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Title: Mobile phone applications for Diabetes management: A systematic review
Aplicaciones móviles para la autogestión de la diabetes: una revisión sistemática

Article Type: Original

Keywords: aplicaciones de salud; mhealth; autogestión; smartphone; español; telemedicina

health apps; mhealth; self-management; smartphone; Spanish; telehealth.

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Abstract: Introducción

La cantidad de aplicaciones móviles (apps) relacionadas con la salud está aumentando y la diabetes mellitus (DM) no es una excepción. El objetivo de este estudio es evaluar las apps móviles gratuitas para el manejo de la diabetes disponibles en español, en el mercado español.

Métodos

GooglePlay (Android) y AppStore (iOS) fueron revisados para identificar apps gratuitas, en español, dirigidas a personas con diabetes. Sus principales funciones y una serie de características de calidad y usabilidad fueron evaluadas y calificadas. Estas puntuaciones se usaron para hacer una lista de las mejores apps.

Resultados

De las 794 apps registradas, 42 fueron evaluadas e incluidas en la evaluación de calidad, mientras que 34 apps se incluyeron en la evaluación de usabilidad. La función principal de la mayoría de las apps era actuar como un diario de glucosa en sangre (n: 30; 71,43%). En cuanto a la privacidad, la mayoría de las apps (33 apps, 78,6%) acceden a datos del dispositivo/personales. Solo una minoría de apps [3 (7,1%)] informaron que se basaban en evidencia científica y sólo 3 apps (7,1%) tenían un certificado de calidad. Las apps mejor puntuadas fueron: OneTouch Reveal™, Social Diabetes™, mySugr: aplicación Diario de diabetes™, Diabetes menú™, Tactio SALUD™ y Diabetes:M™.

Conclusiones

Hay pocas apps gratuitas disponibles en español para el manejo de la diabetes, la mayoría carecen de certificado de calidad y muy pocas proporcionan referencias científicas sobre su contenido. Asimismo, la mayoría de las apps acceden a datos del dispositivo/personales.

Introduction

The number of mobile applications (apps) related to health is increasing, and Diabetes Mellitus (DM) is not an exception. The aim of this study was to assess the free mobile applications for the management of diabetes available, in Spanish, in the Spanish market.

Methods

GooglePlay (Android) and AppStore (iOS) were reviewed to identify free apps, in Spanish, aimed at people with diabetes. Their main functions and a series of quality and usability features were evaluated and scored. These scores were used to make a top list with the best apps.

Results

Out of 794 registered apps, 42 were evaluated and included in the quality assessment, while 34 apps were included in the usability assessment. The main function of most of the apps was to act as a blood glucose diary (n:30; 71,43%). As for privacy, most of the applications (33 apps; 78,6 %) access device/personal data. Only a minority of apps [3 (7.1%)] reported being based on evidence, and only 3 apps (7.1%) had a quality label. The top scored apps were: OneTouch Reveal™, Social Diabetes™, mySugr: App Diario de diabetes™, Diabetes menú™, Tactio SALUD™ and Diabetes:M™.

Conclusions

There are few free apps for diabetes management available in Spanish, most lack quality certification and very few provide scientific references about their content. Furthermore, most of the apps access personal/device data.

Suggested Reviewers:

Opposed Reviewers:

Response to Reviewers: Estimados/as revisores/as

Agradecemos el tiempo y cuidado empleado en la revisión de nuestro trabajo. Creemos que, gracias a sus sugerencias, que hemos contestado de la mejor manera posible, el trabajo ha mejorado sustancialmente.

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Hemos resaltado los cambios en el manuscrito, para que sea más sencilla su revisión

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Quality Criteria sería recomendable nombrar además del Servicio Andaluz de Salud , otros sellos de calidad y catálogos como: AppSalut, Fundación iSYS y My Health Apps, así como evaluar el grado de concordancia entre las recomendaciones de los mismos

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- Especificar si ha habido Apps excluidas por resultar fraudulentas o considerarse un plagio y enumerar las que son (de interés para profesionales y pacientes)

Las Apps eliminadas por este motivo fueron relativamente pocas y se enumeran a continuación:

Copia de otra app?? Sospecha: no acceso a condiciones de privacidad
Diabetes Pro - Free (1.2)
Copiada? Diabetes mellitus treatment (1.2)
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Copia de otra appLibro de recetas vegetarianas
Sospechosa. Evidencia?? Incluir?? NaturalSlim
clon Recetas olla de cocción lenta
clon Bajo Colesterol recetas gratis
CLON Recetas con bajo contenido en grasa: Food Book (2.0)
03/02/18: BUG?? No permite crear cuenta CareUP (0.5.0)
Duplicado?? Contador Carbohidratos (3.5.5)

- En General Aspects aportar si se tienen datos no solo de descargas sino de número de usuarios.

Me temo que no tenemos recogida esa información. De hecho, el número de descargas sólo pudo obtenerse de las aplicaciones que estaban en Android, ya que GooglePlay ofrece esa información.

En la discusión , pagina 10, mencionar otros catálogos y sellos y nombrar las Apps que tienen algún reconocimiento a través de los mismos (p.e: iSYS Score)

Se ha incluido un párrafo al respecto

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- Se encontraron 794 apps empleando la keyword "diabetes". ¿Podría replantearse emplear otras como "glucose" o "glucosa"?

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- La exclusión de apps de pago debería reconsiderarse ya que no creemos que una revisión sistemática pueda omitir opciones sólo por este criterio, considerando además que los precios no suelen ser demasiado altos para un uso puntual con el fin de testarlas. En este sentido muchas apps siguen el modelo "freemium" por la que algún contenido es gratuito y otras opciones requieren un pago previo. Debería quizás aclararse, al menos en las apps, mejor valoradas qué características están sujetas a pago. En el apartado 3.1 aparecen los precios de los contenidos premium de las apps pero no se especifica si es mensual o anual.

