Mobile Applications Available in Germany Supporting Breast Cancer Patients During Treatment and Aftercare: a Systematic Review

Gesundheits-Apps zur Unterstützung von Brustkrebspatientinnen während der Behandlung und der Nachsorgezeit in Deutschland: eine systematische Überprüfung









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Key words

breast cancer, app, health app, privacy, remote breast cancer monitoring

Schlüsselwörter

Brustkrebs, App, Gesundheits-App, Datenschutz, Fernüberwachung von Brustkrebs

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ABSTRACT

Purpose Systematic evaluation of health apps designed to support and aid remote monitoring of patients during breast cancer treatment and aftercare.

Method A systematic search and assessment of apps was conducted using search terms: breast cancer; breast cancer therapy; and breast cancer aftercare. Evaluation criteria were user assessments, scientifically published benefits, user-friendliness, data protection, app individualization, motivation, and financial aspects. Up to two points (P) could be awarded per criterion. The lowest possible score was 0 P and the maximum was 28 P. Three examiners from different institutions independently assessed the apps according to the specified criteria. Reference value was defined as the average value given by the examiners. Apps with >18 P were classified as "recommended"; $\geq 11-\leq 18 \, P$ as "partially recommended" and $\leq 10 \, P$ as "not recommended".

Results A total of 776 apps (n = 24 from the Apple App Store, n = 752 from the Google Play Store) were identified via search query. After applying exclusion criteria, 36 apps (n = 1 from the Apple App Store; n = 35 from the Google Play Store) were evaluated. Using the mean point values of the examiners, 20 apps were classified as not recommended and 12 as partially recommended (≥11-≤18 P). Four apps were rated partially recommended by two examiners and recommended by one examiner. Three apps were rated as recommended by all examiners.

Conclusion Only a small minority of available apps meet recommendation criteria. Use of these apps may benefit breast cancer patients.

ZUSAMMENFASSUNG

Zielsetzung Eine systematische Auswertung von Gesundheits-Apps, die zur Unterstützung und Fernüberwachung von Patientinnen während ihrer Brustkrebsbehandlung und in der Nachsorgezeit entwickelt wurden.

Methode Es wurde eine systematische Suche und Auswertung von Gesundheits-Apps durchgeführt. Die folgenden Such-



begriffen wurden verwendet: Brustkrebs; Brustkrebstherapie; und Brustkrebsnachsorge. Auswertungskriterien waren: Benutzerbewertung, wissenschaftlich belegte Vorteile, Benutzerfreundlichkeit, Datenschutz, App-Individualisierung, Motivation und finanzielle Aspekte. Es gab ein Maximum von 2 Punkten (P) für jedes Kriterium. Die niedrigstmögliche Punktzahl war 0 P, und die höchstmögliche Punktzahl betrug 28 P. Drei Prüfer von verschiedenen Institutionen bewerteten die Apps unabhängig voneinander entsprechend vorgegebener Kriterien. Als Referenzwert wurde der Mittelwert der von den Prüfern vergebenen Bewertungen definiert. Apps mit > 18 P wurden als "empfehlenswert" eingestuft, ≥ 11-≤ 18 P als "teilweise zu empfehlen" und ≤ 10 P als "nicht zu empfehlen".

Ergebnisse Es wurden insgesamt 776 Apps (n = 24 vom Apple App Store, n = 752 vom Google Play Store) mithilfe der Suchbegriffe identifiziert. Nach Anwendung von Ausschlusskriterien wurden 36 Apps (n = 1 aus dem Apple App Store; n = 35 aus dem Google Play Store) bewertet. Basierend auf den Mittelwerten der Prüfer wurden 20 Apps als nicht zu empfehlen und 12 als teilweise zu empfehlen (≥ 11−≤ 18 P) eingestuft. Vier Apps wurden von 2 der Prüfer als teilweise zu empfehlen und von 1 Prüfer als empfehlenswert eingestuft. Drei Apps wurden von allen Prüfern als empfehlenswert bewertet.

Schlussfolgerung Nur eine kleine Minderheit der existierenden Apps erfüllen die empfohlenen Kriterien. Die Verwendung dieser Apps könnte für Brustkrebspatientinnen vorteilhaft sein.

Introduction

In the digital age, numerous aspects of everyday life are facilitated or supported by mobile applications (apps). Increasingly, this also applies to health issues. Health apps are mainly found on the topics of fitness, nutrition, lifestyle changes, and primary prevention. They perform various functions, such as reminding users of appointments, and providing information on diagnosis. They may also serve as a companion and advisor during treatment or rehabilitation, such as from various mental disorders or cancers.

In general, these apps behave like a personal assistant and often communicate through a speech recognition system such as Siri (iPhone), Alexa (Amazon), or Google Assistant (Google).

Health insurance companies are increasingly offering their members service apps. These are intended to facilitate online communication with health insurance, help with the search for a doctor, or manage health data. In the EU, medical apps must be approved as medical devices [1] and bear the CE marking [2]. However, the CE marking is not an indicator of a health benefit. In Germany, there are still no uniform quality criteria for such apps and their content, functions and data protection. Medical apps that have been tested by the Federal Institute for Drugs and Medical Devices (BfArM) for data security [3], data protection and functionality are listed as "digital health applications" [4]. These DiGA (= digitale Gesundheitsanwendung) are intended to help detect, monitor, treat or alleviate health conditions, and attending physicians have been able to prescribe them as a health insurance benefit since October 2020.

In this mapping review, breast cancer health apps with a focus on the treatment and/or aftercare phase were systematically evaluated for scientific accuracy (including whether scientific papers had been written evaluating them), user evaluation, user-friendliness, data protection, possibility of individualization, costs and motivational aspects. Motivational aspects were defined as the likelihood that a breast cancer patient would continue to use the app. According to these criteria, the apps were evaluated and categorized by three independent people into three categories: recommended, partially recommended, and not recommended.

Materials and Methods

Search strategy and app selection

A search for breast cancer apps was conducted in the Apple App Store (iPhone 8, software version 14.3) and the Google Play Store (Samsung Galaxy A5, Android version 8.0.0.) with a German IP address, and the apps to be evaluated were identified. The following keywords were used: breast cancer; breast cancer therapy; breast cancer aftercare. No restrictions were set on app store search parameters. The search took place on January 29, 2021.

