VNIVERSITAT DE VALÈNCIA

Facultat de Medicina i Odontologia

TESIS DOCTORAL EN MEDICINA

REMINDCARE:

UNA APLICACIÓN PARA PRIMEROS EPISODIOS PSICÓTICOS INTEGRADA EN LA PRÁCTICA CLÍNICA DIARIA.

Lucia Bonet Mora

Director de la tesis: Dr. Julio Sanjuán Arias

DEPARTAMENTO DE MEDICINA
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Fecha: 31 de Marzo de 2021

Fdo.: Dr. Julio Sanjuán Arias

Director

ESCUELA DOCTORAL

UNIVERSITAT DE VALÈNCIA

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LISTA DE SIÍMBOLOS, ABREVIATURAS Y SIGLAS:

APP: Aplicación para *smartphone*

eHealth: *Electronic Health*, intervenciones en el ámbito de la salud que hacen uso de las nuevas tecnologías, ya sea mediante el uso de intervenciones online, mediante *werables*, aplicaciones móviles, etc.

HCUV: Hospital Clínico Universitario de Valencia

mHealth: *Mobile Health*, intervenciones en el ámbito de la salud que hacen uso de dispositivos móviles.

PEP: Primeros Episodios Psicóticos

In the post-feasibility era of mobile mental health,
it is now time to consider
efficacy, effectiveness, and efficiency.

(John Torous, 2018)

1. PRESENTACIÓN

El objetivo de esta tesis doctoral, es el de presentar la aplicación ReMindCare. Una aplicación para smartphone diseñada para el seguimiento de pacientes con psicosis y desarrollada por la *Unidad de Primeros Episodios Psicóticos* del *Hospital Clínico Universitario de Valencia*.

Como se expone a lo largo de este escrito, si bien es cierto que el desarrollo de nuevos sistemas tecnológicos en el ámbito de la salud mental cobra cada día mayor interés entre la comunidad científica, aún existe una gran distancia entre la investigación experimental y su aplicación en la práctica clínica diaria.

El proceso de creación de ReMindCare estuvo guiado por dos objetivos fundamentales, sencillez en su diseño y utilidad clínica. Para alcanzar ambos, se realizó tanto un análisis de la bibliografía existente como un estudio de los intereses de los pacientes.

ReMindCare, se aleja de aplicaciones más novedosas orientadas a la obtención masiva de datos cuantitativos, y mediante sus tres preguntas de evaluación diaria y su evaluación semanal más exhaustiva, busca elaborar un esquema sencillo, que retrate el estado global de salud del paciente, con el que poder trabajar durante la sesión clínica. El objetivo de ReMindCare es, por lo tanto, conseguir un cambio cualitativo real en la atención al paciente psiquiátrico, mejorando la calidad de la entrevista psicológica, la rapidez en la comunicación entre el paciente y el clínico, y la atención temprana a los pacientes.

Se trata de un enfoque innovador, puesto que hasta donde nosotros conocemos, no existe ninguna aplicación para el paciente con psicosis, que haya sido sistemáticamente implementada en la práctica clínica diaria. Por ello, esperamos que este estudio pueda servir de referencia para posteriores investigaciones, y que sirva como muestra de los potenciales beneficios que la introducción de nuevas tecnologías en el ámbito sanitario puede suponer en el tratamiento de los pacientes con psicosis. Puesto que, según nuestro punto de vista, la innovación tecnológica en el ámbito sanitario no debe ser un fin en sí mismo, sino que siempre debe estar orientada a la mejora del tratamiento de los pacientes. Y esta mejora, solo se producirá si estos sistemas se integran de forma real en la práctica clínica cotidiana.

Finalmente, cabe destacar que desde el inicio de la pandemia por COVID-19 y las limitaciones que ha impuesto en el acceso de los pacientes a los servicios sanitarios, intervenciones como ReMindCare deben ser un objetivo prioritario con el que tratar de minimizar el impacto de esta crisis en el sistema sanitario y con el que tratar de garantizar el acceso de los pacientes a servicios psiquiátricos de calidad.

2. INTRODUCCIÓN

2.1. La Psicosis

Según el *National Alliance on Mental Illness* (NAMI, 2021), la psicosis hace referencia a un conjunto de disrupciones en los pensamientos y percepciones del individuo que provoca una ruptura con la realidad. Pese a que la psicosis enmarca un amplio conjunto de síntomas, los dos más característicos de esta reacción aguda son: las alucinaciones y los delirios. Las alucinaciones hacen referencia a fenómenos perceptivos aberrantes e inconscientes, mientras que los delirios hacen referencia al conjunto de creencias o interpretaciones erróneas de la realidad (Sanjuán, 2016).

Las causas que pueden llevar a un individuo a padecer un episodio psicótico son diversas. En la actualidad, se barajan diferentes factores que podrían influir en el desarrollo del episodio.

Entre estos factores destacan (NAMI, 2021):

- *Genética:* Las personas con antecedentes familiares de patologías psicóticas cuentan con un riesgo más elevado de desarrollar estos cuadros. A su vez, se han identificado diferentes genes que podrían incrementar el riesgo a padecer esta patología.
- *Traumas:* Eventos con una gran carga emocional, tales como una muerte, guerra o agresión sexual, pueden favorecer a la aparición de sintomatología psicótica.
- *Abuso de sustancias:* Existen sustancias, tales como la marihuana, anfetaminas o LSD, cuyo uso puede aumentar el riesgo de psicosis en personas con vulnerabilidad genética.
- *Enfermedades físicas:* Ciertos daños orgánicos pueden provocar la presencia de cuadros psicóticos, tales como lesiones cerebrales, tumores, infartos o enfermedades del sistema nervioso como la enfermedad de Parkinson o el Alzheimer.
- *Enfermedades mentales:* En ocasiones la psicosis puede aparecer como síntoma dentro de patologías como la Esquizofrenia, el Trastorno Bipolar o la Depresión.

La psicosis, por lo tanto, aparece como una reacción aguda, común a muchos procesos. Algunos de los cuáles evolucionan hacia la cronicidad y el deterioro, mientras que en otros casos, puede aparecer de forma aislada con deterioro asociado o no (Sanjuán, 2016). Todo

ello, provoca una gran heterogeneidad clínica entre los pacientes con psicosis, que dificulta el estudio de estas patologías (Addington et al., 2020) y que requiere de planes de tratamiento individualizados.

A su vez, son trastornos con altas tasas de recaídas y reingresos hospitalarios (Leucht et al., 2012) debido principalmente a la baja adherencia de los pacientes al tratamiento (Lieberman et al., 2005; Acosta et al., 2012). Entre los factores modificables más relevantes asociados a esta baja adherencia, destacan la falta de conciencia de enfermedad y la falta de conciencia acerca de los beneficios e importancia del tratamiento farmacológico (García et al., 2016).

2.2. Programa de Primeros Episodios Psicóticos (PEP)

Dentro de los diferentes abordajes terapéuticos y farmacológicos existentes para el tratamiento de los pacientes con psicosis, destacan los programas de Primeros Episodios Psicóticos (PEP). Estos programas, buscan aumentar la detección precoz de la psicosis, facilitar el acceso a los servicios sanitarios y promover la recuperación del paciente y su entorno (Sanjuán, 2016), puesto que se ha visto, que cuanto mayor es el tiempo que transcurre desde que el paciente presenta los síntomas hasta que recibe tratamiento, peor es la evolución clínica del paciente, tanto a corto como a largo plazo (Marshall et al., 2005; Pelayo-Terán et al., 2018). Sin embargo, debido a las características de nuestro sistema sanitario, este tipo de intervenciones son muy reducidas y no cuentan con los profesionales, herramientas, ni apoyo financiero suficiente para poder llevarse a cabo adecuadamente (Arango et al., 2017). Ciertos estudios incluso sugieren que, pese a los potenciales beneficios que sugiere la investigación, cuando comparamos el efecto de los tratamientos convencionales frente a los programas de atención temprana, no se observan diferencias significativas, ni a nivel de eficacia ni de eficiencia (Marshall et al., 2011).

Desarrollar programas orientados a la detección precoz de la psicosis y a la mejora del tratamiento de los pacientes en las primeras fases de la enfermedad, ofreciendo intervenciones inclusivas y multidisciplinares, es uno de los objetivos prioritarios que debe guiar la práctica clínica en el cuidado del paciente con psicosis (Arango et al., 2018; MSCBS, 2019).

En este sentido, el desarrollo de las tecnologías de la información y comunicación, puede suponer una gran mejora con respecto al tratamiento psiquiátrico tradicional, al permitir un seguimiento personalizado del paciente, que ya no solo permita una mejor evaluación de su estado de salud, sino que refuerce la implicación de este en el tratamiento en general.

2.3. eHealth y mHealth

El término *e-Health* (Electronic Health) o también llamado *digital health*, hace referencia a un conjunto de estrategias y servicios, en los cuales se hace uso de las tecnologías de la información y comunicación, con el fin de mejorar la prevención, diagnóstico, tratamiento, seguimiento y manejo de la enfermedad o de aquellos hábitos de la vida cotidiana que pueden impactar en la misma. Este conjunto de innovadoras intervenciones busca, no solo aumentar el acceso al sistema sanitario, sino también aumentar su eficiencia y calidad (Comisión Europea, 2021)

Ya en 2005, la *Asamblea de la Organización Mundial de la Salud*, en su resolución WHA58.28, instaba a los países miembros a elaborar planes estratégicos a largo plazo para la implementación de servicios eHealth con los que hacer frente a los desafíos a los que se enfrentan los sistemas de salud actuales (WHO, 2005). Este conjunto de desafíos se resumió recientemente en la *guía de clasificación de intervenciones eHealth* (WHO, 2018) publicada en 2018. Entre el conjunto de retos a los que el sistema sanitario debe hacer frente, destaca la falta de acceso a la información, el seguimiento inadecuado e insuficiente de los pacientes, la baja adherencia a los tratamientos por parte de los pacientes, la escasez de recursos o su difícil acceso, entre otros (WHO, 2018).

Con el fin de alcanzar la consecución de estos objetivos, nace el *mHealth* (mobile Health), como una subsección del *eHealth* orientada al uso de las tecnologías móviles aplicadas al ámbito de la salud. Mediante el uso de estos aplicativos, se espera aumentar el empoderamiento de los pacientes, facilitando el acceso a su información clínica, así como mejorar la eficiencia y calidad de los tratamientos que reciben por parte de los clínicos (Comisión Europea, 2021).

En la actualidad, existen más de 100,000 aplicaciones de tipo *mHealth*, disponibles en múltiples plataformas como *Google Play* o *iTunes,* llegando a los 231 millones de descargas en las aplicaciones de salud más comunes (Comisión Europea, 2021). A su vez, la comunidad científica cada vez muestra más interés por estos servicios. Según la *Web of Science*, en la actualidad existen un total de 27 revistas dedicadas específicamente al estudio de las

ciencias de la informática aplicadas a la salud. Entre ellas, desataca la revista *Journal of Medical Internet Research* con un total de 16,349 citas en el 2019 y un factor de impacto del 5.034. (Journal Citation Reports, 2021)

2.4. eHealth y la psicosis

En base a lo expuesto anteriormente, podemos afirmar que el uso de nuevas tecnologías aplicadas al ámbito de la salud, es un sector en pleno crecimiento (Miralles et al., 2020).

Desde que se introdujo internet a principios de los años 90, su uso ha crecido exponencialmente. El número de usuarios de internet se situó en torno a los 3.4 billones ya en 2016 (Roser et al., 2015) y según los últimos informes (Kemp, 2020), en la actualidad alcanza el 4.54 billón de usuarios. En concreto, en España observamos que el uso de internet en los años 90 no superaba el 0.01% de la población, mientras que ya en 2016 el 84.6% de los ciudadanos contaban con acceso al mismo. A su vez, el acceso a móviles se sitúa en la actualidad en el 5.19 billón de usuarios, y la media mundial de uso de internet diario es de 6:43h (Roser et al., 2015).

Resulta indudable, por lo tanto, que el uso de las nuevas tecnologías cada vez se encuentra más extendido en la población general. Sin embargo, la heterogeneidad clínica del paciente con psicosis requiere un estudio específico con el que garantizar que estas intervenciones se ajustan a las características y necesidades de los pacientes (Batra et al., 2017).

En la actualidad, contamos con numerosos estudios que han mostrado que el uso de dispositivos móviles en pacientes con psicosis no sólo es viable (Aref-Adib et al., 2016; Camacho et al., 2019; Lewis et al., 2020), sino que son intervenciones eficaces a la hora de evaluar el estado clínico del paciente, prevenir posibles recaídas y promover su adecuada recuperación (Wang et al., 2016; Bucci et al., 2018; Ben-zeev et al., 2019). No obstante, cabe destacar, que si bien existe un gran número de estudios que confirman la eficacia de estos dispositivos *e-Health* a nivel experimental, no existe suficiente evidencia que permita trasladar los resultados obtenidos en estos estudios, a la práctica clínica habitual (Lauckner et al., 2016; Zanaboni et al., 2018). Es por ello que la viabilidad de estas intervenciones en un contexto real, así como su efecto y potenciales beneficios a largo plazo permanecen aún inexplorados.

Finalmente, desde que comenzó la situación excepcional de pandemia que estamos viviendo en la actualidad, son muchos los estudios que señalan el potencial efecto negativo que esta crisis sanitaria puede producir en la salud mental de la población general (Brooks et al 2020; Salari et al., 2020). Este aumento general del riesgo de patología mental, se ha visto incrementado entre los pacientes con enfermedad mental grave. Diferentes estudios señalan que estos pacientes tienen más riesgo de padecer ansiedad, estrés y depresión (García-Álvarez et al., 2020; González-Blanco et al., 2020) así como, de realizar conductas desadaptativas durante el periodo de confinamiento (Solé et al., 2020).