Debido a la estrategia de búsqueda utilizada y que ninguna de las plataformas consultadas dispone de filtros de idioma, hubo que descargar más de 700 apps para su valoración inicial. Este hecho y la falta de financiación para este trabajo, nos hizo decidirnos por las apps gratuitas (o, al menos, parcialmente gratuitas). Hemos incluido esta limitación en la discusión. Las características sujetas a pago no fueron valoradas en las apps "freemium"

- Reconsideraría también las apps exclusivas para un dispositivo concreto ya que aunque limitadas para usuarios de éste, la evaluación sigue siendo de alto interés. Desconozco si OneTouch permite una funcionalidad completa sin emplear los medidores de LifeScan. En caso contrario incurriría en uno de los criterios de exclusión pre-especificados en la revisión.

OneTouch permite utilizar datos introducidos manualmente, no necesariamente a través de medidores de LifeScan. Por eso fue incluida. La correcta evaluación de cada una de las apps asociadas a dispositivos concretos habría complicado mucho la búsqueda, ya que habría que haber contado con datos de cada dispositivo para su evaluación. Hemos incluido esta limitación en la discusión

- Con el objetivo de aumentar la transparencia creo imprescindible incluir un listado de todas las apps que fueron finalmente evaluadas y, al menos de las mejor evaluadas, las puntuaciones obtenidas por apartados. La información ofrecida no nos permite por ejemplo saber su gluQUO, una app muy utilizada por pacientes ha sido evaluada.

Se ha añadido una tabla con el listado de las 20 mejor puntuadas y sus puntos correspondientes a calidad y usabilidad. En el material suplementario, se adjunta un Excel con los datos crudos del análisis. Precisamente, gluQUO es de las mejor puntuadas en cuanto a usabilidad (probablemente por eso la usen mucho los pacientes), pero no tanto en calidad.

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* Con respecto a SocialDiabetes parece ser penalizada en la evaluación por cuestiones relacionadas con la privacidad entre las que destaca que la app cargue contenido premium sin previo aviso. Me llama mucho la atención este aspecto ya que las apps no tienen acceso a datos bancarios de los usuarios. Este grave hecho no se ha producido en nuestra experiencia con la app ni nos ha sido referido en ningún momento por la multitud de pacientes que la emplean.

En la guía del usuario de SocialDiabetes se advierte "Al cambiar de plan, no se realizará ningún cobro hasta que hayan transcurrido dos semanas. Si no cancelas el plan durante este periodo de prueba, una vez agotado se realizará el cargo de forma automática, sin posibilidad de reembolso. El plan se mantiene activo durante un año y se renueva de forma automática". Hemos argumentado algo más esta opinión con algunas líneas adicionales en los resultados y hemos matizado los comentarios de la discusión, enfatizando que se trata de la opinión personal de los autores.

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MOBILE PHONE APPLICATIONS FOR DIABETES MANAGEMENT: A SYSTEMATIC REVIEW

APLICACIONES MÓVILES PARA LA AUTOGESTIÓN DE LA DIABETES: UNA REVISIÓN SISTEMÁTICA

Adrián Quevedo Rodríguez¹, Ana M Wagner^{2*}

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Abstract

Introduction

The number of mobile applications (apps) related to health is increasing, and Diabetes Mellitus (DM) is not an exception. The aim of this study was to assess the free mobile applications for the management of diabetes available, in Spanish, in the Spanish market.

Methods

GooglePlay (Android) and AppStore (iOS) were reviewed to identify free apps, in Spanish, aimed at people with diabetes. Their main functions and a series of quality and usability features were evaluated and scored. These scores were used to make a top list with the best apps.

Results

Out of 794 registered apps, 42 were evaluated and included in the quality assessment, while 34 apps were included in the usability assessment. The main function of most of the apps was to act as a blood glucose diary (n:30; 71,43%). As for privacy, most of the applications (33 apps; 78,6 %) access device/personal data. Only a minority of apps [3 (7.1%)] reported being based on evidence, and only 3 apps (7.1%) had a quality label. The top scored apps were: OneTouch Reveal™, Social Diabetes™, mySugr: App Diario de diabetes™, Diabetes menú™, Tactio SALUD™ and Diabetes:M™.

Conclusions

There are few free apps for diabetes management available in Spanish, most lack quality certification and very few provide scientific references about their content. Furthermore, most of the apps access personal/device data.

Key words: health apps; mhealth; self-management; smartphone; Spanish; telehealth.

Resumen

Introducción

La cantidad de aplicaciones móviles (apps) relacionadas con la salud está aumentando y la diabetes mellitus (DM) no es una excepción. El objetivo de este estudio es evaluar las apps móviles gratuitas para el manejo de la diabetes disponibles en español, en el mercado español.

Métodos

GooglePlay (Android) y AppStore (iOS) fueron revisados para identificar apps gratuitas, en español, dirigidas a personas con diabetes. Sus principales funciones y una serie de características de calidad y usabilidad fueron evaluadas y calificadas. Estas puntuaciones se usaron para hacer una lista de las mejores apps.

Resultados

De las 794 apps registradas, 42 fueron evaluadas e incluidas en la evaluación de calidad, mientras que 34 apps se incluyeron en la evaluación de usabilidad. La función principal de la mayoría de las apps era actuar como un diario de glucosa en sangre (n: 30; 71,43%). En cuanto a la privacidad, la mayoría de las apps (33 apps, 78,6%) acceden a datos del dispositivo/personales. Solo una minoría de apps [3 (7,1%)] informaron que se basaban en evidencia científica y sólo 3 apps (7,1%) tenían un certificado de calidad. Las apps mejor puntuadas fueron: OneTouch Reveal TM, Social Diabetes TM, mySugr: aplicación Diario de diabetes TM, Diabetes menú TM, Tactio SALUD TM y Diabetes:MTM.

Conclusiones

Hay pocas apps gratuitas disponibles en español para el manejo de la diabetes, la mayoría carecen de certificado de calidad y muy pocas proporcionan referencias científicas sobre su contenido. Asimismo, la mayoría de las apps acceden a datos del dispositivo/personales.