Duplicate entries between the three search terms in the same app store and across the two app stores were excluded, as were applications in a category other than medicine or health and fitness.

Inclusion criteria: All apps available in the Apple App Store and Google Play Store with the term:

- Breast cancer
- Breast cancer therapy
- Breast cancer aftercare

Exclusion criteria:

- Apps about cancer in general
- Apps about other cancers
- Apps about medical guidelines
- Apps only about lifestyle (e.g. nutrition, meditation, sports, or similar)
- Apps not available in German and/or English
- Apps with downloads < 100+ in the Google Play Store (the Apple App Store does not specify the number of downloads)
- Apps no longer available or apps with error messages

A pseudo-profile of a cancer patient was created to generate app accounts where necessary and to test the app as described below.

The profile had the following characteristics:

Female German L. B. (username LindaLästermaus), aged 56 years (01.01.1966), 2 children (not pregnant, now in menopause), weight 76 kg and smoker of 12 cigarettes per day, breast cancer diagnosis in the left breast in 2018. Wire-quided breast-

conserving surgery (BCS) was performed with sentinel lymph node biopsy (SLNB). The tumor formula was pT1 c pN0 (Sn) M0, estrogen receptor (ER) 12%, progesterone receptor (PR) 10%, Her2+ (Cish negative), Ki67 = 30%. Adjuvant chemotherapy with epirubicin and cyclophosphamide, followed by docetaxel, then radiation and then treatment with anastrozole. So far, relapse-free. The patient complains of joint problems and a weight gain of 5 kg.

A German free email account (l.-b.@***.de) was set up in order to be able to create app accounts where required. If a question about data not listed above came up in the app, (e.g stage, degree or tumor size, breast cancer family history, resection margins) the default answer "I don't know" was chosen.

Data collection and evaluation process

A rubric for the assessment of breast cancer apps (> Table 1) was created based on the following criteria [5]: user rating, scientific accuracy, user-friendliness (the ability to adapt functions to the needs of individual users to motivate the user to interact with the app), data protection (data protection according to EU regulations, which ensures the security of users' medical data), app individualization, motivation (i.e. likelihood of a user downloading and/or continuing to use the app), and financial aspects. To assess motivation, user rating in the app store as the first motivation to download the app and scientific accuracy as a basis for discussion with treating physicians were assessed (see > Table 1 for more details). To assess scientific accuracy, a PubMed search was carried out with app names and/or the name of the development company. Where evaluations of the app appeared in PubMed search results, the PubMed impact factor of the journal was used for evaluation [6], with a higher impact factor resulting in the app being awarded more points (P). The privacy policy, where available, was examined for compliance with the European General Data Protection Regulation (GDPR) [7]. Available functions of each app and their performance in the test were briefly summarized.

The criteria are listed line by line in **Table 1**. Up to 2P could be awarded for each criterion. The maximum achievable value for an app was thus 28P, while the minimum was 0P. The sum of the points awarded were categorized as follows: Each app with > 18P was rated as "recommended", each app with $\ge 11-\le 18P$ as "partially recommended" and apps with $\le 10P$ were rated as "not recommended".

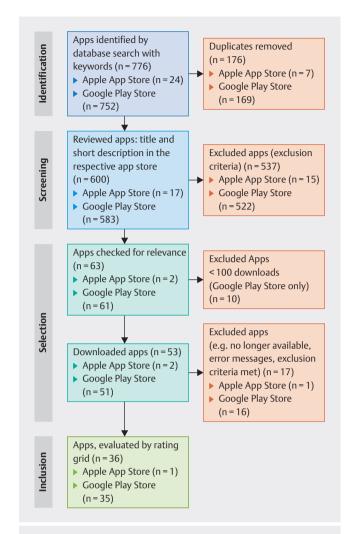
After applying the inclusion and exclusion criteria described above, the remaining apps were evaluated and categorized. After a single evaluation of the apps, the mean value of the three assessments was determined as a reference value. In the case of divergent assessments regarding the degree of recommendation, the dispersion around the mean value was calculated in order to reflect the "unity" of the assessors.

Results

App selection

A detailed app search flowchart is shown in ▶ Fig. 1.

One of the reviewers tested the apps on an iPhone 8 (iOS software version 14.3) and a Samsung Galaxy A5 (Android version 8.0.0.). At least two download attempts were made on subse-



▶ Fig. 1 Flowchart of app identification, screening, eligibility, and inclusion.

quent dates. A total of 776 apps (n = 24 from the Apple App Store, n = 752 from the Google Play Store) were identified by search query. After applying the inclusion and exclusion criteria, 36 (two approved in Germany and 34 not approved) apps (n = 1 from the Apple App Store, n = 35 from the Google Play Store) remained for evaluation. The evaluations were performed by 3 independent persons from different institutions (Examiner A: long-standing clinical research scientist in the clinical research department of an international pharmaceutical company; Examiner B: long-term senior physician in a clinic with a specialization in gynecological oncology; Examiner C: teacher at a secondary school, biologist at the Institute for Alpine Environment at the European Academy in Bolzano (Italy); diagnosed with breast cancer in April 2015 at the age of 32, triple negative, G3; no children at the time; now 2 sons aged 5 and 2 years; occasional assistance with statistical evaluations at the Hemato-Oncological Day Clinic, Hospital Merano, Italy). All three examiners used the above-mentioned patient profile according to the evaluation criteria defined in advance. An overview of the results is given in ▶ Fig. 1.



▶ Table 1 App Assessment Criteria.