Estos datos se han reflejado en la práctica clínica diaria, en forma de aumento del número de nuevos episodios, de ingresos forzosos y del tiempo de los ingresos hospitalarios (Rodríguez et al., 2020)

Por todo lo expuesto anteriormente, y en respuesta a la excepcional situación que estamos viviendo en la actualidad, son muchos los estudios que señalan los potenciales beneficios de las intervenciones e-*Health* para paliar las limitaciones al acceso sanitario y el aislamiento social, y poder así combatir los efectos perniciosos de esta pandemia (Kannarkat et al., 2020; Torous et al., 2020; Wang et al., 2020).

3. HIPÓTESIS Y OBJETIVOS

3. 1. Hipótesis

Las hipótesis de este estudio son las siguientes:

1. El interés y el uso de internet y dispositivos móviles por parte de una muestra de pacientes con psicosis se corresponderá con el observado en los datos poblacionales generales en España.

2. La aplicación ReMindCare será aceptada por la mayoría de los pacientes (>70%) que acuden a la unidad de PEP del *Hospital Clínico Universitario de Valencia (HCUV).*

3. Los pacientes mostrarán una alta adherencia al aplicativo. Entendida como, un porcentaje de respuesta a los cuestionarios de la app ReMindCare superior al 70%.

4. Los pacientes que hagan uso de la aplicación ReMindCare presentarán un menor número de recaídas, visitas a urgencias y hospitalizaciones (en el seguimiento tras 12 meses) que los pacientes que no utilicen el aplicativo.

3. 2. Objetivos

El objetivo general de este proyecto, en torno al cual se orienta la tesis, es el de desarrollar y aplicar un sistema de atención sanitaria *e-Health* (App para smartphone) integrado en la unidad de PEP *del HCUV*.

Mediante el uso de este aplicativo móvil, se espera producir una mejora significativa en la calidad de la evaluación del estado de salud de los pacientes y con ello, mejorar las decisiones clínicas y atención sanitaria. A su vez, se espera mejorar la atención temprana ante posibles recaídas, así como reducir las visitas a urgencias y las rehospitalizaciones debidas a empeoramientos clínicos.

En cuanto a los objetivos específicos de esta tesis son los siguientes:

1. Realizar una revisión sistemática de programas *mHealth* para pacientes con psicosis. Analizar sus características y limitaciones.

2. Elaborar y administrar una encuesta a pacientes con psicosis con la que analizar el acceso, uso e impacto de las nuevas tecnologías en su salud mental. Analizar su interés en disponer de un dispositivo *mHealth*.

3. Desarrollar una aplicación móvil que permita monitorizar la adherencia al tratamiento del paciente, así como su evolución clínica.

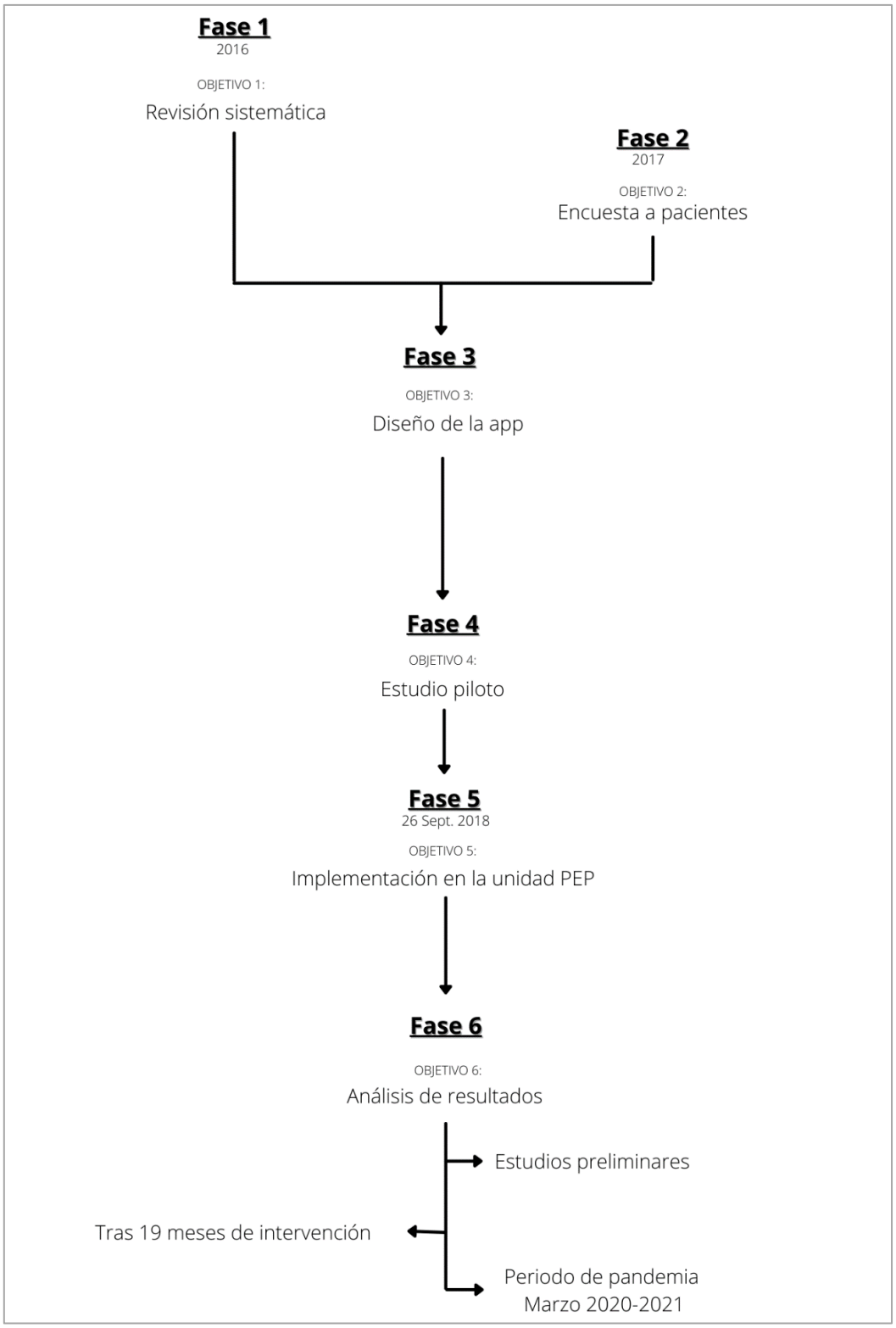
4. Realizar un estudio piloto con el que valorar la viabilidad y buen funcionamiento de la app.

5. Integrar la aplicación en la práctica clínica diaria en la unidad PEP *del HCUV* e integrar los datos obtenidos por esta, en la Historia Clínica Electrónica del paciente.

6. Analizar los resultados del uso de la app, comparando la evolución clínica de los usuarios de la app, frente a la de los pacientes que rechazan su uso.

4. METODOLOGÍA

4.1. Representación esquematizada de las fases de desarrollo y aplicación de ReMindCare en base a los objetivos propuestos



4.2. Proceso de desarrollo de la app

El proceso que ha guiado el desarrollo de la app ReMindCare puede dividirse en diferentes etapas (Fases 1-4):

a. *Revisión sistemática sobre las características y limitaciones de los programas e-Health para pacientes psicosis, analizando sus características y limitaciones* (**Bonet et al., 2017**). [**Objetivo 1**]:

Para garantizar que la app respondiera a las demandas y requisitos de los pacientes con psicosis, en primer lugar, realizamos un análisis de las intervenciones con dispositivos móviles que había hasta el momento. En este estudio, se mostró la potencial viabilidad, aceptación, validez y beneficios para la salud mental del paciente con psicosis mediante el uso de intervenciones móviles.

Estos sistemas, que permiten el registro en tiempo real del estado de salud del paciente, se mostraron como medidas más fiables que los registros retrospectivos, sobre todo si el paciente presentaba deterioro cognitivo. Así los estudios sugerían, que los sistemas *mHealth* podrían ayudar a mejorar la calidad de las decisiones clínicas, reducir la distancia entre el paciente y el personal sanitario y mejorar la detección precoz de los síntomas de recaída, lo que podría reducir las visitas a consulta y supondría un ahorro económico en los servicios sanitarios.

No obstante, pese a los potenciales beneficios observados, encontramos dos limitaciones importantes a señalar. En primer lugar, ninguna de las intervenciones analizadas en nuestro estudio, implementaba estas herramientas como parte de la práctica clínica, sino que se hacía uso de ellas dentro de ensayos clínicos aleatorizados. Por otra parte, algunas intervenciones señalaban los potenciales efectos negativos que una exposición excesiva a estos dispositivos puede provocar en la salud mental de los pacientes con psicosis.

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REVIEW ARTICLE

Use of mobile technologies in patients with psychosis: A systematic review☆

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KEYWORDS
Mobile;
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Schizophrenia;
Adherence;
Psychopathology

Abstract There is a growing interest in mobile Health interventions (m-Health) in patients with psychosis. The aim of this study is to conduct a systematic review in order to analyse the current state of research in this area. The search of articles was carried out following the PRISMA criteria, focusing on those studies that used mobile technologies in patients with psychosis during the period from 1990 to 2016. A total of 20 articles were selected from the 431 studies found. Three types of studies are distinguished: (1) Analysis of quality and usability, (2) Improving treatment adherence and reducing hospital admissions, and (3) Analysis of patient symptoms. Conclusions: m-Health interventions are feasible, and are easy to use for patients with psychosis. They evaluate the evolution of psychotic symptoms more efficiently, and improve adherence to treatment, as well as symptoms and hospital admissions. However, a particular strategy does not stand out over the rest, because differences in methodology make them difficult to compare.

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PALABRAS CLAVE
Móvil;
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Adherencia;
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Utilización de tecnologías móviles en pacientes con psicosis: una revisión sistemática

Resumen Hay un creciente interés en las intervenciones mobile Health (m-Health) en pacientes con psicosis. El objetivo de este estudio es realizar una revisión sistemática para analizar el estado actual de la investigación en este ámbito. La búsqueda de publicaciones se llevó a cabo siguiendo los criterios PRISMA, centrándose en aquellos estudios que utilizan tecnologías móviles en pacientes con psicosis durante el periodo de 1990 a 2016. Se seleccionó un total de 20 artículos de los 431 estudios que se encontraron. Se diferencian 3 tipos de intervenciones: 1) análisis de calidad y usabilidad; 2) mejora de la adherencia, síntomas y reducción de hospitalizaciones, y 3) análisis de la sintomatología del paciente. Conclusión: Las intervenciones m-Health son viables y resultan fáciles de utilizar para los pacientes con psicosis. Evalúan de forma más eficiente la evolución de los síntomas psicóticos y mejoran la adherencia al tratamiento, los síntomas y las hospitalizaciones. No se puede destacar una estrategia sobre las demás debido a que las diferencias en la metodología las hace difícilmente comparables.

Introduction

In recent years information and communication technology (ICT) applied to health have evolved extremely quickly. This has led to a change in the patient-doctor relationship, as now the ''empowered patient'' has emerged. This refers to individuals who are knowledgeable and have information about their disease, who are involved in their treatment and able and interested in contributing and deciding about it (equipped, enabled, empowered and engaged).[1]

Electronic Health (e-Health) technologies combine the use of electronic communications and ICT have clinical, educational, ethical and administrative uses, with the aim of improving the healthcare system, promoting health and increasing the access of the whole population to healthcare. One of its components is mobile Health or m-Health, defined by the World Health Observatory as ''the medical or public healthcare practice supported by mobile devices, patient monitoring devices, personal digital assistants (PDA) and other wireless devices''.[2]

These technologies have been used in the treatment of a wide range of physical and mental pathologies.[3,4] Of these, psychosis is an interesting field due chiefly to the low level of adherence of these patients, as 70% will have abandoned their antipsychotic treatment 18 months after commencing it.[5] The use of m-Health interventions which enables continuous, direct and personalised evaluation, gives the patient a greater role in his treatment and may improve this situation.

A growing number of studies have been undertaken during the past 20 years with the aim of increasing psychosis patient adherence through the use of mobile applications. However, it is hard to extract conclusions from these studies due to the differences between them in terms of sample selection, study procedure or the technique used.

The aim of this study is to carry out a systematic review of the literature to obtain an overview of the state of research into the use of mobile applications in patients with psychosis to improve adherence to treatment.

Methodology

Some of the recommendation and criteria of the PRISMA[6] declaration were followed in undertaking this review. Studies were selected that centre on the analysis of the acceptability, viability, use and possibilities of therapy using mobile devices in the treatment of psychotic patients. The following inclusion/exclusion criteria were applied:

1) We considered mobile device (PDA, mobile telephone and/or smartphone) based interventions to be those which use SMS (short message service) and/or mobile applications (apps). This therefore exclude mobile interventions that only use services based on telephone calls.
2) Studies were selected that covered patients diagnosed with psychotic disorder according to the definition and classification of the fourth and fifth editions of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, DSM-IVR and DSM-5), including: schizophrenia, schizoaffective disorders, bipolar disorder and other psychoses. Studies were included with hospitalised patients as well as follow-ups in outpatient departments.
3) Articles published in the English language from 1990 to 2016.

The data bases PsycINFO, PubMed, Scopus, Medline, ISI Web of Knowledge and the bibliographical data of the CSIC IME were used to search for publications. The following terms or key words were used: ''Cell phone AND schizophrenia'', ''Cell phone therapy AND mental health'', ''Mobile assessment AND treatment schizophrenia'', ''Mobile phone applications (apps) AND mental health'', ''Smartphone AND schizophrenia adherence'', ''The use of smartphones in antipsychotic adherence'', ''The use of smartphones in psychosis'', ''Cell phone AND psychosis'' and ''SMS AND psychosis''.