Palabras clave: aplicaciones de salud; mhealth; autogestión; smartphone; español; telehealth.

1. Introduction

The mobile technology used to improve health results, known as mHealth (1), is a practice in development (2). As a result, the number of mobile applications (apps) related to health is increasing: more than 100,000 health applications are available in the most used app stores (3), and their use in diabetes (DM) is no exception (4). Indeed, several systematic reviews and meta-analyses assess the effects of mobile applications on glycaemic control (5–11).

Since these mobile apps can be used to make health-related decisions, their reliability is crucial. Thus, the working groups “Tecnologías aplicadas a la diabetes” and “Diabetes 2.0” from the “Spanish Diabetes Society” have developed recommendations on the use of Apps in DM, both for health professionals and for people with the disease (12). This guideline emphasizes aspects such as: the functionalities of the app, the identification of the people in charge of the app, clear identification of advertisements, the frequency in the update of the contents, the presence of reliable sources of information, the existence of clear terms and conditions of use, the consumption of device resources, adherence to data protection rules, the importance of checking with your doctor the use of the app and certification with a quality label.

Previous systematic reviews have been performed of DM apps available in English and German (13-14). Arnhold et al. (13) considered the number of recently launched DM apps, their functions, target user groups, languages (English and German), price, user ratings, available interfaces and the association between price and user ratings. A similar study was carried out by Brzan et al. (14), who only included apps in English and did not evaluate the quality characteristics of the apps.

Therefore, the objective of this study was to evaluate mobile apps for the management of DM, in Spanish, available in the Spanish market and identify some that could be recommended to patients with the disease.

2. Methods

2.1. Search method

A systematic review was made of mobile applications available in the main platforms on the Spanish market: GooglePlay (Android) and AppStore (iOS). Data collection was performed by one reviewer (AQR), with the support and supervision of a second reviewer (AMW) between 10/31/2017 and 03/03/2018, using the keyword “Diabetes”. Neither GooglePlay nor AppStore for iPad have a filter to select apps according to language, so apps with free access were downloaded and their language was checked.

Inclusion criteria were: free access, Spanish language and people with DM as intended users. Apps that did not work, premium, unavailable, fraudulent and plagiarized apps and those aimed at health professionals were excluded.

Apps or their functionalities were considered premium if they required a payment or a specific device (e.g. a certain glucometer) to be used and they were considered for professionals if it was specified in the description, if they were intended for hospital use or required advanced, specific knowledge.

2.2. Data collection

The names and the version of all the apps that came up in the search results on each platform were collected in a spreadsheet. Subsequently, for those that met the inclusion criteria, the following, additional variables were collected: date of last update, description, store, operating system, developer, premium content, utilities and price, number of downloads (only available in GooglePlay), educational component, user rating, target audience (including type of diabetes), privacy (if the app accesses device data), scientific evidence, advertising, data importation from other devices (e.g. glucometers), hypoglycaemia indicator, ketone management, glycated haemoglobin (HbA1c) management, insulin dose calculation, contact with physician, generation of graphs, results registry, schedule notifications, lipid profile, other utilities, need for internet connection, memory consumed by app, account requirement

1 and presence of a quality certification. For data collection, the information provided by the
2 page of the app in the store was taken into account, as well as the information provided by the
3 app itself. After collecting the data of the selected apps, quality and usability criteria were
4 applied.
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10 The data related to "privacy" were collected based on the permissions requested by the app
11 and the privacy policies provided by the Store page or the app itself. Those apps whose
12 privacy policies were not accessible, or which provided links that did not work, were
13 considered as if they accessed private data. Time since last update of each app was broken up
14 into five categories (on the 03rd March 2018): [0-3], (3-6], (6-9], (9-12], >12 months.
15 Regarding users' ratings, for apps with ratings from both stores, their mean was calculated; if
16 the app was available in both Stores but only one had the rating available, the available rating
17 was the only one that was taken into account. Those apps that have functionalities restricted
18 by premium pass have been classified as if they did not have that function.
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30 The apps were downloaded and tested on a Samsung Galaxy S6 SM-G920F 32GB mobile
31 device (Android Version 7.0 - Kernel Version 3.10.61-10958180) and on an Apple iPad Air 2
32 - 64 GB WiFi device (Model: MH182TY / A Version 11.2.6). Since the variable "operating
33 system" has been qualified based on the result of the search for the keyword "diabetes", there
34 may be apps available in both stores, which were not registered. In addition, we evaluated the
35 AppStore via an iPad. Thus, apps which are exclusive for iPhone devices could not be
36 included in the evaluation. Additional devices were used and both stores re-checked, to assess
37 selected apps at a later stage (see below), in June 2018.
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48 **2.3. Quality criteria**

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53 The quality criteria were developed based on the recommendations of the Andalusian Health
54 Service. This organization has developed a quality and safety strategy for mobile health apps
55 and has created a certification, called "AppSaludable" [Healthy App] (15). To obtain this
56 certification, a series of 31 quality and safety recommendations are provided that an
57 application should meet. Apps with this certification should allow citizens to use them
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reliably, minimizing risks. Most of the items were used to assess the quality of the apps, although some have been excluded, because they were assessed anyway, because they were aimed at app developers, or for pragmatic reasons, due to difficulties in their evaluation through the use of the app (see appendix. Table 1). Thus, a list of 24 recommendations remained (see appendix. Table 2.) and an *ad hoc* score was developed for each item: 0: does not comply with the recommendation; 1: partially complies with the recommendation; 2: fully complies with the recommendation. Those apps that do not have advertising or do not access personal data have been rated with the highest score (2 points) in the respective items. Finally, the total score of each application has been calculated as the sum of the scores of each of the 24 recommendations (maximum score of 48 points).

2.4. Usability criteria

The choice of "usability criteria" was based on the study by Arnhold et al. (13), which were rated by means of a 5-point Likert scale (1-5) or a dichotomous scale (0-1) (see appendix. Table 3). We added up these scores to obtain a total usability score for each app (maximum score: 47 points). The educational only apps, that did not allow any kind of interaction (e.g, enter values), were excluded from the usability criteria because there were difficulties assessing some of the variables.