		2 points	1 point	0 points	
User motivation	Category	exceeds expectations	meets expectations	below expectations	Points
User rating as motivation to download the app	User Rating ¹	4–5 points/stars in the App Store (highest rating in both Google Play Store or Apple App Store)	3 points/stars in the App Store (middle rating in both Google Play Stores or Apple App Store)	0–2 points/stars in the App Store (lowest rating in both Google Play Store or Apple App Store)	
Scientific solidity as a basis	c : '.c	High journal impact factor (IF > 5)	Low journal impact factor (IF \leq 5)	No journal impact factor/ No publication found	
for discussion with the treating doctor/oncologist	Scientific accuracy ²	Interaction with attending physician possible	Interaction with the attend- ing physician partially possi- ble or possible with difficulty	Interaction with attending physician not possible	
Relationship between	- (independent, intuitive operation	Can be used with little support	Use only possible with a lot of support	
effort and benefit	Ease of use	App explanations are simple and the app includes user guides	App explanation is simple	The explanation of the app is complicated	
Data protection of sensi-		BS EN ISO/IEC 27 001: 2017 certified ³	The app includes user guides EN ISO/IEC 27 001:2017 Idified 3 Not BS EN ISO/IEC 27 001:2017 certified Does not meet GDPR/EU/EU data protection standards Trinterface can be tomized (e.g. font, size, pumper of objects or number of object		
tive medical data as the key to user acceptance	Privacy	Meets GDPR/EU privacy standards ⁴	-	GDPR/EU/EU data	
Differentiation possi-	Individual-	User interface can be customized (e.g. font, size, color, number of objects displayed)	tially customized (e.g. font,		
bilities as the key to user acceptance	ization				
to user acceptance		Hassle-free import of your own content	Import of own content only partially possible or possible with difficulty	No import of own content possible	
		Community available	_	Community not available	
Motivational aspects as the key to consistent app use	Motivation	Timer, journal, reminder etc. available with export/connec- tion to other systems/apps	Timer, journal, reminder etc. only partially available with only partial export/connec- tivity to other systems/apps	Timer, journal, reminder not available, no export/ connection to other systems/apps	
Cost/Advertising as		No in-app purchases	_	In-app purchases	
the key to download	Financial aspects	No advertising	_	Advertising in the app	
Acceptance	аэрссіз	Free app	-	App must be purchased	
					Total points

¹ Points are counted according to mathematical rounding: 0–2.49; 2.50–3.49; 3.50–5.00.

After calculating the value of the three independent examiners, 20 apps were classified as not recommended (\leq 10 points [P]), and 12 apps were rated as partially recommended (\geq 11– \leq 18 P). For 4 apps, there were differences in the degree of recommendation between the examiners: "Breast Examination: "Breast Cancer (NextGen eSolutions Pvt. Ltd.)" (14–12–20 P), "Becca – Breast

Cancer Support (Breast Cancer Now – Becca)" (16–15–24 P) and "Know your Lemons (Know Your Lemons Foundation)" (14–13–26 P), were rated as recommended by examiner C and "Meine Busenfreundin (Meine Busenfreundin GmbH)" (20–15–not available [N/A] P) was rated as recommended by examiner A. The average point value of all four apps "Breast Examination: Breast Cancer

 $^{^{\}rm 2}$ 2018 Journal Impact Factor quoted by PubMed [6] of the magazine in which the app was quoted.

³ BS EN ISO/IEC 27 001:201748 is the internationally recognized standard for the secure management of information. It is the basic standard of the ISO 27 000 series of international information security management standards and the basic standard for the implementation of an information security management system (ISMS) [8].

⁴ The GDPR/ Data Protection General Data Protection Regulation (EU) (GDPR)] is a regulation in EU law on data protection and privacy in the European Union (EU) and the European Economic Affair (EEA) [9]. It also deals with the transfer of personal data outside the EU and EEA area.

(NextGen eSolutions Pvt. Ltd)": (16 P), "Becca - Breast Cancer Support", "Know your Lemons" and "Meine Busenfreundin": (18 P) fell into the "partially recommended" category. The app "Meine Busenfreundin" (Meine Busenfreundin GmbH) could not be found by one examiner in the App Store. The app "Outcomes4Me - Breast Cancer Care" was rated as partially recommended by one examiner and recommended by two examiners (16–19–25 P), with an average value of 20 P, over the defined threshold for rating an app as "recommended." Additionally, the app "OWise" was rated as recommended by all three examiners (20–19–28 P) and the average value of the assigned points (23 P) was also over the threshold to rate an app as recommended. In Germany, two apps "Mika (Fosanis GmbH)" and "CANKADO PRO-React Onco" are approved as health apps and can be prescribed by doctors. Mika (Fosanis GmbH) (Px HealthCare Group Ltd.) (18-19-N/A P) was rated as recommended with a mean value of 19, although this app could not be found in the App Store by one of the reviewers. The second app approved as a health app in Germany, CANKADO PRO-React Onco (CANKADO Service GmbH) (18–19–20 P), was rated as only partially recommended by one reviewer with 18 P, though the average value of all three reviewers' ratings put it in the "recommended" category.

Following a PubMed search, publications evaluating n = 10 apps were located, and for n = 2 the impact factor was available at PubMed [6]. All apps (n = 36) were free, n = 2 (13.9%) of apps had an online store for in-app purchases, and n = 21 (58%) showed ads. No app was "BS EN ISO/IEC 27001:2017" certified and only n = 5 (9%) apps were compliant with GDPR/EU regulations [8]. Most apps were rated as intuitive and easy to use for users with normal IT user expertise. A detailed overview of the individual assessments can be found in \blacktriangleright Table 2, \blacktriangleright Table 3, \blacktriangleright Table 4, \blacktriangleright Table 5.

The Federal Agency for child and youth media protection divides entertainment software into 5 USK age codes (USK 0, USK 6, USK 12, USK 16 and USK 18) [10]. The age rating of the apps was inconsistent between the two app stores as age rating categorization in the Apple App Store and Google Play Store are different in both age rating and definition. The age rating subdivisions for both app stores are listed below:

Apple App Store:

- 4+: Apps "contain no objectionable material."
- 9+: Apps "may contain mild or infrequent occurrences of cartoon, fantasy or realistic violence; and infrequent or mild mature, suggestive or horror-themed content."
- 12+: Apps "may [...] contain infrequent mild language; frequent or intense cartoon, fantasy or realistic violence; mild or infrequent mature or suggestive themes; and simulated gambling."
- 17+: Apps "may [...] contain frequent and intense offensive language, [...] cartoon, fantasy or realistic violence; and frequent and intense mature, horror and suggestive themes; plus sexual content, nudity," and substance use [11].

Google Play Store (for Germany):

- USK 0 All ages: Content "without youth protection relevance"
- USK 6 Ages 6 and above: "Can contain elements that may not be appropriate for pre-school children."
- USK 12 Ages 12 and above: May include "scary elements, shock effects, some explicit language, sexual contents or occasional violent imageries."
- USK 16 Ages 16 and above: May include "some realistically designed displays of violence, an accumulation of shock and horror elements, consistently explicit language or apps with an erotic or sexual focus are summarized in this category."
- USK 18 Ages 18 and above: May include "realistic and explicit violence" or "unquestioned drug use" [12].