The publications were first screened by reading their titles and summaries of their results contained in the databases, checking to see whether they fitted the above

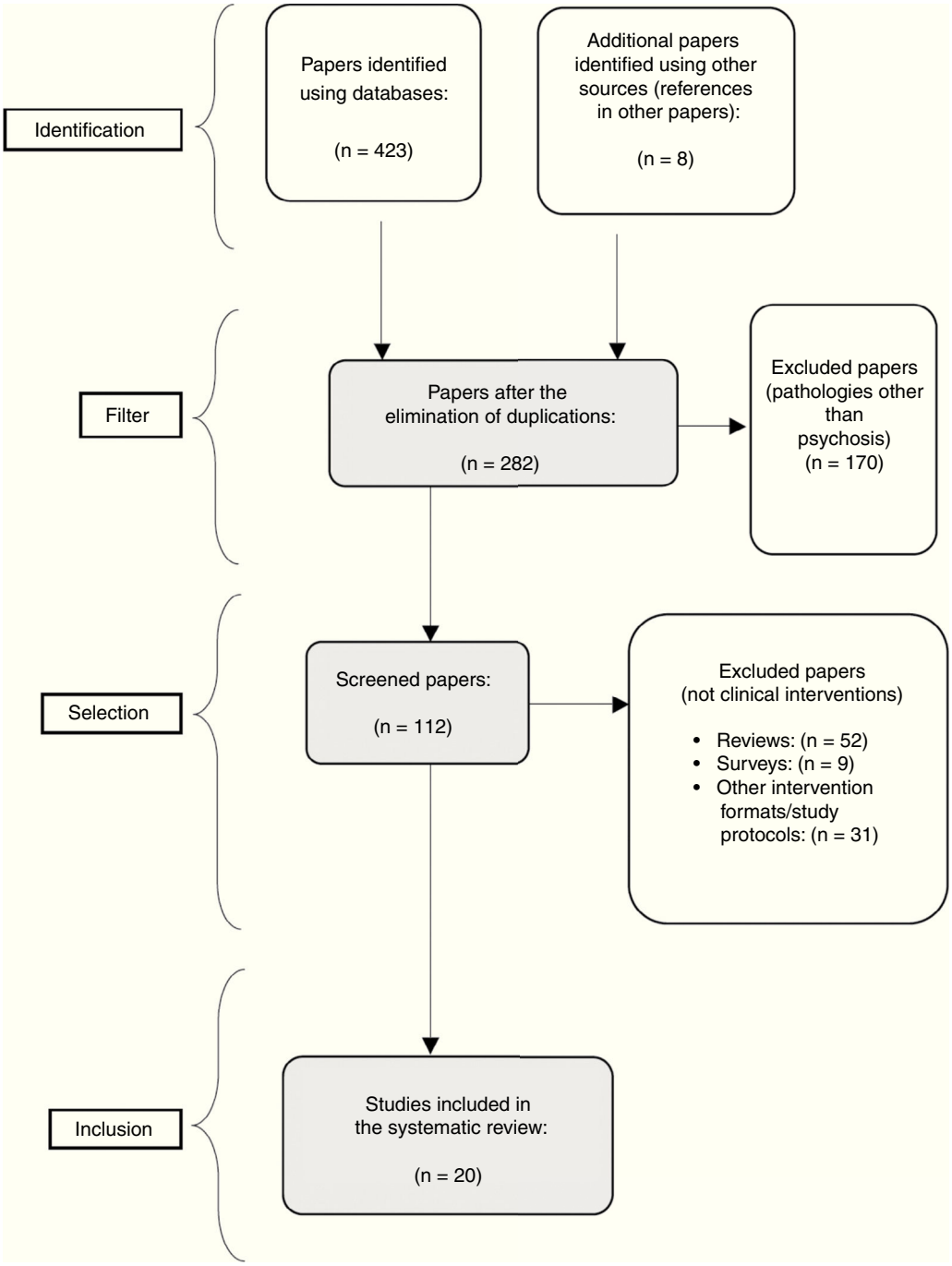

Figure 1 The results of applying the system for searching for and systematically selecting papers.

criteria. In a second phase the papers that had not been excluded were read completely, to evaluate whether they fitted our search criteria. Their references were also studied to find new publications that would complete our registry (Fig. 1).

The papers finally selected were evaluated to check: their date of publication, type of study, duration, objective, sample size, patient epidemiological data (age and sex), evaluation method (scales), m-Health intervention method, mobile device used and the results obtained. These data are shown in Table 1.

Results

As Fig. 1 shows, at first a total of 431 papers were identified. These were reduced to 112 after the elimination of duplications and publications that were not about patients with psychotic disorders. After this, 92 publications were excluded as they did not refer to clinical interventions but were rather systematic reviews (57%), surveys (10%) and study protocols or other intervention formats (33%). Finally a sample of 20 papers was selected, of which 17 were independent interventions.[7–26]

Table 1 Papers included on the use of mobile applications in psychosis.

Author/year [Ref.]	Study/duration	Aim	Sample	Diagnosis	Evaluation technique	M-Health intervention technique	Results
Spaniel et al., 2008[7]	Quantitative analysis 1 year	Reduce the number of hospital admissions	No. = 73 (family members n = 56) Average age: 30 Men: 54.8%	Schizophrenia (64.4%), schizoaffective (20.5%), acute psychosis (15.1%)	EWSQ CGI	ITAREPS: app that evaluates early signs of relapse	Reduction: Hospitalisations (77%) Number of days hospitalised (58%)
Pijnenborg et al., 2010[8]	Quantitative and qualitative analysis 7 weeks	Evaluate the efficacy of the SMS to improve patient functioning with cognitive deterioration	No. = 62 Average age: 28.8 Men: 79%	Schizophrenia (85%), schizoaffective (6%)	Test de cognitive evaluation, functional, psychiatric, motivation and self-esteem	SMS reminders: attaining specific objectives	Increase attaining objectives (77%), but this fell after withdrawal 70% positive evaluation
Granholm et al., 2012[9]	Quantitative analysis 12 weeks	Improve adherence to medication, socialisation and auditory hallucinations using a SMS system	No. = 55 Average age: 48.7 Men: 69%	Schizophrenia (80%), schizoaffective disorder (20%)	PANSS BDI-II ILSS ANART	MATS: behavioural–cognitive intervention using interactive SMS	Increasing adherence to medication and socialisation Reducing auditory hallucinations
Palmier-Claus et al., 2012[10]	Quantitative analysis 1 week	Study of the validity of the ClinTouch app to evaluate patients with psychosis and examine adherence according to their severity	No. = 44 (n = 12 in each group) Average age: 31.4 Men: 78%	3 Groups: Acute and in remission: schizophrenia (80%), schizoaffective (12%), schizophreniform (8%) Group at risk: no diagnosis	PANSS CAARMS CDS	ClinTouch (app for smartphone): monitoring psychotic and affective symptoms	Validity: varies according to item (mainly high) Good internal consistency and sensitivity to change No differences in adherence according to severity (82%)
Montes et al., 2012[11]	Quantitative analysis 6 months (SMS: 3 months)	Evaluate the efficacy and impact of a SMS intervention on improving the adherence to anti-psychotic treatment	No. = 254 (SMS: n = 100; control: n = 154) Average age: 39.6 Men: 67%	Schizophrenia (paranoid 80%)	MAQ CGI-SCH DAI-10 SUMD EQ-5D	SMS to remind patients to take medication	Increasing adherence to treatment in the SMS group, but the effects fall off significantly in the follow-up
Palmier-Claus et al., 2013[12]	Qualitative analysis 2 weeks	Explore patient perceptions of 2 types of mobile intervention, their impact and implications	No. = 24 Average age: 33.04 Men: 79%	Schizophrenia (92%), schizoaffective (8%)	Semi-structured interview	Two phases: SMS App Evaluating psychotic and affective symptoms	Usability: smartphone Messages: complaints due to repetitiveness and negative effects of increased insight Better clinical attention (coadjuvant)

Table 1 (*Continued*)

Author/year [Ref.]	Study/duration	Aim	Sample	Diagnosis	Evaluation technique	M-Health intervention technique	Results
Ainsworth et al., 2013[13]	Quantitative analysis 2 weeks	Idem previous	Idem previous	Idem previous	PANSS Test: acceptability, usability	Idem previous	Entries: smartphone (69%) vs SMS (56%) Preference: smartphone (67%) vs SMS (13%)
Palmier-Claus et al., 2014[14]	Quantitative analysis 2 weeks	Study of the relationship in time between thoughts of self-harm and psychotic symptoms	No. = 36 (n = 12 per group) Average age: 31.4 Men: 78%	3 Groups: Acute and in remission: psychotic disorder High risk of psychosis: no diagnosis	CAARMS	Idem previous	Relationship: between thoughts of self-harm and hallucinations measured by level of paranoia Thoughts of self-harm do not predict an increase in psychotic symptoms
Kimhy et al., 2014[15]	Quantitative analysis 2 days	Study of the use of mobile technologies in hospitalised patients and analysis of clinical characteristics	No. = 33 Average age: 27.8 Men: 55%	Schizophrenia (77%), schizoaffective (21%), psychotic depression (6%), delirious disorder (3%)	Test: symptoms, affects, localisation and social context	App that evaluates psychiatric symptoms, state of mood and patient context	Response: 81% More depressive symptoms alone Less severe psychotic symptoms in activity wards and at midday
Ben-Zeev et al., 2014a[16]	Quantitative analysis 1 month	Study of the feasibility, acceptance and efficacy of a mobile intervention for patients with schizophrenia	No. = 33 Average age: 45.9 Men: 61%	Schizophrenia and schizoaffective disorder	WRAT-4 PANSS BDI-II ISI BMQ BACS SUS PSSUQ TAMMS USE	FOCUS: Smartphone app to improve self-management of the disease in psychosis	Viability: used 86% days, no interaction with clinical symptoms Acceptance: 90% Efficacy: improve positive, general and depressive symptoms
Ben-Zeev et al., 2014b[17]	Quantitative analysis 12 weeks	Viability, use and satisfaction study of a SMS system for patients with dual pathology	No. = 17 Average age: 40.47 Men: 59%	Dual pathology: schizophrenia and schizoaffective disorder and past or present substance abuse	WRAT-4 PANSS BDI-II BMQ BACS USE WAI	SMS	Viability: 87% SMS response High usability and satisfaction (90%) Increased alliance with the clinic
Brenner y Ben-Zeev, 2014[18]	Quantitative analysis 1 week	Analysis of the relationship between affective predictions and real affective experiences	No. = 24 Average age: 44.88 Men: 71%	Schizophrenia and schizoaffective disorder	PANAS	Affect evaluation system using a PDA (reminders and answering a digital questionnaire)	Over-estimation of affects in predictions vs actual experience (more for positive affects) Response: 98.1%

Table 1 (*Continued*)

Author/year [Ref.]	Study/duration	Aim	Sample	Diagnosis	Evaluation technique	M-Health intervention technique	Results
Moore et al., 2015[19]	Quantitative analysis 1 day	Study of the feasibility and validity of the UPSa test version for mobile telephone and tablet	No. = 34 (patients n = 21; control: n = 13) Average age: 48.9 Men: 51%	Schizophrenia and schizoaffective disorder	UPSA UPSA-*Brief* UBACC RBANS PANSS	UPSA-M: UPSA test app that evaluates functionality	Viability and validity: discriminating patients with schizophrenia, UPSA-M (80%) and UPSA-M *Brief* (87%)
Blum et al., 2015[20]	Quantitative analysis 2 days	Evaluate validity and discriminatory power measured in real time of the depressed affect and association with long-term memory	No. = 73 (patients: n = 51; control: n = 22) Average age: 27.02 Men: 55.2%	Schizophrenia (68%), schizoaffective disorder (24.5%), delirious (2.5%), unspecified psychosis (5%)	DIGS BDI-II MoD LM-II WMS-R PSRS QoLS SAPS SANS	Experience Sampling Method (ESM): app that records mood and symptoms in real time	High discriminatory validity of real-time measurements: Better in evaluating affective experiences (less influenced by long-term memory distortions)
Forchuk et al., 2015[21]	Qualitative analysis 12–18 months	Patient experience analysis using Lawson Smart Record	No. = 95	Psychotic disorder	Not specific	Lawson Smart Record: a smartphone app that measures state of health	Most useful for: reminding of appointments and recording activity Complaints: the need to register and too many message
Kauppi et al., 2015[22]	Quantitative analysis 12 months	Study of the relationship between patient characteristics and their preferences for a SMS	No. = 562 Average age: 38.6 Men: 47%	Schizophrenia, schizoaffective disorder and delirious (37%), depression (28%), personality disorder (12%)	Not specific	SMS selected by the patient about treatment	Relationship between socio-demographic variables and No. of SMS/month and times Selection of SMS: 30% medication 28% appointment reminders 42% leisure
Kannisto et al., 2015[23]	Quantitative and qualitative analysis 12 months	Explore patient feedback after using a SMS to increase adherence to treatment	No. = 558 (responded: n = 403) Average age: 39.7 Men: 44%	Schizophrenia, schizoaffective disorder and delirium disorder (38%), affective disorder (29%), other psychotic disorders (33%)	TAM	SMS selected by the patient	Response rate: 72% Feedback: easy to use (98%), satisfied (72%), may cause damage (13%)

Table 1 (*Continued*)