It is worth noting that, for those applications available in both Android and iOS, the criteria of quality and usability have been applied to the Android version only.

Finally, a top list was developed with the applications that obtained the highest score in the quality and usability criteria. Two reviewers (AQR and AMW) reassessed these apps.

Although we used the Andalusian AppSalud criteria for the quality assessment of the selected apps, three additional certification sources were explored: AppSalut, developed by the Catalanian Government (16), iSYScore, developed by the Spanish, non-profit organisation Internet, Health and Society Foundation (Fundación Internet, Salud y Sociedad) (17,18) and MyHealthApps, a UK-based, Patient View initiative (19).

1 To certify an app, AppSalut assesses usability, technology, safety and contents (16). ISYScore
2 includes popularity (user ratings, the use of two different platforms), reliability (validation by
3 official body, authors and responsible entity identified, dedicated website, cites sources of
4 scientific evidence, updated in the last year, funding information available) and utility (as a
5 tool, as a learning means or as a social actor) in its rating, and the apps are assessed by a team
6 of experts (17). MyHealthApps, on the other hand, represents the users' perspective only, i.e
7 the patients and the carers who use health apps (19).
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16 **2.5. Statistical analysis**

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21 The SPSS™ (IBM SPSS Statistics 24.0.0) package for Windows (64 bits) was used.
22 Normality distribution was assessed using the Kolmogorov-Smirnov and Shapiro-Wilk tests.
23 Correlations between quantitative variables were performed with Spearman's rank correlation
24 coefficient. Comparisons between two groups were performed using the Mann-Whitney U
25 test. A p value below 0.05 was considered significant.
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32 **3. Results**

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38 In total, 794 apps were registered: 215 exclusive for Android (27.1%), 554 exclusive for iOS
39 (69.8%) and 25 available on both platforms (3.1%). Many (725) applications were excluded
40 for different reasons (see flow-chart in figure 1). Thus, 42 apps were included in the Quality
41 assessment and 34 apps were included in the Usability evaluation.
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48 **3.1. General aspects**

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54 The majority of the apps had been updated in the previous 3 months (n= 18; 43.9%), whereas
55 4.9%, 17.1%, 4.9% and 29.3% had been updated in the (3-6], (6-9], (9-12] and > 12 months
56 period previous to the review. Among the 27 apps with a users' rating, the mean score was
57 4.24 (SD: 0.43), out of a maximum of 5 points. Eighteen (42.9%) apps had premium content
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(1 of them, because it had the function to add values via one specific glucometer), with prices ranging between 0.50 € and 54.99 €. The mean number of downloads (applicable to GooglePlay only), was 63295 (SD: 103614).

3.2. Features

The main function of most of the apps was to act as a blood glucose diary (n:30; 71.43%); while the remaining were educational only apps (n:12; 28.57%). Almost one quarter of the apps (n:9; 21.4%) allowed importation of blood glucose values. Furthermore, 5 apps had the function to indicate if the data entered was in the hypoglycaemia range. In addition, 5 apps (11.9%) had some form of ketone management function. Ten (23.8%) apps estimated HbA1c from glucose measurements, 3 (7.1%) allowed manual entry of the HbA1c value and 3 apps (7.1%) included both. In addition, 6 apps (14.3%) had the function to calculate pre-prandial insulin dose. Moreover, 3 apps (7.1%) allowed contact with their physician. Twenty apps (47.6%) had a function to export data and more than half of the apps (57.1%) generated graphs with the results. In addition, 28 apps (66.7%) provided a results history, 19 (45.2%) allowed to schedule notifications and 5 apps (11.9%) had a field to enter the lipid profile manually. Finally, 23 apps (54.8%) had some form of educational content.

Regarding the type of DM at which they were aimed, the majority of apps did not specify this (25 apps: 59,5%), 9 (21,4%) were oriented to DM1, DM2 and others, 6 to DM1 and DM2, 1 to DM1 only and 1 to DM2.

3.3. Quality features

Most apps (33 apps; 78.6 %) accessed device / personal data. There were 24 apps (57.1%) that did not require an account in order to be used, while 13 apps (31%) did and 5 apps (11.9%) had optional accounts to have access to certain functionalities. In contrast, very few apps [3 (7.1%)] refer to the scientific evidence used during their development and only 3

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(7.1%) had some form of quality certification. In terms of advertising, 14 apps (33.3%) had some kind of ads.

In total, 42 apps were included in the quality score, whose mean was 28.2 (CI 95%: 25.3-31.0) (out of a maximum of 48 points). In agreement with the description above, the recommendations with highest mean scores were the recommendations “The health app adapts itself to its target audience” (mean: 2.00; SD: 0), “The health app neither presents any sort of known susceptibility nor any type of malicious code” (mean: 2.00; SD: 0) and “The health app follows the Principles of Universal Design, as well as reference accessibility standards” (mean: 1.95; SD: 0.216), while the lowest were “The health app offers concise information about the procedure used in order to select its content” (mean: 0.26; SD: 0.544), “The health app is based on one or more reliable information sources and takes into account the available scientific evidence” (mean: 0.31; SD: 0.643) and “The health app offers information about its funding sources, promotion and sponsorship, as well as about possible conflicts of interests” (mean: 0.48; SD: 0.804). **For more details, see supplementary file including the raw data.**

3.4. Usability

The mean total usability score of the 34 apps assessed was 32.2 (SD: 1.0) (out of a maximum of 47) and the criterion mean score was 3.58 (SD 0.46) (maximum of 5 points). The criterion with the highest score was the “High fault tolerance/efficient fault management” (mean: 4.41; SD: 0.557). However, the “Simple, self-explanatory menu structures” was the variable with the lowest mean: 2.82 (SD: 1.218). Furthermore, only 2 apps (5.9%) had the ability to adapt the size of operating elements and displayed images; on the other hand, 16 apps (47.1%), had password-protected services. **For more details, see supplementary file including the raw data.**

3.5. Correlations

Total quality score was correlated with total usability score ($R=0.534$, $p<0.001$), number of downloads ($R=0.459$, $p<0.05$) and time since the last update ($R=-0.430$, $p<0.05$), but not with users' rating ($R=0.208$, $p>0.05$). There were no differences in the quality score in apps with and without premium content ($z = -0.127$, $p=0.90$), or with and without quality certification ($z = -1.615$, $p=0.11$). Regarding the usability score, it was not correlated with number of downloads ($R=0.361$, $p>0.05$), number of functions ($R=-0.169$, $p>0.05$) or users' rating ($R=-0.126$, $p>0.05$).

