine, or for modulation of hearing aid settings. Additionally, apps can be found on the market that belong to the area of information provision such as for example dictionaries for ENT-specific diseases, digital surgery manuals, or pollen forecasts. Apps may also be used as documentation tools, e. g. for assessing allergic symptoms via a visual analogue scale or cancer-specific symptoms. All this shows that the use of such apps may encompass the whole field of otorhinolaryngology whereas crucial criteria of the quality and sustainability on a scientific level still have to be elaborated.

Thus, mobile health provides a large potential for the discipline of otorhinolaryngology. The nation-wide availability of this technique coupled with a pioneering spirit for practice-oriented applications represents a large variety of options for new approaches. The basis in this context must be the development of high-quality, reliable, and sustainable products corresponding to a standard that has to be clearly defined. In order to achieve this objective, the active participation of all protagonists in healthcare services is essential. One possibility to improve the quality of medical apps consists of establishing interdisciplinary and inter-professional quality criteria with regard to ethical safety, validity, risk appropriateness, transparency, and usefulness as well as technical factors. These criteria for identifying suitable apps and their evaluation that have to be found in an interdisciplinary consensus have to be communicated to all involved parties. Only in this way, the necessary transparency can be achieved that is the basis for a generally accepted use of such medical apps also in the field of otorhinolaryngology. By means of targeted quality management, all protagonists (i. e. developers, users, and medical professionals) may benefit on the long term. Digitalization in otorhinolaryngology does not only comprise the field of medical apps, the significance of this topic is also reflected in the motto of the 90th Annual Meeting of our society. The foundation of the commission on "Digital future in healthcare services" is also an element to establish mobile information and communication technology in the context of medical and healthcare services for the benefit of all. We have an exciting future ahead of us.

Conflict of Interest

The author states that there is no conflict of interests.

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