Author/year [Ref.]	Study/duration	Aim	Sample	Diagnosis	Evaluation technique	M-Health intervention technique	Results
Macias et al., 2015[24]	Quantitative and qualitative analysis 1 month	Analysis of acceptance and usability of a prototype app to promote physical activity in psychiatric patients	No. = 10 Age: 50% ≥50 Men: 50%	Schizophrenia and schizoaffective disorder (40%), bipolar (30%), severe depression (30%), chronic disease (60%), over weight (50%)	Not specific	Wellwave app (smartphone): increasing physical activity and monitoring patients	Used app: 94% days Response (73%): Highest (98%): personal messages Lowest (39%): reminders for daily walks
Spaniel et al., 2015[25]	Quantitative analysis 18 months	Analysis of the efficacy of ITAREPS in reducing hospitalisations	No. = 146 (patient − partners − family) (active group: n = 74; control group: n = 72) Average age: 36.5 Men: 56.2%	Schizophrenia (70%), schizoaffective disorder (30%)	CSI HMCS EWSQ	ITAREPS: app tat evaluates early signs of relapse	No significant differences between the active and control groups for: Relapse (16.2% vs 19.4%) Days hospitalised (11.3 vs 13.4)
Deep et al., 2016[26]	Quantitative analysis 1 week	Study of social and affective experiences in patients with schizophrenia and suicidal thoughts	No. = 93 (suicidal thoughts group: n = 18; group no suicidal thoughts: n = 75) Average age: 45.8 Men: 62%	Schizophrenia and schizoaffective disorder Major cognitive deterioration	BPRS BDI-II	Purdue Momentary Assessment Tool: evaluates social interaction (reminders and response to the questionnaire)	Suicidal thoughts group: Greater solitude predicted in the future Less anticipated enjoyment of social relationships and more negative affect of being alone

ANART: American National Adult Reading Test; BACS: Brief Assessment of Cognition in Schizophrenia; BDI-II: Beck Depression Inventory-2 Edition; BMQ: Brief Medication Questionnaire; BPRS: Brief Psychotic Rating Scale; CAARMS: Comprehensive Assessment of At Risk Mental State; CDS: Calgary Depression Scale; CGI: Clinical Global Impression; CGI-SCH: Clinical Global Impression-Schizophrenia scale; CSI: Clinical Global Impression Scale; DAI-10: 10 − item Drug Attitude Inventory; EQ-5D: Health Quality of life assessed using the second part of the Spanish version of the EuroQol; EWSQ: Early Warning Sings Questionnaire; HMCS: Hayward Medication Compliance Scale Score; ILSS: Independent Living Skills Survey; ISI: Insomnia Severity Index; ITAREPS: Information Technology Aided Relapse Prevention Programme in Schizophrenia; LM-II: Logical Memory II; MAQ: Morisky Green Adherence Questionnaire; MATS: Mobile Assessment and Treatment for Schizophrenia; MoD: Experience Sampling Method with Mobile Devices; PANAS: Positive and Negative Affect Schedule; PANSS: Positive and Negative Syndrome Scale; PDA: personal digital assistants; PSRS: Provision of Social Relations Scale; PSSUQ: Post Study System Usability Questionnaire; QoLQ: Quality of Life Questionnaire; RBANS: Repeatable Battery for the Assessment of Neuropsychological Status; SANS: Scale for the Assessment of Negative Symptoms; SAPS: Scale for the Assessment of Positive Symptoms; SMS: short message service; SUMD: Scale to Assess Unawareness of Mental Disorder; SUS: System Usability Scale; TAM: Technology Acceptance Model; TAMMS: Technology Assessment Model Measurement Scales; UBACC: UCSD-Brief Assessment of Capacity to Consent; UPSA: University of California San Diego (UCSD) Performance Skills Assessment; USE: Usability and User Experience; WAI: Working Alliance Inventory; WMS-R: Wechsler Memory Scale-Revised; WRAT-4: Wide Range Achievement Test (reading subsection)-Fourth Edition.

Of these interventions, 35% were published from 2008 to 2014 and 65% were published from 2014 to 2016. 75% analysed data quantitatively, 10% were qualitative and 15% used both types of analysis. The duration of these studies runs from transversal studies of a single day's intervention to follow-up studies lasting for 18 months.

The average total number of participants per study is 113. However, if the outlying values of 2 studies with samples of 562 and 558 subjects are eliminated, this average falls to 63 participants per study. The total average age of the participants is 37.3 years old. In 90% of the interventions the percentage of men is higher than that of women. The main diagnosis of the participants is schizophrenia, followed by schizoaffective disorder.

The most common evaluation methods use standardised scales, although their own scales were designed in 15% of studies. 3 types of interventions were differentiated: interventions using PDA (10%), SMS services (25%) and smartphone apps (50%). The remaining 15% used SMS and app interventions simultaneously.

The objectives may be divided into 3 major sets of interventions:

1) *Analysis of the quality and usability of mobile interventions*: 11 interventions have the aim of analysing the validity, feasibility, usability and utility of interventions using mobile devices.[10,12,13,16,17,19–24]

   Four studies analysed the usability and viability of their interventions; among these, Ainsworth et al.[13] offered the possibility of choosing between an app or SMS, and they found that patients used the app service 13% more than they did the SMS. Ben-Zeev et al.[16] observed that the FOCUS app for improving self-management of the disease was used on 86% of days, with a 90% acceptance rate, while in his second study,[17] 90% of the patients used a text messaging service and were satisfied with it. Finally, in the study by Macias et al.[24] the Wellwave app, which encourages walking every day, was used on 94% of days, although only 39% of answers were confirmations to the daily reminders to take a walk that this activity had been undertaken.

   Three studies analysed the discriminatory validity of the devices. The study by Moore et al.[19] shows the validity of a mobile application that implements the UCSD Performance-Based Skills Assessment (UPSA). This evaluates its functionality in discriminating patients with schizophrenia (80%). The study by Blum et al.[20] confirmed the discriminatory validity of momentary measurements to evaluate depressive state of mood, and the one by Palmier-Claus et al.[10] concluded the validity, internal consistency and sensitivity of the switch to the ClinTouch app, which monitors psychotic and affective symptoms.

   Finally, 4 studies analysed patient perceptions and opinions after they had used different types of mobile interventions. In the study by Palmier-Claus et al.[12] the participants would prefer to use a mobile app rather than a SMS, and they complained about the repetitive nature of messages and the negative effects of constantly focussing their attention on their symptoms. In the study by Forchuk et al.[21] the participants stated that the most useful functions of the Lawson Smart Record app were the appointment reminder, while their complaint referred to the excessive number of messages and the laborious nature of using the system. In the study by Kauppi et al.[22] the patients expressed their preference for reminders associated with leisure (42%) and medication (30%). And to finish, in the study by Kannisto et al.,[23] 98% of the patients considered that SMS is easy to use, while 13% considered that they may be harmful.

2) *Improving adherence, symptoms and reducing hospitalisations*: 5 interventions aim to increase adherence to antipsychotic treatments, improve symptoms and reduce hospitalisations.[7–9,11,25]

   Two studies used the SMS to improve adherence to medication: the study by Granholm et al.[9] increased adherence to medication and improved other symptoms of schizophrenia (socialisation and auditory hallucinations) by means of a mobile cognitive-behavioural intervention. The study by Montes et al.[11] used the SMS to remind patients to take their medication and increased adherence, although the results were not maintained following the end of this service. Two studies seek to reduce the number of admissions to hospital by using the ITAREPS application: in the first study by Spaniel et al.[7] in 2008, a fall of 77% was found, while in the 2015[25] study no significant differences were observed between those participants who used this app and those who did not. Finally, the intervention by Pijnenborg et al.[8] used the SMS to increase the functionality of psychotic patients, obtaining a 77% improvement in the attainment of objectives.

3) *The analysis of patient symptoms:* 4 interventions used mobile devices to measure clinical variables associated with patient emotions and thoughts.[14,15,18,26]

Two studies analysed thoughts of self-harm: the study by Palmier-Claus et al.[14] found a relationship between the worsening of auditory hallucinations and thoughts of self-harm, measured by degree of paranoia. Deep et al.[26] observed that patients with symptoms of self-harm presented greater negative affect when they were alone, predicting increased solitude in the future. Two studies analyse patient affects: the study by Kimhy et al.[15] found by using an app that patients experience more depressive and psychotic symptoms when they are alone, while the study by Brenner and Ben-Zeev[18] observed by using a PDA that patients over-estimate predictions and their affects, chiefly the positive ones.

Finally, the methodological quality of the interventions was analysed using a Jadad scale that includes: randomisation, masking/double blind and a description of losses during follow-up.[27] The variable of the existence or not of a ''control group'' was added to the said scale. We considered scales to be of poor quality when they scored less than 3 points, and they were considered to be of maximum quality at 5 and 6 points. These data are shown in Table 2.

No study attained the highest score for methodology, as the lack of masking was their main limitation. The study by Montes et al.[11] scored the highest for methodological quality, at 4 on the Jadad scale, followed by the studies by Ainsworth et al.,[13] Moore et al.,[19] Forchuk et al.,[21] Kauppi et al.[22] and Spaniel et al.,[25] which all scored 3.

Table 2 The methodological quality of the studies analysed.

Author/year	Randomised	Double blind	Losses	Sufficiently randomised[b]	Sufficiently double blind[a]	Control group	Total
Spaniel et al., 2008	0	0	0	0	0	0	0
Pijnenborg et al., 2010	1	0	1	0	0	0	2
Granholm et al., 2011	0	0	1	0	0	0	1
Palmier-Claus et al., 2012	0	0	1	0	0	0	1
Montes et al., 2012	1	0	1	1	0	1	4
Palmier-Claus et al., 2013	1	0	0	0	0	0	1
Ainsworth et al., 2013	1	0	1	1	0	0	3
Palmier-Claus et al., 2014	0	0	0	0	0	0	0
Kimhy et al., 2014	0	0	1	0	0	0	1
Ben-Zeev et al., 2014a	0	0	1	0	0	0	1
Ben-Zeev et al., 2014b	0	0	1	0	0	0	1
Brenner y Ben-Zeev, 2014	0	0	1	0	0	0	1
Moore et al., 2015	1	0	1	0	0	1	3
Blum et al., 2015	0	0	1	0	0	1	2
Forchuk et al., 2015	1	0	1	0	0	1	3
Kauppi et al., 2015	1	0	1	1	0	0	3
Kannisto et al., 2015	0	0	1	0	0	0	1
Macias et al., 2015	0	0	1	0	0	0	1
Spaniel et al., 2015	1	0	1	0	0	1	3
Deep et al., 2016	0	0	0	0	0	1	1

0 = no; 1 = yes.

[a] Double blind: this is impossible in psycho-social interventions. Thus no study fulfils this criterion or that of being suitably double blind.

[b] Sufficiently randomised: studies that indicate the randomisation technique used (computer-generated table of random numbers, throwing a coin, properly shuffled envelopes, etc.).

Discussion

All of the 20 studies analysed in this systematic review confirm the growing clinical interest in interventions using mobile devices for psychotic patients, given that 65% of the articles found that were written in the past 26 years were published from 2014 to 2016. This is reasonable, given that smartphone use had only spread to 21% of the population in Western Europe in 2013.

Mobile interventions were shown throughout the studies analysed to be a viable strategy for psychotic patients. Patient response to communications using devices is above 70% in the studies that analyse this variable.[9,10,13,15–18,24,25] Additionally, when patients responses are studied, the majority express their satisfaction with these interventions, finding them useful, beneficial and easy to use.[8,9,12,13,16,17,23,24] No relationship was found between patient symptoms[16] and their severity[10] when responding to reminders. All of this suggests that these interventions are suitable and well-accepted by patients.

Nevertheless, and in spite of the generally positive results of these interventions, small percentages of patients (10–12%) said they encountered difficulties in using these devices[16] and consider that too many communications per day may be found intrusive and tedious.[12,21] In turn, in 2 studies a minority of the sample thought that the continuous recording of symptoms increased their worries and thoughts about the disease.[12,23] Nevertheless, these were isolated cases which never brought about a worsening in the health of the patients, so that these problems are not significant or widespread.

The real-time evaluation of patient symptoms, cognitions, emotions and behaviour using mobile applications has been shown to achieve good validity and correlation with traditional psycho-pathological evaluation scales.[12,14,15,18–20,25] Regarding the benefits of these interventions in improving adherence to treatment, reducing hospitalisation and improving psychiatric symptoms, the results are promising.[7–9,11,16] All of the studies which gather data on the symptoms have an alarm system to urgently respond to the patient if they have suicidal ideas or symptoms that indicate a psychotic relapse. These benefits increase the more a device is used and are reduced if a device is withdrawn, while improved attitudes to medication, social relationships and symptoms are maintained over time.[9,11]

These studies contain multiple limitations that have to be taken into account. Firstly, the methodological quality of the studies analysed is quite low. This is due to the nature of the psycho-social interventions, which prevents the use of masking, together with the lack of randomisation in the sample selection of some studies. Secondly, the short duration of some of these studies and the small size of some of their samples render them insufficient to obtain results that are conclusive and which can be extrapolated. Thirdly, 25% of these publications include a qualitative analysis of the data which, although it may increase internal validity, is more liable to distortion by the patients and hinders the external validity of the conclusions. When scales are used to

measure the acceptability and usability of devices, these scales are not validated for mental health or schizophrenia in particular. Fourthly, as Ben-Zeev et al.[17] underline, patients respond to device communications without any supervision by medical staff, so that it is impossible to directly check the quality and emotional context of their answers.

This review has shown that mobile interventions are potentially viable, usable, acceptable, valid and beneficial for patients' mental health in improving the self-management and treatment of psychotic disorders. These devices make real-time recording possible, not only of patient symptoms but also of their associated ecosystem. They are more reliable than the retrospective records obtained when patients visit, above all if they present cognitive deterioration.[20] They are therefore able to help to improve the quality of clinical decisions, and to aid patients in giving a more accurate description of their experiences.[18] They also make it possible to reduce the distance between research and clinical practice and between patients and healthcare staff.[17] Nevertheless, one problem with these studies are the ethical and practical questions about confidentiality and data use. In the studies that collect clinical data, these will only be accessible to the research personnel using a specific password. Although this resolves the problem of confidentiality, it does not clarify how to translate research data into clinical practice. Finally, the early detection of symptoms using real-time recording systems and reducing the number of visits by patients to the surgery may lead to an economic saving for healthcare services (above all in preventing admissions to hospital). However, we are not aware of any economic study that proves the efficiency (a good cost/effectiveness ratio) of these devices.