3.6. Top apps

Finally, the apps with the best results in the total quality and usability score were: OneTouch Reveal™, Social Diabetes™, mySugr: App Diario de diabetes™, Diabetes menú™, Tactio SALUD and Diabetes:M™ (see key features in figure 2). Social Diabetes™ and mySugr: App Diario de diabetes™ are certified health products, whereas Tactio SALUD includes a list of references as supporting evidence. A list of the top 20 app, with their corresponding scores, is shown in table 1.

No diabetes apps are available yet in AppSalut (16). In the iSYScore, 5 diabetes apps were included in the top 20 health apps for patients in 2017: Social diabetes (37 out of a maximum of 47 points), OneDrop (36 points), mySugr:App Diario de diabetes (31 points), Contour Diabetes (27 points) and Diabetes a la carta (24 points) (18). All of them were included in our top 20 list, too, except for Contour Diabetes, which was not assessed, given the fact that it was linked to a specific device. In MyHealthApps, mySugr is included, with a comment by Diabetes Voice 2013 (IDF), but the link provided is not active. None of the other apps in our top 20 list is present in this platform (19).

4. Discussion

In view of these results, there are few apps available in Spanish in comparison with other languages like English. Furthermore, very few apps had scientific evidence and a quality certification, which is worrisome, considering that they are used by patients, who could follow the advice provided. Other problems are the privacy elements and the use of data that apps can access when they are installed, since most of the apps reviewed were able to access device and personal data; some may even share personal information with third parties. In addition, more than half of the applications did not specify what type of DM they were targeting, which can be a problem for patients when using the apps, since the different types of DM have specific needs. In favour of the apps, most had been updated in a period of 3 months, which reflects the attention of the developers to keep them free from errors and with updated content.

In terms of functionalities, the insulin dose function deserves to be mentioned. As Hirsch et al. stated, the safety and clinical efficacy of these smartphone-based bolus calculators are not known (20). Therefore, it should be checked if the applications provide some type of scientific reference and / or the procedures carried out to develop the insulin dose calculators. With regard to quality criteria, the mean total score was just above half of the maximum score. Thus, it is reasonable to say that the contents provided by most of the applications should be taken with caution.

As far as the usability criteria are concerned, the average total score was also half-way to the maximum score. The variable with the best result was High fault tolerance / efficient fault management, which shows the care that the developers of the applications have in the possibility of modifying the results, while the variable with the worst average (Simple, self-explanatory and menu structures) reflects that more effort should be put not only to improve the contents of the applications but also the presentation and the ability to adapt to the user, since only 2 apps had the ability to adapt the size of operating elements and displayed images.

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2 There were no apps for diabetes with a quality certification from the Andalusian Health
3 Service (15) , although there are several in the applications process. It is worth noting that this
4 quality certification and the Decalogue from the Spanish Diabetes Society are relatively
5 recent, so it is expected that more apps will be included in the near future. Indeed, some of the
6 apps do have the EC “health product” certification. Regarding other quality criteria, the
7 Spanish iSYScore included, 5 diabetes apps among their the top 20 health apps, 4 of them
8 among our top 20 apps, too (see table 1) (18).

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18 Regarding the top app list, for people with type 1 diabetes, the authors would probably
19 recommend mySugr™, since it has a high total quality score, is less intrusive in terms of
20 privacy compared to Social Diabetes™ and has an insulin dose calculator (with health product
21 certification). Even though OneTouch Reveal™ had the highest total quality score, it does not
22 include an insulin dose calculator, which is a feature that is highly valued by patients with
23 type 1 diabetes, proficient in carbohydrate counting. Diabetes:M™, on the other hand,
24 includes an insulin dose calculator and allows to count carbohydrates based on a food
25 database, but it does not have a health product certification or provides scientific references
26 about its contents. Regarding people with type 2 diabetes, Tactio Salud™ may be an
27 interesting app, since it allows to monitor, not only blood sugar, but associated cardiovascular
28 risk factors, too.

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41 The main strength of this study is that, to our knowledge, it is the first systematic review
42 about apps available in Spanish, and could be helpful for patients in Spanish-speaking
43 countries. Furthermore, we have extensively assessed the quality properties of the apps and
44 ranked the top 20. We believe that we provide valuable information to health care
45 professionals who might want to recommend an app to their patients. Finally, we used
46 adapted, PRISMA-based methods, a recognised reference in the performance of systematic
47 reviews (21).

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58 If we stop to appreciate the differences with the rest of studies, we should compare this study
59 with those performed by Arnhold et al (13). and Brzan et al (14). Regarding Arnhold’s study,
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1 the main similarities are that we both included apps only available in Android and iOS and
2 evaluated the usability of the apps. On the other hand, we have some differences with that
3 study: they included premium apps, whereas we included only free apps. In addition, their
4 search method included, not only diabetes, but also other keywords such as “Blood
5 Sugar/Blutzucker, Glucose/Glukose” and chose the subcategories “Health and Fitness” and
6 “Medicine” on AppStore, so they may have included a wider variety of apps. In addition, the
7 usability criteria were assessed by three evaluators, whereas, in this study, we only had one
8 evaluator, so the results may be more subjective than the results from the cited study. They
9 also examined if the available applications served the special needs of DM patients aged 50 or
10 more. However, they only focused on usability, and did not include quality criteria, as we did
11 (13).