The only app found in both app stores "Meine Busenfreundin" was rated for the age group of 17+ years in the Apple App Store and as USK 0 in the Google Play Store [8], which illustrates the differences between the rating systems. Two apps ("Breast Cancer Guide (Expert Health Studio)" and "breast cancer guide (Free Apps For Everyone)") were rated USK 12 and n=1 app "Breast cancer (Canada Dev Apps)" was rated USK 6, while the remaining (n=30) apps were rated USK 0.

The six highest-rated applications and the two apps recommended by the examiners are described in more detail below:

Breast Examination: Breast Cancer (NextGen eSolutions Pvt. Ltd.)

This app requires an account with a valid phone number and address. Access to photos and camera is requested when the app is first opened. Descriptions are very detailed; in fact, the medical content is too detailed for lay people. According to the Google Play Store description, the app is designed to help health care professionals make women aware of the earliest signs of breast cancer through self-examination. Breast exam results and pattern history, photos of the examination and sketches in a diagram can be saved. There is also a link to a self-examination video visible when the app is first launched. A database backup and database import can be performed and data uploaded to a server, implying a connection to a hospital's IT network.

The data protection policy, which does not comply with the European Standard, is linked in the Google Play Store. The homepage of the Indian IT company NextGen eSolutions Pvt. GmbH [13] provides detailed information about its development of IT solutions and applications for healthcare.

The app was evaluated as partially recommended because it does not touch on the topic of breast cancer treatment or aftercare.

Becca - Breast Cancer Support

This app was developed by the British breast cancer charity "Breast cancer now". The user receives five personalized flashcards daily with hints, tips, information, recipes, and training programs. A nurse can be contacted if needed. The app is only available in English and for residents of the UK. The app is not designed as an assistant in treatment or aftercare, but rather as a reference on the

► Table 2 Evaluation of the apps.

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App store stars	0	2	0	2	2	7	2	2	2	0	2	2	0	¥ Y	N A	2	7	2 (0 0	0	0	0	0	0	0	0
Journal impact factor	0	0	0	0	0	0	0	0	-	0	-	0	0			0	0	0	0 1	0	0	0	0	0	0	0
Interaction with treating physician possible	0	0	-	0	0	0	_	2	2	0	0	0	0			0	2	-	0 2	0	0	0	0	0	0	0
Usage	2	2	-	2	-	7	2	1	2	2	0	-	2			_	0	-	2 1	2	2	2	-	2	0	-
Explanation of the app	-	2	-	7	-	-	-	1	2	-	2	-	-			-	2	1 1	- 2	-	-	2	-	-	2	-
BS EN ISO/IEC 27 001 : 2017 certified	0	0	0	0	0	0	0	0	0	0	0	0	0			0	0	0	0 0	0	0	0	0	0	0	0
GDPR/EU data pro- tection applicable	0	0	0	0	0	7	2	-	2	0	0	7	0			0	0	0	0 0	7	0	0	0	0	0	2
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Timer etc. available, export/connectivity		0	0	-	0	-	0	0	-	-	2	-	0			0	0	0	0 0	0	0	-	0	0	0	0
In-app purchases	2	2	7	0	0	7	2	0	2	2	2	2	2			2	2	2	2 2	2	2	0	2	2	2	2
Advertisements	2	2	2	2	0	0	2	0	2	2	2	0	0			2	2	2 (0 2	2	0	2	0	0	2	2
App for free	2	2	2	2	2	2	2	2	2	2	2	2	2			2	2	2	2 2	2	2	2	2	2	2	2
Total points	6	12	1	13	∞	14	16	15	24	10	13	1	7			10	12	11	7 1	12 11	1 7	6	9	7	∞	10
Min		6			∞			15			10			7			10		7			9			7	
Max		12			4			24			13			7			12		_	12		6			10	
Mean value		10.7			11.7			18.3			11.3			7			=		_	10		7.3			8.3	

► Table 3 Evaluation of the apps.

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	<	2	0	0	2	-	0	0	-	0	0	0	2	0	7	10			
BREAST CANCER ASSESSMENT (CompuRx Info- tech Pvt. Ltd.	U	0	0	0	-	-	0	0	0	0	0	0	2	7	7	∞			
BREAST CANCEL ASSESSMENT (CompuRx Info- tech Pvt. Ltd.	8	0	0	0	-	7	0	0	0	0	0	0	2	2	7	6	∞	6	8.7
BRI AS	<		0	0	0	2	-	0	0	0	0	0	2	7	2	6			
incer oile is)	U	0	0	0	-	-	0	7	0	0	0	0	0	0	7	9			
Breast Cancer (Guide) (Free Mobile Shop Apps)	20	0	0	0	-	7	0	-	0	0	0	0	7	0	7	∞	9	∞	7
P O F S	<	0	0	0	2	-	0	0	0	0	0	0	2	0	2	7			
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breast cancer (Digital Planete Space)	ω	0	0	0	0-1	7	0	-	0	0	0	0	2	2	7	6	7	6	∞
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vity	U	0	0	0	-	-	0	0	0	0	0	0	0	2	7	9			
Breast Cancer (freeCreativity 2019)	8	0	0	0	0	7	0	-	0	0	0	0	2	7	7	6	9	6	7.3
Breast (freeCr 2019)	<	0	0	0	2	-	0	0	0	0	0	0	2	0	7	7			
nani)	U	2	0	0	-	-	0	2	0	0	0	0	0	7	7	10			
Breast Cancer (Z_T Gurmani)	8	2	0	0	2	-	0	0	0	0	0	0	2	7	7	1	6	11	10
Bre (Z_	<	2	0	0	2	-	0	0	0	0	0	0	2	0	7	6			
	Assessor	App store stars	Journal impact factor	Interaction with treating physician possible	Usage	Explanation of the app	BS EN ISO/IEC 27 001 : 2017 certified	GDPR/EU data pro- tection applicable	User interface possible customisation	Own content can be imported	Community available	Timer etc. available, export/connectivity	In-app purchases	Advertisements	App for free	Total points	Min	Max	Mean value



► Table 4 Evaluation of the apps.