Higher methodological quality research is needed in the future to analyse the reliability of these interventions and to make it possible to extrapolate the above-mentioned benefits. Nor has the long-term effect of these interventions been studied, or whether the results and patient involvement are maintained over time. Finally, in reply to the complaints expressed by patients, it is indispensible to develop devices that are simple and easy to use, in direct collaboration with the patients themselves. The core objectives of these devices must be firstly to achieve a suitable degree of application integration in patients' everyday lives, without interfering in them, and secondly to tailor them to their specific needs and interests.[22,23]

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Conflict of interests

The authors have no conflict of interests to declare.

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b. Encuesta a potenciales pacientes con psicosis **(Bonet et al., 2018 (a))** [**Objetivo 2**]**:**

En segundo lugar, se realizó una encuesta con la que se analizó el acceso, uso e impacto de las tecnologías en una muestra de pacientes con trastorno psicótico. También se valoró su interés en disponer de una app que les ayudara en el manejo de su enfermedad. Para la elaboración de esta encuesta, se llevó a cabo una revisión de las principales publicaciones en referencia a estos objetivos. La encuesta, fue administrada a una muestra de 113 pacientes con psicosis con diferentes características demográficas y clínicas. Los resultados de este estudio subrayaron la viabilidad de implementar programas de atención sanitaría *e-Health* en una muestra de pacientes con trastorno psicótico de Valencia, puesto que esta muestra disponía de un acceso y uso a tecnologías equivalente al de la población general. A su vez, el 70% de los pacientes se mostró interesado en disponer de un recurso de *mHealth*, en especial, en disponer de sistemas que les permitiera mejorar la comunicación y cercanía con los servicios sanitarios.

No obstante, en este estudio se encontraron porcentajes entre el 19-38% de pacientes que señalaban haber padecido experiencias negativas vinculadas al uso de internet y como se encontró en un posterior análisis (Bonet et al., 2018 (b). [**Apéndice I**]), la frecuencia de acceso a internet y el acceso a redes sociales se relacionó con una mayor probabilidad de padecer recaídas psicóticas, así como de realizar un uso patológico de estos servicios.

Original Paper

Differences in the Use and Opinions About New eHealth Technologies Among Patients With Psychosis: Structured Questionnaire

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Abstract

Background: Despite a growing interest in the use of technology in order to support the treatment of psychotic disorders, limited knowledge exists about the viability and acceptability of these eHealth interventions in relation to the clinical characteristics of patients.

Objective: The objective of this study was to assess the access and use of, as well as experiences and interest in, new technologies using a survey of patients diagnosed with early psychosis compared with a survey of patients diagnosed with chronic psychotic disorders.

Methods: We designed a structured questionnaire. This questionnaire was divided into five parts: (1) clinical and demographic information, (2) access and use of the internet, (3) use of the internet in relation to mental health, (4) experiences with technology, and (5) patients' interest in eHealth services. In total, 105 patients were recruited from early psychosis units (n=65) and recovery units (n=40).

Results: In this study, 84.8% (89/105) of the patients had access to the internet and 88.6% (93/105) owned an electronic internet device. In total, 71.3% (57/80) of patients who owned a mobile phone were interested in eHealth systems and 38.2% (37/97) reported negative experiences related to the internet usage. We observed differences between the groups in terms of device ownership (P=.02), the frequency of internet access (P<.001), the use of social media (P=.01), and seeking health information (P=.04); the differences were found to be higher in the early psychosis group. No differences were found between the groups in terms of the use of internet in relation to mental health, experiences and opinions about the internet, or interest in eHealth interventions (P=.43).

Conclusions: The availability and use of technology for the participants in our survey were equivalent to those for the general population. The differences found between the groups in relation to the access or use of technology seemed to due to age-related factors. The use of technology involving mental health and the interest in eHealth interventions were mainly positive and equivalent

between the groups. Accordingly, this group of patients is a potential target for the emerging eHealth interventions, regardless of their clinical status. However, 28.7% (23/80) of the studied patients rejected the use of internet interventions and 38.2% (37/97) had unpleasant experiences related to its usage; thus, more in-depth studies are needed to better define the profile of patients with psychosis who may benefit from eHealth treatments.

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KEYWORDS

eHealth; internet; mobile phone; viability; acceptability; psychosis; schizophrenia

Introduction

The relevance of early intervention (EI) in psychotic disorders in order to prevent the pathological development of the illness is well known [1]. However, some studies have shown that the current models of EI do not produce any different results in terms of efficacy or efficiency when compared with treatment as usual [2,3]. In this vein, technological developments could make a difference by adapting these traditional models of psychiatric and psychological health care to an electronic form, which would allow interactive and more personalized tracking of patients and Web-delivered therapy such as psychoeducational services or cognitive behavioral treatments [4]. These technological health interventions are known as eHealth [5]. The recent examples of these interventions that are being currently tested are Actissist [6], Prime [7], and SlowMo [8].

Nevertheless, before proceeding further in developing these eHealth interventions, it is important to better understand the relationship between patients with psychosis and technology resources. Psychotic disorders are characterized by their clinical heterogeneity [9]; thus, it is necessary to study if these eHealth interventions are equally accepted for all patients with psychosis, regardless of their demographics or clinical characteristics, especially if they are in an early psychosis (EP) condition or a chronic psychosis (CP) condition.

First, it is important to assess whether the access and use of technology are equivalent between EP and CP patients and whether the access and use are equivalent to those among the general population. Depp et al [10] conducted a survey of CP patients and found that these patients had substantial cognitive and functional deficits and that high punctuations in these impairments were related to the less use of technology. Moreover, in 2014, the National Alliance on Mental Illness (NAMI) [11] showed that 54% of American patients with schizophrenia owned a mobile phone compared with 64% of the general American population [12]; similar results have been shown in other studies [13]. However, recent studies have shown that these rates have changed and that the access of these patients to technology is similar to that of the general population at the moment [14-16].

Second, 80% of patients with psychosis are permitted to use internet resources in relation to their illness management [17]. Nevertheless, we could not find any study that investigated whether this use of technology is equivalent between EP and CP patients, who are usually more aged persons with more associated morbidities [10].

Third, despite the majority of patients who report positive feelings and experiences in response to the internet usage [4,18], there are some patients who experience anxiety or paranoid feelings while using this resource [18]. Moreover, some patients admitted that they had stopped taking medication on their own because of the information they read on the internet [17]. In relation to this, it is important to better understand the effect that technologies have on these patients and whether these experiences are similar between EP and CP patients.

Finally, there are several studies that have confirmed the interest of patients experiencing psychotic disorders in using the emerging eHealth systems to help them cope with their illness [4,14,18,19]. Specially, it has been found that 60%-75% of patients with psychosis would be interested in receiving information and feedback from their clinicians [19,20] and in contacting them in case of emergency [20]. However, there is a lack of studies that have assessed this interest in relation to the evolution of the disease (EP compared with CP). There are a few studies that have found some controversial results when studying this interest among individuals of different age groups. Some of these studies have suggested that younger patients would be more willing to endorse eHealth treatments [14,18], while others have suggested the opposite [21,22]. Consequently, it is necessary to study the variations in the interest in these services in relation to the evolution of the illness.

The main objective of this study was to assess the access and use of and experiences with technology in a survey of patients diagnosed with EP compared with a survey of patients diagnosed with CP disorder. In addition, we aimed to analyze the interest in these two groups regarding using an eHealth system and regarding the different tracking eHealth services suggested.

Methods

Measures and Design

The data were collected through a cross-sectional questionnaire that we designed for the purpose of this investigation. To elaborate this questionnaire, we reviewed studies about the use, access, and impact of technology on patients with psychosis. Based on these studies, we elaborated the survey, which is divided into five parts: the items for the first part, which aims to assess clinical and demographic information, and the items for the second part, which measures the access and use of the internet, mobile, and social media, were taken from the Spanish National Statistics Institute [23] survey and from studies by Trefflich et al [17] and Robotham et al [24]. In addition, the items for the third part of the questionnaire, which assesses the use of internet in relation to mental health, and the items for the

fourth part, which measures experiences with technology and the effect of internet usage on patients' health, were based on a survey of the NAMI [11] and on studies by Gay et al [18], Miller et al [25], and Borzekowski et al [26]. The last part of the survey, which rates the interest of the patients in using an eHealth app and their interest in different tracking and reminder services, was an originally developed section.

Once the instrument was made and prior to its use, a pilot study was conducted to check the acceptability and relevance of the measure. Overall, 14 representative patients participated; consequently, 3 ambiguous items were corrected in order to make them easier to understand for the patients, and 2 redundant items were removed.

The 10-minute, structured questionnaire (Multimedia Appendix 1) was completed face-to-face. Initially, the patients were informed about data extraction ethics and confidentiality following the information sheet (Multimedia Appendix 2); subsequently, the patients completed the questionnaire. All the patients signed the informed consent before participating in this survey. The survey was conducted from February to May 2017 and was approved by the Clinical Hospital of Valencia's Ethics Committee.

Sample and Recruitment

A total of 113 participants were eligible for inclusion. They met the following criteria: (1) diagnosis of a psychotic disorder according to the International Classification of Diseases, Tenth Revision [27]; (2) clinically stable; (3) outpatient from the first episode units at the Clinical Hospital of Valencia and from the Primary Care Centre Font of Sant Lluis in Valencia or outpatient from association for comprehensive care of the mental health patient or from aid association for mental health patients in the Valencia community recovery units; and (4) able to communicate in Spanish. Patients were excluded if they had severe cognitive impairments or did not complete the entire questionnaire.

Data Analysis

We analyzed data using the statistical program IBM SPSS Statistics version 22. We excluded 8 patients from this analysis for not having totally filled the survey; due to this, data of 105 patients were considered for the analysis. The cohort was divided into two groups: the EP group, with a duration of illness of ≤72 months, and the CP group, with a duration of illness >72 months. This division was based on the fact that EP patients are treated in EP units until a maximum period of 72 months. Descriptive statistics (mean, standard deviation, frequencies, and percentages) were determined, and chi-square test and analysis of variance were performed in order to compare the differences between the EP and CP groups.

Results

The data in Tables 1, 2, 3, and 4 are shown in the following order: First, the EP results are shown, followed by the CP results and the total results (which are the global results of the sample in each category). It is important to mention that the sample is not the same in every category due to the fact that some questions in the survey were exclusionary. If the patients did not fulfill the profile for one question, they did not have to complete the rest of the questions that were related to the first one. We have marked this condition in every table.

Sample Characteristics

A total of 105 participants were enrolled in the study. Based on the duration of their illness, we assigned 65 patients to the EP group (≤72 months) and 40 patients to the CP group (>72 months). The mean age of the sample was 38.1 (SD 13) years; the patients were mostly male (76/105, 72.4%) and single (89/105, 84.8%) and had achieved a secondary level of education (compulsory schooling: 26/105, 24.8%; secondary education: 39/105, 37.1%).

We found significant differences between the two groups. EP patients were mostly in the first episode of psychosis (FEP), while CP patients were mostly diagnosed with schizophrenia. The duration (months) of illness was higher in the CP group. The patients in the EP group were younger and mostly employed, while those in the CP group were mostly unable to work or were not employed. There were no significant between-group differences in terms of gender, marital status, or the level of education. These clinical and sociodemographic characteristics are displayed in Table 1.

Access and Use of the Internet, Mobile and Social Media

Of all the participants, 84.8% (89/105) had access to the internet in the 3 months prior to the study, and there was high electronic device availability in the survey (93/105, 88.6%). After the first two questions, 8 patients did not continue with completing the survey as they were considered "electronic excluded" patients because they were not using or had not used the internet sufficiently to consider their experience relevant for the aim of this study. From that moment on, the total sample consisted of 97 patients (EP, n=63; CP, n=34).

Differences between the groups (Table 2) were found in terms of electronic device availability (χ^2_5=13.8, P=.02), the frequency of access to the internet (χ^2_2=31.8, P<.001), and the use of social media (χ^2_4=13.9, P=.01). Electronic device availability was higher in the EP group (63/65, 97%) than in the CP group (30/40, 75%), and while 81% (51/63) patients in the EP group had daily access to internet, 52.9% (8/34) of the patients in the CP group had only weekly access. However, no differences were observed in terms of the type of device used to access (χ^2_2=5.6, P=.06), mobile ownership (χ^2_5=10.2, P=.07), or the most used functions of the mobile phone, which were calls (74/88, 84.1%; χ^2_1=0.7, P=.41) and texting or WhatsApp (72/88, 83.8%; χ^2_1=0.4, P=.51) for both groups. Social media ownership was higher in the EP group (51/63, 81%) than in the CP group (15/34, 44.1%); however, Facebook was the most used social media site in both the groups (47/66, 72.3%; χ^2_1=1.6, P=.21), and patients' main goal in using this social media platform was to communicate with people (55/66, 83.3%; χ^2_1=1.4, P=.24).

Internet and Mental Health

Internet is a resource that 61.9% (60/97) of the patients used to seek information about health. EP patients (45/63, 71.4%) used this resource to a greater extent than CP patients (15/34, 44.1%; χ^2_5=11.5, *P*=.04). The most wanted information was regarding symptoms (47/60, 78.3%) or diagnosis (40/60, 66.7%), which was more sought after by CP patients (14/15, 93.3%) than by EP patients (26/45, 57.8%; χ^2_1=6.4, *P*=.01). Of all the patients, 37.1% (36/97) stated that the internet was their first resource for seeking health information, whereas 58.8% (57/97) consulted clinical services as a first option.