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23 With respect to Brzan’s study, the main similarities are that they only included free apps and
24 used the keyword “diabetes” in their search. However, they also included apps for windows
25 phone, which may be of interest to patients that have devices with that operating system. Like
26 Arnhold et al. three independent experts were included in the assessment for eligibility and in
27 the testing phase. Again, they did not evaluate the quality characteristics of the apps. It should
28 be noted that they used demanding inclusion criteria, which resulted in only 9 apps being
29 analysed (14).

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39 We also acknowledge that this study has some limitations. The exclusion of the paid apps
40 (and exclusive access apps) may have left out relevant, even high-quality, apps, and we are
41 also aware of the fact that including an additional reviewer throughout the whole process
42 would have made the results more robust.

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50 To summarize, there are few free apps available for diabetes management, in Spanish, in
51 comparison with other languages and most of them act as a blood glucose diary. In addition,
52 most of the available apps lack any kind of quality certification and very few provide
53 scientific references about their content. Therefore, we recommend developers to focus on
54 improving the quality of their applications. In addition, most of the apps accessed
55 personal/device data, which should alert app users to read the terms and conditions

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2 thoroughly. In the future, quality elements should be considered when evaluating an app.
3 Indeed, clear-cut recommendations are available for this purpose in Spain.
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Table 1: Top 20 Apps and their quality, usability and total scores*

Name and version of the app	Quality	Usability	Total
OneTouch Reveal (3.3)	45	39	84
Social Diabetes (4.2.4) / (2.5.17)	40	40	80
mySugr: App Diario de diabetes (3.44.1)	40	39	79
Tactio SALUD (7.14)	40	37	77
Diabetes menú (1.1.1/1.1.2)	38	39	77
Diabetes:M (5.6.3)/(1.4.1)	41	33	74
expertSalud (2.23)	35	38	73
ÍG/CG: Índice y Carga Glucémicos: Dietas Low Carb (2.2.1)	39	32	71
El círculo de la Salud (1.1.3)	32	39	71
Dottli: La diabetes fácil (1.32/1.13)	39	31	70
One Drop - Administración de la Diabetes (1.8.13)	39	31	70
Diabetes a la carta (2.1)	25	41	66
Monitor de glucosa (3.4.2)	35	30	65
ClepIO(1.29)	34	31	65
MedM Diabetes (2.2.85)/(2.3.44)	35	29	64
Andaman7 (2.3.3)	33	30	63
Diaguard: Diabetes Tagebuch (2.4.1)	25	38	63
gluQUO: Tu mejor asistente para la diabetes (1.1.8)	21	42	63
YouShield (1.0)	33	28	61

Estudios de Diabetes (2.20.14)	21	39	60
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*Maximum scores were: 48 points for quality, 47 for usability and, thus, 95 for the total score.

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Figure 1

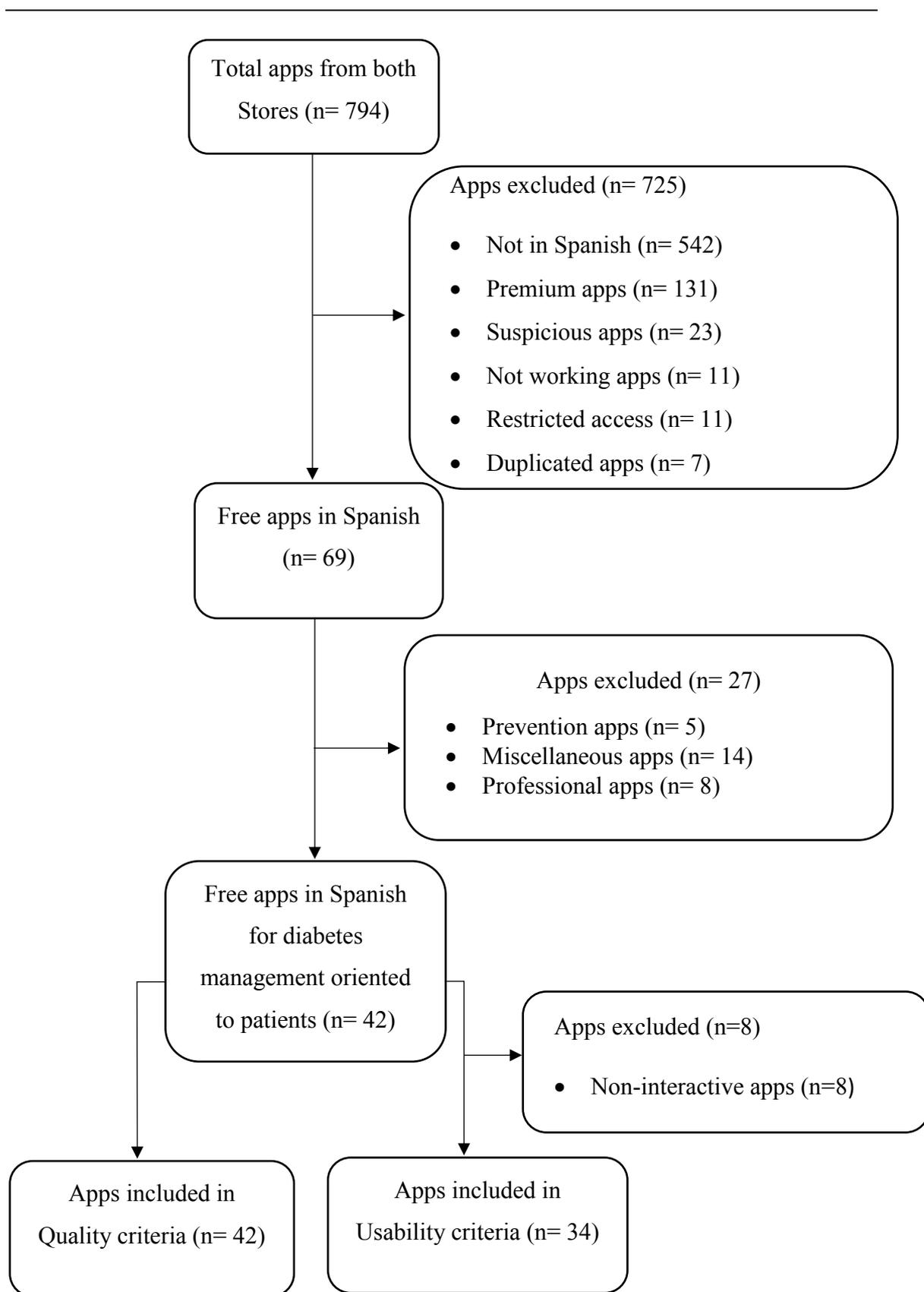


Figure 1. App search flow-chart.