	Breast Cancer Guide (Galaxy Studio Digital)	incer tudio	\$ 3 ° \$ 5	Breast Cancer Guide with Cancer Symptoms (Charli)	h s	Breast Info (lifey)	ist Cancer	ia.	Questions (Srinath Sri	Breast Cancer Questions (Srinath Sridar)		Breast Cancer Risk Assess- ment (miz software)	Cancer sess- tware)	8 8 2 6 9	Breast Cancer Stages, Signs, Food and Meal Plans (Best Top Daily Guide & Info)	gns, Meal Daily	Bre Sur for (firs	Breast Cancer Survival Guide for Patients (first-rate-apps)	ide ips)	Breas (daga	Breast Care (dagana Apps)		Breast Check Now Now)	Check Cancer	
Assessor	В	U	∢	8	U	A	ω	U	⋖	æ	U	A B	U	4	œ	U	∢	ω	U	<	œ	U	A B		U
App store stars	0 1	-	0	0	0	0	0	0	7	2	2	_	-	2	2	2	0	7	2	2	-	0	2 2		2
Journal impact factor	0 0	0	0	0	0	0	0	0	0	0	0	0 1	0	0	0	0	0	0	2	0	0	0	0		_
Interaction with treating physician possible	0 0	0	0	0	0	0	0	0	0	0	-	0 0	0	0	0	0	0	7	-	0	0	0	0 1		-
Usage	2 1	-	2	0	0	2	-	-	2	2	2	1	2	-	-	-	2	-	-	2	2	-	2 2		_
Explanation of the app	1 2	-	-	-	0	-	2	-	-	2	7	1	2	-	0	-	-		-	-	_	-	2 1		_
BS EN ISO/IEC 27 001 : 2017 certified	0 0	0	0	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0	0	0	0	0	0	0 0		0
GDPR/EU data pro- tection applicable	0 1	2	0	0	0	0	-	0	0	0	5	0 0	2	0	0	7	0	0	2	0	-	2	0 2		2
User interface possi- ble customisation	0 0	0	0	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0	0	0	0	0	0	0 0		_
Own content can be imported	0 0	0	0	0	0	0	0	0	0	0	0	0 1	2	0	0	0	0	0	0	0	0	0	0 0		_
Community available	0 0	0	0	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0	0	0	0	0	0	0 0		0
Timer etc. available, export/connectivity	0 0	0	0	0	0	0	0	0	0	0	0	0 0	0	0	0	0	0	0	0	0	0	0	1 2		_
In-app purchases	2 2	2	2	2	7	2	2	2	2	2	7	2 2	2	7	0	0	7	2	2	2	0	2	2 0		2
Advertisements	0 2	2	0	2	0	0	0	0	2	_	2	0 2	2	0	0	7	0	-	2	0	2	2	2 1		2
App for free	2 2	2	7	2	7	2	2	2	2	2	2	2 2	2	7	7	7	7	7	2	2	2	2	2 2		2
Total points	7 11	=	7	7	4	7	∞	9	1	=	. 15	7 11		15 8	72	10	7	10	15	6	6	10	13 1	14	17
	7			4			9			1		7			2			7			6		_	13	
	=			7			∞			15		15	2		10			15			10		_	17	
mean value	9.7			9			7			12.3		1	_		7.7			10.7			9.3		_	14.7	

► Table 5 Evaluation of the apps.

	Brea (Nas	Breast Disorder (NassApp)	rder	Breast nation: Cancer (NextGe	Breast Examination: Breast Cancer (NextGen eSolutions Pvt. Ltd.)	st (:	Breast can (Ana-store)	tore)		Know your Lemons (Know Your ons Foundat	Know your Lemons (Know Your Lem- ons Foundation)		My bosom í (My Bosom- freundin Gm	My bosom friend (My Bosom- freundin GmbH)		Outcomes4N - Breast Cancer Care (Outcomes4N	Outcomes4Me - Breast Cancer Care (Outcomes4Me Inc.)		OWise (Px HealthCare Group Ltd.)	.)	Mika (Fosal (Px He	Mika (Fosanis GmbH) (Px HealthCare Group Ltd.)	GmbH) ICare I.)	CAI Rea (CA	CANKADO PRO- React Onco pending (CANKADO Service GmbH)	o O O O O O D D D D H D H D
Assessor	A	ω	U	∢	В	U	<	В	0	A B		C A	В	U	⋖	Ω	U	∢	В	U	V	B	U	∢	В	U
App store stars	0	0	0	2	2	2	2	A N	¥.	2 1		2 2	0		NA 2	2	2	2	2	2	7	2	NA	2	2	2
Journal impact factor	0	0	0	0	0	0	0			0 0		2 0	0		0	0	-	-	0	2	0	0		0	-	0
Interaction with treating physician possible	0	0	0	0	0	2	0			0 1		2 0	0		0	_	2	-	-	2	0	-		0	-	-
Usage	2	.	0	2	0	2	2			2 1		2 2	2		2	2	2	2	2	2	2	2		2	2	2
Explanation of the app	-	2	0	-	0	2	-			2 0		2 2	2		2	2	2	2	7	2	2	2		2	2	2
BS EN ISO/IEC 27 001:2017 certified	0	0	0	0	0	0	0			0 0		0 0	0		0	0	0	0	0	7	0	0		0	0	0
GDPR/EU data pro- tection applicable	0	0	0	0	2	2	0			0 2		2 2	2		0	2	2	2	7	2	2	2		2	2	7
User interface possible customisation	0	0	0	0	0	2	0			0 0		2 1	0		-		2	-	0	2	-	-		-	0	-
Own content can be imported	0	0	0	-	2	2	0			0 0		2 1	-		2	2	2	2	7	2	-	2		-	2	7
Community available	0	0	0	2	0	0	0			2 0		2 2	0		0	0	2	0	0	2	0	0		0	0	0
Timer etc. available, export/connectivity	0	0	0	0	0	0	0			2 2		2 2	7		-	2	2	-	7	7	7	-		7	-	7
In-app purchases	2	7	2	7	2	7	2			0 2		2 2	7		2	2	2	7	7	7	7	7		7	7	7
Advertisements	0	2	2	2	2	7	0			2 2		2 2	2		2	2	2	2	2	2	2	7		7	2	7
App for free	2	7	2	7	2	7	7			2 2		2 2	7		2	2	2	7	7	7	7	7		7	7	7
Total points	7	6	9	14	12	20	6			14 1	13	26 2	20 15	2	_	16 1	19 25	5 20	19	28	18	19		18	19	20
Min		9			12			6		-	13		15	2		_	16		19			18			18	
Max		6			20			6		2	56		20	0		2	25		28			19			20	
Mean value		7.3			15.3			6		_	17.7		=	17.5		2	20		22.3	3		18.5	2		19	



after-effects of treatment, body image and nutrition. The privacy policy complies with the European Standard.