In relation to the feelings that the use of internet provided to the patients, we found that 60.9% (59/97) felt socially linked when using internet and that 78.4% (76/97) felt informed. However, 22.7% (22/97) of the patients felt frustrated or anxious in relation to the internet and 19.6% (19/97) felt suspicious or paranoid.

Table 1. Demographic and clinical characteristics.

Characteristics	Early psychosis (N=65)	Chronic psychosis (N=40)	Total (N=105)	*P* value (χ^{2a} or t^b, df^c)
Diagnosis, n (%)				**<.001 (61.9[a], 7)**
Schizophrenia	9 (13.8)	29 (72.5)	38 (36.2)	
First episode of psychosis	44 (67.7)	0 (0.0)	44 (41.9)	
Other psychotic disorder[d]	12 (18.5)	18 (27.5)	23 (21.9)	
Duration of Illness (months), mean (SD)	28.8 (21.3)	253.3 (115)	114.3 (131.3)	<.001 (235.9[b], 1)
Age (years), mean (SD)	32.9 (11.8)	46.6 (10.3)	38.1 (13)	<.001 (−6.1[b], 103)
Gender, n (%)				**.38 (.8[a], 1)**
Female	16 (24.6)	13 (32.5)	29 (27.6)	
Male	49 (75.4)	27 (67.5)	76 (72.4)	
Marital status, n (%)				**.07 (7.2[a], 3)**
Single	56 (86.2)	33 (82.5)	89 (84.8)	
Married	7 (10.8)	1 (2.50)	8 (7.6)	
Widowed	0 (0)	1 (2.50)	1 (1.0)	
Divorced	2 (3.1)	5 (12.5)	7 (6.7)	
Education, n (%)				**.43 (3.8[a], 4)**
Primary school	11 (16.9)	8 (20)	19 (18.1)	
Compulsory schooling[e]	17 (26.2)	9 (22.5)	26 (24.8)	
Secondary education	22 (33.8)	17 (42.5)	39 (37.1)	
University degree	15 (23.1)	6 (15.0)	21 (20.0)	
Employment status, n (%)				**<.001 (27.7[a], 6)**
Employed	18 (27.7)	4 (10.0)	22 (21.0)	
Not employed	16 (24.6)	11 (27.5)	27 (25.7)	
Student	16 (24.6)	1 (2.5)	17 (16.2)	
Unable to work	9 (13.8)	18 (45.0)	27 (25.7)	
Others	6 (9.3)	6 (15.0)	12 (11.5)	

[a]Chi-square (χ^2) values.

[b]Student *t* values.

[c]*df*: degrees of freedom.

[d]Referring more than one psychotic episode or a specific disorder (bipolar, schizophreniform, schizoaffective, major depression, personality disorder).

[e]Until the age of 16 years.

Table 2. Access to and use of the internet, mobile, and social media.

Access and use of technology	Early psychosis (N=65), n (%)	Chronic psychosis (N=40), n (%)	Total (N=105), n (%)	*P* value (χ^2, *df*[a])
Internet access (last 3 months)	**N=65**	**N=40**	**N=105**	**.05 (7.5, 3)**
Yes	59 (90.8)	30 (75)	89 (84.8)	
No	6 (9.2)	10 (25)	16 (15.2)	
Electronic device availability	**N=65**	**N=40**	**N=105**	**.02 (13.8, 5)**
Yes	63 (97)	30 (75)	93 (88.6)	
No	2 (3)	10 (25)	7 (11.4)	
Device type	**N=63**	**N=30**	**N=93**	**.06 (5.6, 2)**
Computer	16 (25.4)	13 (43.3)	29 (31.2)	
Mobile	47 (74.6)	16 (53.3)	63 (67.7)	
Tablet	0 (0)	1 (3.3)	1 (1.1)	
Frequency of internet access	**N=63**	**N=34**	**N=97**	**lt;.001 (31.8, 2)**
Daily	51 (81)	11 (32.4)	62 (63.9)	
Weekly	3 (4.8)	18 (52.9)	21 (21.6)	
Less than once a week	9 (14.3)	5 (14.7)	14 (14.4)	
Mobile ownership	**N=63**	**N=34**	**N=97**	**.07 (10.2, 5)**
Yes, cell phone	7 (11.1)	6 (17.6)	13 (13.4)	
Yes, mobile phone	54 (85.7)	21 (61.8)	75 (77.3)	
No	2 (3.2)	7 (20.6)	9 (9.3)	
Mobile use[b]	**N=61**	**N=27**	**N=88**	
Calls	50 (82)	24 (88.9)	74 (84.1)	.41 (.7, 1)
Texting or WhatsApp	51 (83.6)	21 (77.8)	72 (83.8)	.51 (.4, 1)
Social media ownership	**N=63**	**N=34**	**N=97**	**.01 (13.9, 4)**
Yes	51 (81)	15 (44.1)	66 (68)	
No	12 (19)	19 (55.9)	31 (32)	
Social media site[b]	**N=51**	**N=15**	**N=66**	
Facebook	351 (68.6)	12 (80)	47 (72.3)	.21 (1.6, 1)
WhatsApp groups	34 (66.7)	12 (80)	46 (69.7)	.32 (.9, 1)
Social media use[b]	**N=51**	**N=15**	**N=66**	
To communicate with people	44 (86.3)	11 (73.3)	55 (83.3)	.24 (1.4, 1)
To stay informed	35 (68.6)	9 (64.3)	44 (67.7)	.76 (.1, 1)

[a]*df*: degrees of freedom.

[b]Sample reduction because of a previous exclusionary question.

Table 3. Internet and mental health.

Experiences and opinions about internet	Early psychosis (N=63), n (%)	Chronic psychosis (N=34), n (%)	Total (N=97), n (%)	*P* value (χ^2, *df*[a])
Internet used to seek health information	**N=63**	**N=34**	**N=97**	**.04 (11.5, 5)**
Yes	45 (71)	15 (44)	60 (62)	
No	18 (29)	19 (56)	37 (38)	
Most sought after health information[b]	**N=45**	**N=15**	**N=60**	
Symptoms	36 (80)	11 (73)	47 (78)	.59 (.3, 1)
Diagnosis	26 (58)	14 (93)	40 (67)	.01 (6.4, 1)
Internet: first information resource	**N=63**	**N=34**	**N=97**	.13 (5.7, 3)
Agree	27 (43)	9 (27)	36 (37)	
Disagree	36 (57)	25 (74)	61 (63)	
Agreement on internet feelings[c]	**N=63**	**N=34**	**N=97**	
Socially linked	28 (60)	21 (62)	59 (61)	.93 (.9, 5)
Informed	53 (84)	23 (68)	76 (78)	.24 (5.5, 4)
Frustrated or Anxious	11 (18)	11 (32)	22 (23)	.08 (8.3, 4)
Suspicious or Paranoid	13 (21)	6 (18)	19 (20)	.46 (3.6, 4)
Agreement on internet experiences[c]	**N=63**	**N=34**	**N=97**	
Internet as a benefit for mental health	27 (43)	18 (53)	45 (46)	.23 (5.6, 4)
Unpleasant experiences related to internet usage	25 (40)	12 (35)	37 (38)	.92 (.9, 4)
Stopped taking medication because of internet information	4 (6)	4 (12)	8 (8)	.84 (1.4, 4)
Relapse related to internet usage	20 (32)	4 (12)	24 (25)	.17 (6.4, 4)
Excessive time spent on internet	20 (32)	6 (18)	26 (27)	.25 (5.4, 4)
Internet increases social isolation	12 (19)	5 (15)	17 (16)	.69 (2.3, 4)

[a]*df*: degrees of freedom.

[b]Sample reduction because of a previous exclusionary question.

[c]Sum of individual scores of "Strongly agreed" and "Somewhat agreed" in each factor.

Regarding experiences related to internet usage, we found that 46.4% (45/97) of the patients thought that the internet is beneficial to their mental health, while 38.2% (37/97) had unpleasant experiences related to its usage, and 24.8% (24/97) patients had experienced relapses perceived as directly related to internet usage. Moreover, 8.3% (8/97) patients had stopped taking medication on their own because of the information they read on the internet. Excessive time on the internet was a concern for 26.8% (26/97) of the patients and 16.2% (17/97) thought that internet increases social isolation. As displayed in Table 3, we could not find any significant between-group differences in terms of the feelings about the internet or experiences related to its usage.

Interest in eHealth Systems (Mobile Phone App)

This part of the survey was completed only by patients who owned a mobile phone. For this reason, the sample size was reduced to 80 patients (EP, n=59; CP, n=21). Of all the patients, 71.3% (57/80) were interested in owning an eHealth app, with no significant differences observed between the EP and CP groups (χ^2_4=3.9; *P*=.43); furthermore, no significant differences were observed in terms of age of the sample (F_1=.08, *P*=.93). The reason for not being interested was "I do not think I will benefit from it" (14/23, 60.9%) or "I have enough information" (6/23, 26.1%).

The services that were perceived as the most interesting were as follows: clinician contact alarm (60/80, 75.1%) and a reminder for clinical appointments (58/80, 72.6%). Mood, mental health, and side effect tracking were perceived as equally interesting (51/80, 63.8%), while the least interesting function for the patients was the reminder to take medication (41/80, 51.3%). As shown in Table 4, no significant differences were found between the groups in terms of their interest in any of the services suggested. Furthermore, no significant differences were found regarding the age of the sample and interest in mood and mental health service (F_1=1.31, *P*=.27), interest in side effect tracking (F_1=1.44, *P*=.24), reminder for clinical appointments (F_1=.99, *P*=.37), reminder to take medication (F_1=.2.35, *P*=.11), and clinician contact alarm (F_1=.47, *P*=.63).

Table 4. Interest in eHealth systems (app).

Opinions about eHealth app services	Early psychosis (N=59), n (%)	Chronic psychosis (N=21), n (%)	Total (N=80), n (%)	*P* value (χ^2, *df*[a])
App interest				**.43 (3.9, 4)**
Yes	42 (71.2)	15 (71.4)	57 (71.3)	
No	**17 (28.8)**	**6 (28.6)**	**23 (28.7)**	
I do not think I will benefit from it[b]	11 (64.7)[c]	3 (50)[d]	14 (60.9)[e]	
I have enough information[b]	5 (29.4)[c]	1 (16.7)[d]	6 (26.1)[e]	
Others[b]	1 (5.9)[c]	2 (33.3)[d]	3 (13)[e]	
App services				
Mood and mental health tracking				**.77 (1.8, 4)**
Interested[f]	38 (64.4)	13 (61.9)	51 (63.8)	
Indifferent	5 (8.5)	3 (14.3)	8 (10)	
Not interested[g]	16 (27.1)	5 (23.8)	21 (26.3)	
Side effect tracking				**.39 (4.1, 4)**
Interested[f]	40 (67.8)	11 (52.3)	51 (63.8)	
Indifferent	4 (6.8)	4 (19)	8 (10)	
Not interested[g]	15 (25.4)	6 (28.5)	21 (26.3)	
Reminder of clinical appointments				**.82 (1.5, 4)**
Interested[f]	41 (69.5)	17 (80.9)	58 (72.6)	
Indifferent	4 (6.8)	1 (4.8)	5 (6.3)	
Not interested[g]	14 (23.7)	3 (14.3)	17 (21.3)	
Reminder to take medication				**.32 (4.7, 4)**
Interested[f]	29 (49.1)	10 (57.1)	41 (51.3)	
Indifferent	11 (18.6)	2 (9.5)	13 (16.3)	
Not interested[g]	19 (32.2)	7 (33.3)	26 (32.6)	
Clinician contact alarm				**.12 (7.3,4)**
Interested[f]	44 (74.5)	16 (76.2)	60 (75.1)	
Indifferent	4 (6.8)	—	4 (5)	
Not interested[g]	11 (18.6)	5 (23.8)	16 (20)	

[a]*df*: degrees of freedom.

[b]Sample reduction because of a previous exclusionary question.

[c]N=17.

[d]N=6.

[e]N=23.

[f]Sum of individual scores of "Very interested" and "Somewhat interested" in each factor.

[g]Sum of individual scores of "Not very interested" and "Not at all interested" in each factor.

Discussion

Access and Use of Technology

The rates of accessibility and usability of the internet, mobile, and social media in our surveyed sample were high and very similar to the rates we found in the general Spanish population [23]. These results contradict the lower rates obtained by the NAMI study in 2014 [11] and are more similar to the results of recent studies [14-16,18,28], which found that the access and use of technology in patients diagnosed with psychotic disorders are equivalent to those in the general population. The differences between the two comparison groups in this study suggested that the access and use are not equivalent between EP and CP patients. As we found, CP patients had less electronic device

availability (CP: 30/40, 75%; EP: 63/65, 97%) as well as lower rates of daily access to the internet (CP: 11/34, 32.4%; EP: 51/63, 81%) and use of social media (CP: 15/34, 44.1%; FEP: 51/63, 81%) than EP patients. However, these differences were not only found in previous studies on patients with psychosis [14,17,24,29] but also found in studies on the general Spanish population [23,30]. All these studies agreed that younger patients (18-34 years) have the highest rates of access and use of technology and that these rates start to decrease with the increasing age. In relation to this, we suggest that the differences found between EP and CP patients might be more related to the fact that EP patients were younger than CP patients (P<.001) than to a pathologically related issue.