Figure2. Key features of the top apps.

App (version), logo & developer	Quality/Usability Score	Store	Key functions	Quality features	Privacy features
 OneTouch Reveal™ (3.3)	45/39	iOS & Android	Daily blood glucose measurement, importation ¹ , insulin register, physical activity and carbohydrate intake	Does not have a Quality certification. Has scientific references for its contents	An account is required to be used (name, birthdate and email needed), collects information about the device passively (it can use this information and share it with third parties)
 LifeScan, Inc.		iOS & Android	Daily blood glucose measurement, importation ² , insulin dose calculation	CE Health product certification. Does not have scientific references. Its Premium version was updated (and charged) without previous notice	It requires extensive, private, medical information to create an account, it also collects technical data and information about the mobile device. It shares the information with 3 rd parties.
 Social Diabetes	40/40	iOS & Android	Daily blood glucose measurement, importation ² , insulin dose calculation	CE Health product certification. Does not have scientific references. Its Premium version was updated (and charged) without previous notice	It requires extensive, private, medical information to create an account, it also collects technical data and information about the mobile device. It shares the information with 3 rd parties.

App logo & developer	(version), Quality/Usability Score	Store	Key functions	Quality features	Privacy features
 mySugr GmbH	App 40/39	Android	Blood glucose register importation, ketone value register, pre-prandial insulin dose calculation, event (meals, exercise, etc.) addition and other data importation ³	CE Healthcare products certification. Does not have scientific references	An account is required (only email is needed). The app processes the date, time and location in which the user enters the data
 Abbott	Diabetes menu™ 38/39	iOS & Android	By access to a food database, it allows to calculate total calories per menu, but does not calculate carbohydrate content	Does not have any kind of scientific references or quality certification	Accesses personal/device data (Photos/multimedia/files. Personal information: name, email address, telephone number and medical information)

App logo & developer	(version), Quality/Usability Score	Store	Key functions	Quality features	Privacy features
 <p>Tactio SALUD™ Tactio Software Internation Inc</p>	40/37	iOS & Android	Daily blood measurement, monitors range of health data (weight, blood pressure, lipids...) and imports data ⁴ . Estimates cardiovascular risk.	Provides scientific references. Does not specify the types of diabetes which it is targeted to and does not have any kind of quality certification. Has some translation errors from English to Spanish	Requires an account to be used (name, email) and collects information about the use of software (refers not to collect the identity of the user but does not specify what it collects)
 <p>Diabetes:M™ Sirma Medical Systems</p>	41/33	iOS & Android	Daily blood glucose measurement, pre-prandial insulin dose calculation, event addition and carbohydrate counting based on food database	Does not have any kind of scientific references or quality certification	The creation of an account is optional. It collects information introduced in the app (only with user's permission), it automatically collects information from the device (ID, IP address, operating system, type of web browsers and information about the use of the app)

1: it can import results from OneTouch Verio Flex™, OneTouch Ultra Plus Flex™ and OneTouch Select Plus Flex™ glucose meters. 2: it is able to import reports generated by Freestyle™ Libre continuous glucose monitor, as well as several glucometers (glucocard SM™, Glucomen Areo 2K™ and contour next one™). 3: import data from apple health™ and freestyle libre™. 4: import glucose data from iHealth™, Medisana™ and Telcare BGM™. It is also compatible with Fibirit™, Garmin™, GoogleFit™, iHealth™, Jawbone™, Medisana™, MyFitnessPal™, Nokia Health™, Omron™, Qardio™, RunKeeper™ and Telcare BGM.

Annex*Table 1. List of recommendations excluded*

Main group/subgroup	Description of the recommendation	Reason to be excluded
Design and appropriateness		
Usability		
	Recommendation 3. The health App follows the recommendations, patterns and directives included in the official manuals of the different platforms	This is the objective of the usability criteria.
Usability/Testing		
	Recommendation 4. The health App has been tested by potential users before its availability to the public	Difficult to be assessed objectively.
Content and Information Sources		
	Recommendation 13. The health App is based on ethical principles and values	Difficult to be assessed objectively.
Risk Management		
	Recommendation 15. The known risks and adverse events (near misses) are analysed, and the convenient actions start to be developed	Aimed at app developers.
Provision of services		
Bandwidth		
	Recommendation 19. The health App makes an efficient use of communications bandwidth	Difficult to be evaluated.
Confidentiality and privacy		
Privacy and Data Protection		
	Recommendation 25. The health App informs the users when it has access to	It has been included in the Privacy and

Main group/subgroup	Description of the recommendation	Reason to be excluded
	other resources of the device, to users' accounts and to profiles in social networks	data protection category.
Logical Security		
	Recommendation 31. When the health App uses services from the Cloud (cloud computing), the terms and conditions of those services are declared, and the pertinent security measures are ensured	It has been included in the Privacy and data protection category.

Table 2. List of recommendations included.