Know Your Lemons (Know Your Lemons Foundation)

An account is required to use this app, and access is secured with an e-mail address and password. The app was a 2019 nominee for a Webby award in the Health & Fitness 2019 category (Webby Award) [14]. Know Your Lemons acts as a coach for breast selfexamination, with a training video, an explanation of the 12 symptoms of breast cancer, a 10-minute audio-guided self-examination, and monthly reminders. Everything is designed using a metaphor of breasts as lemons, which all three examiners reported finding aesthetically pleasing and amusing. The Mona Lisa serves as a guide through the app, as she claims to have over 500 years of experience of examining her breasts. The second tab of the app explains 9 things that increase the risk of developing breast cancer. Breast cancer incidence in the US is mapped, but the user can also choose a global map. The third tab provides information on a personal screening plan. A disclaimer must be accepted in order to continue. Here, the user can schedule reminders, book a mammogram (in the USA) or find the nearest diagnostic and treatment center for breast cancer. The fourth tab is about donations, following the Know Your Lemons Foundation on social networks, and using educational tools. The Know your Lemons shop (which recognizes the user IP address and asks if the user would prefer to see prices in € instead of \$) sells educational materials and other products for the user's selected country. A chatbot can be used to obtain recommendations or ask questions, e.g. about order status.

A detailed usage policy is linked to the Google Play Store, but neither this policy nor a privacy policy is displayed in the app or in the online shop.

The app programming is sophisticated and is set up to educate users on the difficult topic of breast cancer self-examination in a humorous way. Its main focus is users from the USA, but it is programmed so that it can be used by English-speaking non-U.S. citizens as well. The examiners rated this app as partially recommended due to its lack of emphasis on treatment aftercare; however, they assigned high points for scientific accuracy and ease of use.

Meine Busenfreundin (Meine Busenfreundin GmbH)

With this German app, the user can create a personal medical profile to get an individual plan for the treatment and aftercare period. The app is also intended to provide information and tips on side effect management, recommendations for stress management, reminders to take medication, testimonials, support, motivation and empowerment. Well-founded medical information is conveyed in simple language. Furthermore, several partnerships with various universities and clinics as well as the Bavarian State Ministry for Economic Affairs, Regional Development and Energy [15] and the Center for Digitization Bavaria [16] are mentioned.

Data protection, data use and revocation of consent to use data options are provided in detail in accordance with GDPR/EU regulations. The app is set up for the treatment and aftercare of breast cancer patients. Although this app meets the necessary requirements for a health app, no peer-reviewed publication or app

store rating could be found reviewing it. Furthermore, Examiner C could not find this app, and therefore could not evaluate it. This app was rated as recommended by examiner A, despite the lack of rating and lack of publication assessing it. It was rated as partially recommended by examiner B. Although the app appears to be very well-structured and German-speaking, based on the mean value of the evaluations, it failed to be rated as recommended by the examiners by a margin of only one point (18 P).

Outcomes4Me – Breast Cancer Care (Outcomes4Me Inc.)

This is a US/Canadian app designed in English only. With a personalized tool, it provides medical records, a personalized treatment path (a snapshot of recommended treatment options, drug information, and procedure alternatives based on medical record history), clinical trial comparison (link to clinical.trials.gov) [17], and symptom management and its progression (logging a feeling, symptom, adding medication, or diary entry). In addition, it is stated that a consolidated medical record can be ordered by experts, and that all medical information submitted by users can be tracked and consolidated in a report that is easy to read and understand. The import of medical records from a medical institution to Outcomes4Me is only possible with an institution number and the last four digits of the user's social security number. The user can access validated external resources with additional verified information on genomics, specialized cases, and guidance from the National Comprehensive Cancer Network [18], Center for Disease Control and Prevention (CDC) [19], American Society of Clinical Oncology (ASCO) [20], and the World Health Organization (WHO) [21]. Comprehensive information about breast cancer diagnosis (insurance, policies and much more) is offered. In addition, the privacy policy is in accordance with the Health Insurance Portability and Accountability Act (HIPAA) [22] so that users have control over their data. All three examiners rated this app as recommended. Unfortunately, the app is not well-suited to German patients as it is only available in English and the complete range of features can only be used by US/Canadian citizens.

OWise (Px HealthCare Group Ltd.)

This is an app that allows the user to add diary entries, notes, audio recordings, photos and questions/answers to their own list of questions. The user can easily add their patient profile. The questions are explained very well in simple language. The efficacy of OWise is in improving patient motivation and activity in women with early-stage breast cancer, and was published in the BMC Trials in January 2020 [23]. The user data protection policy was in accordance with the latest EU data protection regulations. This app was rated as recommended by all three examiners, but it is only offered in English and abroad (in the Netherlands and the United Kingdom). ▶ Table 6 compares the six apps rated as recommended by at least one reviewer and two DiGa approved apps [4].

Mika (Fosanis GmbH)

With the support of the Charité and the University Hospital Leipzig, this app was developed as a personalized accompaniment and support for people with all types of cancer (including breast cancer

patients) before, during and after treatment. It offers practical tips and ideas on general aspects such as gaining control, reducing stress, activating sources of strength, controlling emotions and accepting one's own body to promote health and quality of life in those affected. Although this app is approved for medical prescription for the support of cancer patients in Germany [24], no peerreviewed publication or review of the app could be found. As expected, the data protection policy was in accordance with the European standard [9, 24]. Furthermore, this app could not be downloaded by Examiner C and was therefore only evaluated by examiners A and B. This app was rated as partially recommended (18P) by examiner A and recommended by examiner B (19P), despite the lack of peer reviewed information, independent confirmation of scientific accuracy, and user rating.