Use of the Internet Related to Mental Health

In accordance with previous studies [17,23,28,31], the internet is a resource that both patients and the general population use in order to seek information about health. Moreover, nearly 40% (39/97) of our patients admitted that the internet is their first source of health information. However, in accordance with previous studies [17], EP patients used this resource to a greater extent than CP patients (EP: 45/63, 71.4%; CP: 15/34, 44.1%; P=.04). Nevertheless, it is important to note that nearly 56% (19/36) of CP patients and 29% (18/63) of EP patients did not use the internet to seek health information and that nearly 63% (61/97) of patients did not regard internet as their first source of information. These results suggest that despite the fact that the internet is an accessible and quick resource to obtain information [28,32], patients still rely on clinicians as their first source of health information.

Experiences and Opinions About the Internet

In line with previous studies [4,18,32], between 60.9% (59/97) and 78.4% (76/97)of patients reported positive experiences related to the internet usage. However, 22.7% (22/97) of the patients felt frustrated or anxious in relation to the internet, and 19.6% (19/97) felt suspicious or paranoid. Moreover, 38.2% (37/97) of the patients had had unpleasant experiences related to internet usage, 24.8% (24/97) had experienced relapses perceived as directly related to its usage, and 8.3% (8/97) of the sample had stopped taking their medication on their own decision because of the information that was read on the internet. It should be noted that despite the fact that the access and use of technology were found to be higher in the EP group, there were no between-group differences in relation to their experiences of or opinions on internet usage. However, these negative experiences have been found in previous studies [18,29,32], and they suggest that although internet could be a great resource to improve the empowerment of the patients in the management of their illness [32] or as an entertainment resource [18], it could also be a source of stress by causing anxious or paranoid feelings [18,29,32]. It is important to mention that 50%-56% of the general Spanish population agrees with "being worried about internet, social media, and government use of personal information given on the internet" [33]; in accordance with this, we suggest that new technologies are a source of information that could be interpreted as a false alarm signal that may trigger paranoid symptoms. However, we could not find any studies concerning this issue.

Moreover, although 60.9% (59/97) of the patients felt socially linked when using the internet, 26.8% (26/97) admitted to spending excessive time on it and 16.2% (17/97) thought that internet increases social isolation. This enhancement of social isolation has also been reported in studies in the general population [34]. In accordance with previous studies, social isolation is a risk factor for psychosis [35], and it is one of the key relapse factors following the FEP [36].

Interest in eHealth Systems (Mobile Phone App)

Consistent with previous studies [4,14,19], the interest in owning an eHealth system (mobile phone app) in our sample was high (57/80, 71.3%), with no differences observed between the two comparison groups. Moreover, we could not find any significant differences between the groups in terms of their interest in the different eHealth services suggested or when comparing the age of the sample. This result has been found in a systematic review of previous acceptance studies [19], which concluded that there is no difference between clinical and demographic characteristics and the acceptance of eHealth interventions. In line with this, the high acceptance of eHealth interventions in our sample could be regarded as a potential confirmation that patients with psychotic disorders are a good target for these emerging interventions, with no differences related to the length of the illness.

However, although the differences were not statistically significant, on comparing both groups, we found that the percentages of interest were higher in the CP group than in the EP group regarding "reminder services" (clinical appointments and taking medication). In a previous study [21], it was found that the older the patients were, the more reminders they would select. In line with that study, we suggest that CP patients, being more aged and impaired than EP patients, as shown in Table 1 and in previous studies [10], could regard reminder services as a helpful tool to manage their illness, whereas the EP group, being younger and having better social support and less associated impairments, would not regard this service as useful.

On the other hand, EP patients found the "tracking services" (mood, mental health and, side effects) more interesting than CP patients. In a systematic review of previous publications [19], it was found that the interest of patients in receiving psychoeducative and symptom information increased to 90% in the EP sample. According to this finding, we speculated that the EP group would consider "tracking services" more interesting due to their more recent diagnosis and need to better understand their illness, whereas the more experienced CP patients would not consider this service useful.

However, as noted before, there were no significant differences between the groups; thus, initially, patients in both the groups (EP and CP) would be interested in any service in an equivalent way regardless of their age.

Finally, it is important to mention that the most interesting service for the patients was the "contact alarm to the clinicians in case of emergency" (60/80, 75.1%); the interest shown by both groups was nearly the same (EP: 44/59, 74.5%; CP: 16/21, 76.2%). This service must be a priority in eHealth developments. Patients are asking for more personalized, interactive, and closer

clinical attention [14,19,20], which could lead to a greater improvement in psychosis EI [4]. However, as noticed in previous studies [37,38], regarding the clinical implications associated to these interventions, it is highly important to design these feedback systems taking into consideration the clinicians' perspective to not overwhelm their capacities to respond to this systems.

Limitations

This study has some limitations. First, we cannot generalize the results to a broader population of individuals with psychotic disorders. We could not conduct a randomized selection of the sample; therefore, it was selected for the purpose of the aim of this study. Moreover, the small sample size (N=105) and the fact that 72.4% (46/105) of the patients were males with a mean age of 38.1 (SD 13) years caused our sample to not be representative of the demographic distribution of individuals with psychosis. In addition, some demographic information, such as the ethnicity of the sample was not collected. However, it is important to note that most of our results are consistent with those of previous publications; thus, we could infer that in a larger, randomized sample, the results would be similar to the ones we obtained in this study.

Second, the data were obtained from a questionnaire designed for the purpose of this investigation. Even though it was based on a previous review of publications and we conducted a pilot study to test its validity, our survey was not a standardized or a properly validated instrument for individuals with psychotic disorders. The quality of data obtained was affected for this reason. Moreover, most of the items in the survey measured nominal information, which hampered the performance of more complex statistical analyses. In relation to this, some items measured opinions or patients' perceptions, and we did not include an open text-box in order to better understand the responses given by the patients to these items.

Finally, regarding items of the final section of the questionnaire, since eHealth services are rapidly progressing, future updates of these items would be needed.

Implications and Orientations for Future Research

This study highlighted the viability and relatively high acceptability of eHealth interventions in a sample of patients diagnosed with psychotic disorders. However, some disregarded issues must guide future investigations in the area of eHealth and psychotic disorders.

First, although the findings of this study that is related to the access and usability of new technologies in patients diagnosed with psychotic disorders are very similar to the data obtained in the previous studies conducted in patients with psychosis [14,17,18,24,31] and in studies conducted in the Spanish general population [23,33], larger studies are needed to generalize our results, based on a small sample, to a broader patient population with psychosis in Spain to confirm that they are a good target for eHealth interventions.

Second, our results showed that there is a widespread use of internet to obtain information about health, not just by patients diagnosed with psychotic disorders but also by the general population [23]. However, we would like to highlight the substantial negative experiences related to internet usage that we found in our sample. Due to the great extent of internet usage in our society, we believe that further studies focusing on how internet usage affects patients are needed to understand the effect that this resource has on these patients and to study its role as a risk factor for psychosis.

Finally, we did not find any differences between the patient groups in terms of interest in eHealth services, allowing us to conclude that regardless of the demographic or clinical characteristics of patients, they would be equally interested in these interventions. However, in every category measured, we found 20%-30% of patients who were systematically "not interested" in the interventions suggested. As it has been shown in previous studies, personality can affect internet and mobile phone use [39,40]. In accordance with this, it would be interesting to replicate this study with a larger sample and to include specific measures of personality, interest, and patients' expectations because we believe that it would not be possible to achieve any promising results with the use of technology advances if the patients do not feel encouraged and motivated to use these resources. This is the reason why future investigations must focus on better understanding the patients' point of view to truly achieve a personalized measure of the patients' health status.

This study is the first approach to such patients' perspective. We aimed to describe patients' current situation in terms of the availability of technology and the experiences and opinions related to its usage. However, further studies are needed.

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Authors' Contributions

LB, BL, MHV, CC, and ME recruited and evaluated the patients. LB, IB, DA, and AMGP drafted and discussed the paper. JS designed and supervised the project. LB and JS analyzed the data and the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey instrument.

[PDF File (Adobe PDF File), 72KB - mental_v5i3e51_app1.pdf]

Multimedia Appendix 2

Ethics and confidentiality. Information sheet for the patient.

[PDF File (Adobe PDF File), 33KB - mental_v5i3e51_app2.pdf]

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Abbreviations

CP: chronic psychosis
EI: early intervention
EP: early psychosis
FEP: first episode of psychosis
NAMI: National Alliance on Mental Illness

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c. *Diseño preliminar de la app ReMindCare, prueba piloto e integración de la misma en la unidad PEP del Hospital Clínico Universitario de Valencia.* [**Objetivo 3-4**]:

En base a la información obtenida en los dos estudios comentados anteriormente y trabajando en colaboración con el Servicio de Informática de la Universidad Politécnica de Valencia, se diseñó un prototipo de aplicación que denominamos "ReMindCare".

Para el diseño de este aplicativo, fue fundamental el trabajo colaborativo entre los diferentes miembros del equipo. Por una parte, fue necesaria la visión clínica aportada de forma mayoritaria por el Doctor Sanjuán, coordinador de la Unidad de PEP del *HCUV*, que además supervisaba a la doctoranda.

Por otra parte, la visión técnica fue aportada tanto por el Profesor Ignacio Blanquer como por el informático-investigador David Arce, ambos pertenecientes al Instituto de Instrumentación para la imagen molecular (i3M) de la Universidad Politécnica de Valencia. El profesor Blanquer se encargó de supervisar, diseñar y coordinar todo el proceso de desarrollo del dispositivo; por su parte David Arce se encargó de su ejecución, diseñando tanto la app como la página web asociada. Además, se encargó de responder y solventar todas las posibles dificultades que surgieron en el proceso. A su vez, ambos se encargaron de la integración del aplicativo en la unidad PEP del *HCUV*, trabajando en colaboración con el Servicio de Informática del propio hospital.

Una vez se dispuso de una versión preliminar de la app, se seleccionaron a 5 pacientes de la unidad de PEP del *HCUV*, con el objetivo de que pusieran a prueba la app. Esta prueba piloto fue llevada a cabo entre los meses de Marzo a Julio de 2018. Estos tres meses de intervención, permitieron garantizar la validez y viabilidad del uso de la app, ya que se obtuvieron unas tasas de respuesta a los avisos de la misma entre el 90 y el 97%. No obstante, cabe destacar que un paciente abandono el estudio a los 5 días de empezar por empeoramientos en su estado clínico.

Como resultado de este estudio piloto, nuevamente David Arce realizó algunas modificaciones en referencia al acceso de los clínicos a la página web, el registro de los datos de los pacientes y algunas cuestiones técnicas de carácter informático. Una vez, comprobado el adecuado funcionamiento de la app, así como la viabilidad de la intervención, se procedió a introducir la app ReMindCare como herramienta terapéutica en la práctica clínica diaria en la unidad de PEP del *HCUV*.

4.3. Muestra

El uso de ReMindCare se ofreció a todos los pacientes de la unidad PEP del *HCUV*, que cumplieran con los criterios establecidos. Tras ser informados adecuadamente y proporcionar su consentimiento para hacer uso de la app, los pacientes pudieron hacer uso de la app durante todo el tiempo que permanecieron en la unidad.

Con el fin de ser considerado como un potencial usuario de la app, los pacientes debían cumplir con los siguientes criterios.

Criterios de inclusión:

- Diagnóstico de Trastorno Psicótico siguiendo los criterios del DSM-5 (*Diagnostic and Statistical Manual of Mental Disorders, 5th Edition,* APA 2013)
- Pertenencia a la *Unidad de Primeros Episodios Psicóticos del Hospital Clínico Universitario de Valencia*. Para pacientes asociados al área 5 de Valencia.
- Edad comprendida entre 16-70 años
- Disponer de un smartphone propio con acceso a internet (no necesariamente de forma permanente) que permita la adecuada instalación y funcionamiento de la app.

Criterios de exclusión:

- Falta de habilidades para manejar el dispositivo móvil
- No firmar el consentimiento informado.
- Nivel de Español o Inglés insuficiente para entender las preguntas administradas por el dispositivo.

4.4. Variables a estudio

a. Variables basales:

Tras ser incluidos dentro de la unidad, los pacientes fueron citados para realizar una evaluación clínica completa. En esta evaluación se recogieron los siguientes datos:

- *Información sociodemográfica*: edad, género, país de origen, etnia, estado marital nivel educativo, situación laboral, convivencia.

- *Información clínica:* tipo de medicación antipsicótica, uso de medicación inyectable, años de enfermedad, enfermedades asociadas, intentos previos de suicidio y puntuaciones en las escalas: *Clinical Global Impression Severity of Illness scale* (CGI-SI; Busner et al., 2007), *Global Assessment of Functioning* (GAF; Endicott et al., 1976), *Positive and Negative Syndrome Scale* (PANSS; Peralta et al., 1994), *Premorbid Adjustment Scale* (PAS; Cannon-Spoor et al., 1982).

b. Variables de Resultados:

- *Beneficios clínicos*: comparación entre el número de recaídas, número de visitas a urgencias y número de hospitalizaciones de los pacientes que usan ReMindCare con respecto a los pacientes que deciden no utilizar el aplicativo.

- *Viabilidad*: número de pacientes que acceden a utilizar la app frente a número de pacientes que no se interesan por su uso.

- *Cumplimentación y compromiso con la app*: Hablaremos de cumplimentación en referencia al número de veces que los pacientes responden a los cuestionarios del dispositivo una vez reciben la notificación. Por otra parte, el compromiso, hace referencia al número de meses que los pacientes usan la app, el número de pacientes que abandonan su uso, así como el número de consultas urgentes solicitadas por los pacientes.

4.5. Ética, seguridad y privacidad de los datos de los pacientes

El proyecto en el que se enmarca el desarrollo y uso de la app ReMindCare, recibió la aprobación tanto *del Comité de Ética de la Facultad de Medicina de la Universidad de Valencia*, como del *Instituto de Investigación Clínica y Sanitaria del Hospital Clínico Universitario de Valencia* (INCLIVA). Estos documentos pueden consultarse en el **Apéndice II,** junto a la hoja de información al paciente y consentimiento informado.