Main group/subgroup	Description of the recommendation	Assessment criteria
Design and appropriateness		
Appropriateness		
	Recommendation 1. The health App clearly defines its functional reach and its purpose, identifying the target groups of information and the aims pursued regarding these groups	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
Accessibility		
	Recommendation 2. The health App follows the Principles of Universal Design, as well as reference accessibility standards and recommendations	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
Quality and safety of information		
Suitability for the Audience		

Main group/subgroup	Description of the recommendation	Assessment criteria
	Recommendation 5. The health App adapts itself to its target audience	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Transparency	
	Recommendation 6. The health App offers transparent information about its owners' identity and location	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Recommendation 7. The health App offers information about its funding sources, promotion and sponsorship, as well as about possible conflicts of interests	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Authorship	
	Recommendation 8. The health App identifies the authors of its content and their professional qualification	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Information Update/Revisions	
	Recommendation 9. The health App includes the date of the last revision made in the published material	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Recommendation 10. The health App warns of those updates which modify or	0-2 scale (0= completely

Main group/subgroup	Description of the recommendation	Assessment criteria
	influence the functioning of health-related content, as well as other sensitive data	disagree;1= partially agree; 2= completely agree)
	Content and Information Sources	
	Recommendation 11. The health App is based on one or more reliable information sources, and takes into account the available scientific evidence	0-2 scale (0= completely disagree;1= partially agree; 2= completely agree)
	Recommendation 12. The health App offers concise information about the procedure used in order to select its content	0-2 scale (0= completely disagree;1= partially agree; 2= completely agree)
	Recommendation 13. health App is based on ethical principles and values	0-2 scale (0= completely disagree;1= partially agree; 2= completely agree)
	Risk Management	
	Recommendation 14. The possible risks for patient safety caused by the use of the health App are identified	0-2 scale (0= completely disagree;1= partially agree; 2= completely agree)
	Provision of services	
	Technical Support/Inquiries	
	Recommendation 16. The health App has a support system about its use	0-2 scale (0= completely disagree;1= partially

Main group/subgroup	Description of the recommendation	Assessment criteria
		agree; 2= completely agree)
	Recommendation 17. The health App offers a contact mechanism for technical support with an assured and fixed response time	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
E-Commerce		
	Recommendation 18. The health App informs about the terms and conditions on the commercialisation of its products and services'	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
Advertisement		
	Recommendation 20. The health App warns of the use of advertisement mechanisms and allows deactivating or skipping them	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
Confidentiality and privacy		
Privacy and Data Protection		
	Recommendation 21. Before downloading and installing it, the health App informs about the kind of user's data to be collected and the reason, about the access policies and data treatment, and about possible commercial agreements with third parties	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Recommendation 22. The health App clearly describes the terms and conditions	0-2 scale (0= completely

Main	Description of the recommendation	Assessment criteria
group/subgroup		
	about recorded personal data	disagree; 1= partially agree; 2= completely agree)
	Recommendation 23. The functioning of the health App preserves privacy in the recorded information, collects express consents granted by users, and warns of risks coming from the use of online mobile health Apps	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Recommendation 24. The health App ensures pertinent security measures when users' health information or sensitive data has to be collected or exchanged	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Recommendation 26. The health App ensures the right of access to recorded information and the updates regarding changes in its privacy policy	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Recommendation 27. The health App has measures regarding minors' protection in accordance with the current legislation	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
Logical Security		
	Recommendation 28. The health App presents no sort of known susceptibility nor any type of malicious code	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)

Main group/subgroup	Description of the recommendation	Assessment criteria
	Recommendation 29. The health App describes the security procedures established in order to avoid unauthorised access to personal data collected, as well as to limit the access by third parties	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Recommendation 30. The health App has encryption mechanisms for the storage and exchange of information, as well as mechanisms for password management	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)
	Recommendation 31. When the health App uses services from the Cloud (cloud computing), the terms and conditions of those services are declared, and the pertinent security measures are ensured	0-2 scale (0= completely disagree; 1= partially agree; 2= completely agree)

Table 3. Evaluated usability and assessment criteria from Arnhold et al.

Main criterion/subcriteria	Description of characteristics	Assessment criteria
Comprehensibility		
Use of understandable semantics		
	Avoidance of foreign language and technical terms	5-point Likert scale (1=does not apply at all;
	Use of generally intelligible symbols and terms	5= does fully apply)
	If necessary, provision of additional explanations	
Simple comprehensibility and interpretability of displayed images and depictions		

Self-explanatory images and depictions, understandable without further support and explanations

5-point Likert scale (1=does not apply at all; 5= does fully apply)

Simple, self-explanatory menu structures

Easily understandable and internally consistent menu structures

5-point Likert scale (1=does not apply at all; 5=does fully apply)

Avoidance of strong hierarchical menu structures and too many functionalities

Presentation (Image and Text)

Sufficient color contrast

Clear, distinguishable colors for images and depictions or choice of color-neutral depictions

Avoidance of too glaring colors

5-point Likert scale (1=does not apply at all; 5=does fully apply)

Large size of operating elements

Sufficient size of screen as well as input and output fields

5-point Likert scale (1=does not apply at all; 5=does fully apply)

Ability to adapt the size of operating elements and displayed images

Ability to adapt size of operating elements and displayed images according to individual needs, capabilities, and preferences

Dichotomous scale (applicable, not applicable)

Usability

Instant and easily understandable feedback

Instant response to entered data, including easily understandable error messages in case of erroneous data input

5-point Likert scale (1=does not apply at all; 5=does fully apply)

Intuitive usability

Ability to use the application without prior knowledge

Ease of learning

Fast achievement of a first feeling of success

5-point Likert scale (1=does not apply at all; 5=does fully apply)

Simple recognition of click-sensitive areas

Simple distinction between click-sensitive and non-click-sensitive areas, also without prior knowledge of the features of the touchscreen technology

5-point Likert scale (1=does not apply at all; 5=does fully apply)

General characteristics**High fault tolerance/efficient fault management**

Reducing probability of erroneous data input by limiting choice to meaningful values

Efficient proofreading mode and/or helpful user feedback, for example, in case of erroneous data input

5-point Likert scale (1=does not apply at all; 5=does fully apply)

Password-protected services

Avoidance of registration at online platforms (but partly contrary to data protection regulations)

Dichotomous scale (applicable, not applicable)

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