CANKADO PRO-React Onco (CANKADO Service GmbH)

This app was one of the first approved web- and app-based digital health applications to support breast cancer patients and is provisionally approved by the BfArM as a DiGA. According to its description, it is "a web- and app-based digital health application to support breast cancer patients. Patients can catalogue their symptoms independently. Depending on the disease and ongoing treatment, automated behavioral instructions are given to discuss the respective symptoms with a doctor." [25] This app is also available in German and can be prescribed by attending physicians. As expected, the data protection policy is in line with the European standard [9, 24]. Although this app has temporary approval as a health app, no peer-reviewed publication or rating of the app could be found. This app was rated as partially recommended by Examiner A with 18P and as recommended by Examiner B (19P) and Examiner C (20P). Since the app, which is temporarily approved as a health app, appears very well structured and is available in German, the mean value (19P) of the examiner ratings put it in the "recommended" category. A detailed overview of the individual assessments can be found in ▶ Table 6.

Discussion

Some studies have shown that health apps can cost-effectively meet hitherto unmet needs of cancer patients and provide symptom-oriented support and remote monitoring [6, 26, 27].

To the best knowledge of the authors, this paper is the first comprehensive review and critical analysis of the applications available in Germany for breast cancer. For the purposes of app evaluation, an objective assessment rubric was created based on already established assessment methods (source: "SchulApp") and app search results were evaluated by three independent examiners according to the specified study protocol. The assessment was carried out by three independent people with different IT skills and different medical and English language skills.

The most common weaknesses of the apps evaluated as "not recommended" were lack of data protection, unsound medical advice, and lack of transparency about source data from the institution or company that developed the app. In view of the seriousness of a breast cancer diagnosis and the long-standing existence of the data protection rules, this is remarkable and demonstrates

the need for an objective assessment of such applications by someone with a medico-legal background.

In terms of content, many apps from the evaluation dealt with general information on breast cancer or breast (self-)examination and screening and less with breast cancer treatment or breast cancer aftercare. Some applications were designed to essentially act as reference works about breast cancer and breast cancer screening. Some apps contained advertisements. Of the applications examined, only one was available in German which comprehensibly presented the medical information, apart from the two apps approved in Germany. In the other applications, adequate health literacy and English language skills were necessary to detect errors in the content. In terms of content, diagnostics and treatment, including rehabilitation, were often not the focus of the applications.

The advantage of the applications is that information can be collected, retrieved and visualized at any place and any time [28]. Here, we break down the advantages and characteristics of the apps in more detail. The use of an app during the treatment and aftercare period gives the patient time to reflect on information given to them by their attending physician following appointments. Apps can include graphic explanations, short videos, and links to other helpful resources. A summary appropriate for lay people is used to explain medical terms. Several apps connect patients to a community or social network. This is very helpful to help patients feel that they are not alone in their situation. Keeping a diary in the app is a possibility and could be a way for patients to experience relief from the disease, process it better, reduce stress, and increase motivation.

The study "CHARISMHA – Chances and Risks of Mobile Health Apps" examined the advantages and disadvantages of medicine and health and wellness-related mobile health apps. It demonstrated that these apps tend not to address disease diagnosis and treatment, a result which was in line with our findings [28].

App store search results vary and depend on the device and the browser used (Apple App Store or Google Play Store). Searching with a different keyword on another day or in another app store can give completely different results because the user has no control over the hit entry and advertising strategies of the store. Additionally, it is important that a health app not contain advertisements and that the user should always be able to get to the right page. This was not the case for all the apps evaluated in this study.

With a health app, both the patient and the attending physician should be able to access patient data and unauthorized access by strangers should be impossible.

Many audited health apps do not meet data protection requirements [28]. There is often a lack of transparency in the privacy policy and in obtaining user consent. Insofar as data is stored abroad, its use is not subject to the German/European data protection regulations [9]. Privacy policies are usually linked, but they are written in legalese and are difficult to understand by those without a legal background. Some apps in the Google Play Store can only be downloaded if consent is given for access to photos/media/data in advance.

In their app search of 200 apps, Follmer et al. demonstrated that the average app privacy policy was about 2900 words long

► Table 6 Comparison of health apps rated as good and two approved health apps by the examiners.

	Becc Can (Bred Now	Becca – Breast Cancer Support (Breast Cancer Now – Becca)	st r	Breastion: (Nextions tions	Breast Examina- tion: Breast Cancer (NextGen eSolu- tions Pvt. Ltd.)	na- ancer u-	Know ye Lemons (Know Ye Foundati	Know your Lemons (Know Your Lemons Foundation)	emons	My B (Meir freun	My Bosom Friend (Meine Busen- freundin GmbH)	puə (+	Outco Breast Care (Outco Inc.)	Outcomes4Me – Breast Cancer Care (Outcomes4Me	<u>а</u> г <u>а</u>	OWise (Px HealthC Group Ltd.)	Owise (Px HealthCare Group Ltd.)		Mika (Fosal GmbH) (Px HealthC Group Ltd.)	Mika (Fosanis GmbH) (Px HealthCare Group Ltd.)		CANKADO React Onco pending (CANKADO Service Gm	CANKADO PRO- React Onco pending (CANKADO Service GmbH)	Q ÷
Assessor	⋖	В	U	⋖	В	U	4	8	U	V	В	U	⋖	B	U	4	8	U	⋖	В	v	⋖	B	v
App store stars	2	2	2	2	2	2	2	-	2	2	0	NA	2	2	2	2	2	2	2	2	NA	2	2	2
Journal impact factor	0	0	-	0	0	0	0	0	2	0	0		0	0	-	-	0	2	0	0		0	-	0
Interaction with treat- ing physician possible	-	2	2	0	0	2	0	-	2	0	0		0	-	2	-	-	2	0	-		0	-	-
Usage	2		2	2	0	2	2	-	2	2	2		2	2	2	2	2	2	2	2		2	2	2
Explanation of the app	-		2		0	2	2	0	2	2	2		2	2	2	2	2	2	2	2		2	2	2
BS EN ISO/IEC 27 001 : 2017 certified	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	2	0	0		0	0	0
GDPR/EU data pro- tection applicable	2	-	2	0	2	2	0	2	2	2	2		0	2	2	2	2	2	2	2		2	2	2
User interface possible customisation	0	2	2	0	0	2	0	0	2	-	0		-		2	-	0	2	-	-		-	0	-
Own content can be imported	0	2	2	-	2	2	0	0	2	-	-		2	2	2	2	2	2	-	2		-	2	2
Community available	2	2	2	2	0	0	2	0	2	2	0		0	0	2	0	0	2	0	0		0	0	0
Timer etc. available, export/connectivity	0	0	-	0	0	0	2	2	2	2	2		-	2	2	-	2	2	2	-		2	-	2
In-app purchases	7	0	7	2	2	2	0	7	7	7	2		7	2	2	2	2	2	2	2		2	2	2
Advertisements	2	0	2	2	2	2	2	2	2	2	2		2	2	2	2	2	2	2	2		2	2	2
App for free	2	2	2	2	2	2	2	2	2	2	2		2	2	2	2	2	2	2	2		2	2	2
Total points	16	15	24	14	12	20	14	13	56	20	15		16	19	25	20	19	28	18	19		18	19	20
Min		15			12			13			15			16			19			18			18	
Max		24			20			56			20			25			28			19			20	
Mean value		18.3			15.3			17.7			17.5			20			22.3			18.5			19	

(30–33 000 words) [29]. An adult reads an average of about 200 to 350 words per minute [30]. To read privacy policies, an app user needs about 12 minutes and, if the complexity of the text is taken into account, even longer. Because of this, there is a high probability that only a few app users read the privacy statements [29]. The purpose of the privacy policy should be to inform app users in a comprehensible way about how their data is processed. Unfortunately, many health app privacy policies do not do this adequately. A health app should respect the privacy of users, but many apps offer neither a privacy policy written in easy-to-understand language nor a privacy policy in line with EU privacy standards. For these reasons, privacy concerns were the most common reason why apps were rated as not recommended in our study.

If health apps contain advertising or offer sales, this indicates a commercial interest of the apps rather than a solid scientific and medical interest for patients. Users should be able to access information in the app or on the Internet homepage regarding scientific advice or connections to medical research. Any possible conflicts of interest should be indicated and the ways in which personal data may be used for advertising, medical research or other applications should be described in a comprehensible way. The apps offered by companies outside the EU rarely state whether their app has a terms of use or complies with data protection regulations.

At the same time, it should be possible for the treatment team and health insurance companies to select, use and recommend suitable apps. A health app should also enable communication between the patient and the treatment team. Furthermore, it makes sense to give the treatment team an overview of the treatment, side effects and possible complications. Only a few of the apps we evaluated offered these features (Meine Busenfreundin, Outcomes4Me, OWise).

In Germany, apps can be prescribed to patients by treating physicians if they are certified by the BfArM and listed in the Digital Health Applications Directory [4]. Among these, only two apps (Mika and CANKADO Pro-React Once) have been approved by the BfArM on the subject of cancer (as of February 24, 2022) [24].

"Mika" (Fosanis GmbH, Germany; provisionally approved) is approved for the management of various types of cancer (cervical cancer, uterine cancer and ovarian cancer), and the "CANKADO PRO-React Onco" (CANKADO Service GmbH, Germany, provisionally approved) is the first approved app for breast cancer care [24]. These two apps are also available in German and can be prescribed by attending physicians. As expected, these apps address data protection in accordance with the European standard [4, 9].

The work of Schinköthe et al. demonstrated that, during the COVID-19 pandemic, web- and app-based secure telemedical communication between doctors and their patients was possible. Furthermore, through these communication channels, infected doctors in quarantine could also continue to provide remote monitoring of patients with chronic diseases via telemedical services, thus improving the safety of people and medical care [31]. Another app available in German, which adequately addressed data protection and was evaluated as recommended, is "Meine Busenfreundin". The two apps "Outcomes4Me – Breast Cancer Care" and "Owise", which were rated as recommended by all three examiners, can be used by German patients, but the full functional-

ity is only available to patients in the USA/Canada (Outcomes4Me), and the Netherlands and the UK (Owise). In addition, these applications are not available in German.

In 2022, Graf et al. published a study including 106 breast cancer patients that showed that electronically based patient questionnaires (ePRO) are suitable for measuring HRQoL among breast cancer patients and that these patients preferred the ePRO assessment to the paper-based patient questionnaire (pPRO) assessment. It was also found that female patients considered the ePRO assessment to be an improvement in hospital health care [32].

For patients with invasive breast carcinoma, the ENABLE study, funded by the G-BA (Federal Joint Committee), is being conducted at Heidelberg, Tübingen, and Mannheim University Hospitals. The aim of this study is to establish and evaluate a close-meshed control of the quality of life (Health-Related Quality of Life [HRQoL]) under therapy with testing of a side effect-based intervention ("Reactive PRO Assessment - RPA"). In addition, laboratory parameters and Patient-Reported Outcome Measures (PROM) will be collected to identify predictive factors and detect high-risk patients. Electronic feedback to the treatment team for higher grade side effects/impairments and monitoring of symptoms in interaction with the treatment team using the app as an information tool are also among the goals of this study [33]. The app can be downloaded from both the Apple App Store and Google Play Store. The app was rated with an average of 4.8 stars by 21 study participants. The three investigators could not rate this app because this app can currently only be used by study participants. For this reason, no general rating and recommendation could be given [34].

Summary

There is a great social and economic need to create a high-quality and cost-effective care model for the long-term management of cancer patients and survivors. The implementation of app-based care enables remote monitoring and tracking of activity changes and symptoms for both care teams and patients. After systematic evaluation of the breast cancer health apps available in Germany, only a few apps met the requirements of physicians, breast cancer patients and survivors. A health app should meet the standards of European data protection laws, use simple and understandable language, and be easy to use. If the above criteria are met, apps for breast cancer patients can be an accompanying partner to patients and physicians with added medical value from the time of diagnosis.

Declarations

Financing: No financial support was received. Contributions of the authors:

- D. Dayan: Manuscript writing, conceptualization, data processing, project development
- S. I. M. Gomm: Manuscript writing, conceptualization, data editing, project development
- B. Stoinschek: Manuscript writing, conceptualization, data processing, project development
- F. Ebner: Protocol/project development, manuscript creation and editing



- S. Lukac: Supervision, review and editing
- Z. El Taie: Supervision, review and editing
- W. Janni: Supervision, review and editing
- U. Schmidt-Straßburger: Supervision, review and editing

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Conflict of Interest

The authors declare that they have no conflict of interest.

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