Para asegurar la privacidad de los datos de los pacientes, la comunicación se encuentra encriptada con un certificado TLS (Transport Layer Security) de la Generalitat Valenciana y es enviada mediante el protocolo HTTPS (Hypertext Transfer Protocol Secure). De esta manera, se asegura que todos los datos transmitidos son completamente privados y sin posibilidad de manipulación externa. Además, la infraestructura donde se aloja la plataforma se encuentra protegida a través de un proxy inverso. Esto favorece la seguridad al establecer un único punto de acceso a él y así ocultar toda la infraestructura interior.
Por otra parte, la integración con el sistema informático hospitalario permite autenticar los clínicos mediante el protocolo LDAP (Lightweight Directory Access Protocol), e identificar los pacientes a través de HL7 (Health Level Seven).

Todo este proceso de integración está supeditado a la LOPD-GDD (Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales), ley orgánica española relativa a la protección de las personas físicas en lo que respecta al tratamiento de sus datos personales y a la libre circulación de estos datos, y que tiene por objetivo adaptar el Derecho interno español al Reglamento General de Protección de Datos.

4.6. Análisis de datos

Para el análisis de los datos, se hizo uso del paquete de análisis estadístico SPSS Statistics version 22 (IBM Corp). El conjunto total de pacientes se dividió en dos grupos: Por una parte, el grupo de pacientes que accedieron a utilizar la app ReMindCare (Grupo RC) y por otra parte, los pacientes que no quisieron hacer uso de la app y por lo tanto recibieron el tratamiento normativo de la unidad PEP (Grupo TAU). Se llevaron a cabo análisis descriptivos (media, desviación típica, análisis de frecuencias y porcentajes) de ambas muestras. A su vez, se realizaron análisis de comparación entre ambas muestras del tipo chi-cuadrado, así como análisis de varianza para las variables de tipo cuantitativo.

Para considerar que un paciente tuvo una recaída haciendo uso de la app, el paciente debía haber utilizado la app los dos meses previos a su recaída. En caso de no haber estado usando la app de forma activa durante ese periodo, se consideró que el paciente no estaba utilizando la app durante el empeoramiento.

Se realizaron dos análisis de datos. El análisis más exhaustivo sobre los efectos de la introducción de ReMindCare en la práctica clínica diaria se realizó entre los meses de Octubre 2018 a Mayo de 2020. Y un segundo análisis más breve, se realizó entre los meses de Marzo del 2020 a Marzo del 2021, periodo correspondiente al inicio de la pandemia y del confinamiento en España.

5. RESULTADOS:

5.1. Desarrollo de la versión definitiva de la aplicación ReMindCare e implementación sistemática en la práctica clínica diaria (**Bonet et al., 2020 (a)**) [**Objetivo 5**].

En base a los estudios expuestos anteriormente, se diseñó la versión definitiva de la app ReMindCare. Se trata de una aplicación para smartphone que recoge información sobre el estado clínico de los pacientes con trastorno psicótico mediante breves cuestionarios que se presentan de forma diaria y semanal.

Esta información, puede consultarse en una página web de acceso restringido, en la que los clínicos pueden visualizar los datos de los pacientes, así como generar informes pdf en los que se resumen los principales datos obtenidos por la app. Estos informes, pueden ser subidos como un archivo adjunto a la historia clínica electrónica del paciente, de forma que pueden ser consultados por cualquier clínico involucrado en el tratamiento de este.

A su vez, la app produce todo un sistema de alertas con las que notificar al clínico las variaciones en el estado del paciente o el cese de uso de la app. Además, los pacientes pueden solicitar una consulta urgente con el clínico, pulsando un botón en la pantalla de inicio de la app denominado "consulta urgente". Como resultado de esta alerta, los clínicos reciben un correo y deben ponerse en contacto con el paciente en un plazo máximo de 48h.

Todos los nuevos pacientes de la unidad PEP de *HCUV* fueron informados sobre la app en la primera entrevista con el clínico. Tras una breve explicación, los pacientes decidieron si estaban o no interesados en utilizar este dispositivo.

En caso de no estarlo, los pacientes continuaron con el tratamiento normativo dentro de la unidad PEP. Y en caso de estar interesados en utilizar la app, los pacientes fueron informados más en detalle por un experto. Se les explicó de forma extendida el funcionamiento de la aplicación, se les indicó como realizar su correcta instalación, y se les informó de todos los aspectos relativos a la ética y privacidad de los datos recogidos por el dispositivo. Seguidamente, los pacientes fueron dados de alta en el sistema y pudieron empezar a hacer uso del dispositivo.

El manual de usuario tanto del clínico como del paciente, pueden consultarse en el **Apéndice III** y **IV**. Por otra parte, toda la información relativa al protocolo que guía la actuación de esta intervención se recogió la siguiente publicación (Bonet et al., 2019).

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ReMindCare, an app for daily clinical practice in patients with first episode psychosis: A pragmatic real-world study protocol

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Abstract

Aim: Despite the potential benefits of e-health interventions for patients with psychosis, the integration of these applications into the clinical workflow and analysis of their long-term effects still face significant challenges. To address these issues, we developed the ReMindCare app. This app aims to improve the treatment quality for patients with psychosis. We chose to study the app in real world and pragmatic manner to ensure results will be generalizable.

Methods: This is a naturalistic empirical study of patients in a first episode of psychosis programme. The app was purpose-designed based on two previous studies, and it offers the following assessments: (a) three daily questions regarding anxiety, sadness and irritability; and (b) 18 weekly questions about medication adherence, medication side effects, medication attitudes and prodromal symptoms. The app offers preset alerts, reminders and the ability for patients to reach out to their clinicians. Data captured by the app are linked to the electronic medical record of the patient. Patients will use the app as part of their ongoing care for a maximum period of 5 years, and assessments will occur at baseline and at the end of the first, second and fifth years of app use.

Results: Recruitment started in October 2018 and is still ongoing.

Conclusions: The ReMindCare app represents early real-world use of digital mental health tools that offer direct integration into clinical care. High retention and compliance rates are expected, and this will in turn lead to improved quality of assessments and communication between patients and clinicians.

KEYWORDS

adherence, app, e-health, psychosis, smartphone

1 | INTRODUCTION

Early intervention programs for first-episode psychosis are effective evidence-based interventions that foster recovery, prevent disability and reduce costs associated with illness in both the short and long

Abbreviations: App, application; e-health, electronic health; EMR, electronic medical record; FEPP, first episode of psychosis program; SQ, satisfaction questionnaire.

term (Arango et al., 2017). However, like all clinical programs, they face implementation challenges. Specific challenges identified by the RAISE study in the United States include workforce development, community activation, fidelity and measurement of outcomes and patient involvement (Dixon, 2017). In Spain, which has a non-contributory health system financed through taxation and supported by public funding, universal health coverage and free health care services result in a lack of professionals, tools and financial support to properly deliver these interventions (Arango et al., 2017). Thus, interventions that reduce the number of consultations and hospital admissions, enhance interview efficiency, increase the early detection of illness and enhance treatment efficacy are highly encouraged (Arango et al., 2018; MSCBS, 2019). Research on smartphone ownership among youth receiving early intervention services suggests that, like the rest of the population, they increasingly own these devices; a 2015 study suggested 81% ownership (Lal et al., 2015), and more recent research studies suggested 85% (Aref-Adib et al., 2016) to 86% (Bonet et al., 2018) ownership. Furthermore, many studies have found high percentages of interest (70%-80%) in e-health interventions among these patients (Bonet et al., 2017; Firth et al., 2016; Gitlow et al., 2017), with no differences related to demographic or clinical characteristics (Berry, Lobban, Emsley, & Bucci, 2016; Bonet et al., 2018).

Thus, in this digital age, it is not surprising that those with psychosis are already turning to the internet and their smartphones for information about their illness, peer support and local treatment resources (Aref-Adib et al., 2016; Torous & Keshavan, 2018), creating an opportunity for community engagement by using early intervention programs. Perhaps, the greatest potential for digital technology for early intervention programs is achieving fidelity and measurement of outcomes through automatically quantifying patients' treatment trajectory through real data, captured via surveys and sensors delivered via patients' phones. Numerous studies have shown the feasibility and acceptability of remotely monitoring location via smartphones and how such data can be used to predict risk and stratify patients with schizophrenia (Barnett et al., 2018; Bucci et al., 2018; Wang et al., 2016). By capturing and quantifying the lived experiences of those with psychosis, digital technology can help early intervention programs measure functional recovery metrics, such as employment, social support and medication adherence, in addition to subjective metrics.

However, despite the potential of digital technology to augment early intervention care, efforts to date have been largely composed of brief feasibility studies rather than actual clinical integration projects. Most interventions analysed have been implemented in periods ranging from 1 to 78 weeks, with the majority only implemented for 4 weeks or less (Berry et al., 2016; Bonet et al., 2017). A second limitation is the feasibility of translating these interventions into daily clinical practice, which has not been properly tested, as many studies were not designed to be implemented in the hospital or clinical workflow (Lauckner & Whitten, 2016; Zanaboni et al., 2018). Moreover, some studies suggested that, to achieve full integration into clinical practice, organizations also need to adapt their systems to these technologies; otherwise, success of the interventions would be harmed (Appelbaum & Wohl, 2000). A third limitation is the impact of digital health interventions on clinicians' workload and clinical efficiency remains understudied (Gitlow et al., 2017; Hoerbst & Schweitzer, 2015; Zanaboni et al., 2018). Finally, it is also important to consider patients' perspectives outside of clinical studies. Although the majority of studies found high levels of acceptance among patients in terms of participation in e-health interventions (Berry et al., 2016; Bonet et al., 2018), some studies have indicated that excessive e-health communications could be regarded as repetitive, intrusive or irritating (Kannisto, Adams, Koivunen, Katajisto, & Välimäki, 2015; Palmier-Claus et al., 2013) or could increase worries about illness (Kannisto et al., 2015). Thus the pragmatic and real world nature of our study offers broad generalizable knowledge that considers not only how the app may impact care but also how it can be implemented into care.

The potential of digital mental health for early course psychosis stands in sharp juxtaposition to the limited real-world clinical evidence for its impact, integration and acceptability among both patients and clinicians. To address these issues and improve the quality of early intervention programs in patients with a first episode of psychosis, we have developed an application (app) called "ReMindCare." The ReMindCare app was created as a tool that could be integrated into standard psychiatric care and treatment, filling the gap between research and clinical practice.

2 | METHODS

2.1 | Study objectives

The main objective of this study is to address whether the introduction of the ReMindCare App into daily clinical practice improves the quality of treatment for patients in a first episode of psychosis programme (FEPP).

Specifically, the aims of the study are (1) to assess the effectiveness of the ReMindCare app, in terms of improvement of adherence to anti-psychotic medication, early detection of relapses and improvement of communication with clinicians, vs treatment as usual in patients with a psychotic disorder; (2) to analyse the use of the ReMindCare app by the patients in terms of rates of adherence, compliance, alerts generated and the total time using the app; and (3) to assess the satisfaction of patients with using the app and the perceived usability of the ReMindCare app.

2.2 | Study design

In the protocol, we describe the ReMindCare intervention as the first prospective naturalistic and empirical study of an app for FEPP. This app aims to improve the quality of the evaluation and treatment of patients. At the time of submitting this article, ReMindCare had been introduced as a clinical tool into daily psychiatric practice for more than a year. However, enrolment of patients continues, and the first analysis of the data will be conducted by March 2020.

2.3 | Study setting

The ReMindCare app was systematically integrated into the daily FEPP workflow at the Public Clinical Hospital of Valencia (Spain), where it is currently being used. This FEPP is a free care service that aims to enhance the quality of the early care of outpatients with a first episode of psychosis, from the early phases of the illness through the first five critical years of treatment (Arango et al., 2017).

Given the pragmatic and naturalistic nature of this study, no remuneration or compensation is offered to patients participating in the programme or using the app. Rather, the app is offered as an additional and free service to the patients in treatment at study sites.

2.4 | Participants

2.4.1 | Recruitment and enrolment

Every outpatient from the FEPP who meets the criteria for inclusion is considered a potential user of the ReMindCare app. Once patients enrol in the study, they are able to use the app for a maximum period of 5 years, which is the time when they would be discharged from the FEPP.

All patients interested in using the app must sign an informed consent form and must complete some baseline assessments before their inclusion in the study.

2.4.2 | Eligibility criteria

To be considered for this study, patients must be accepted into the FEPP at the Clinical Hospital of Valencia. Criteria for inclusion in the FEPP are:

Diagnosis of psychotic disorder following DSM-5 (APA, 2013) criteria, interview conducted by a licensed clinician.
Less than 5 years of illness duration.
Residence associated with the hospital area of correspondence (Area 5 of Valencia).
Age between 17 and 65 years old
Ownership of a smartphone with an internet connection that allows the proper installation and functioning of the app.

Exclusion criteria include the following:

Inability to use and master a mobile device and the Internet.
Refusal to sign an informed consent form.
Spanish/English language fluency limiting ability to partake in clinical conversations or to understand the app questionnaires.

2.4.3 | Discontinuation and withdrawal

A patient's participation in the study will be discontinued if:

The patient provides an explicit notification of not wishing to continue using the app.
Lack of use the app for a period longer than 2 months after having been contacted by the research group over that period of inactivity.
Discharged from the FEPP or if their consent is revoked.
Given the naturalistic nature of this study, in case of discontinuation or withdrawal, patients will continue with the usual psychiatric treatment at the hospital.

2.5 | Intervention

2.5.1 | Application development

The development process for the ReMindCare app can be divided into different phases, including review of the literature, a survey study, a design phase, a pilot study phase and a final version phase.

We first conducted a systematic review of previous publications on apps for psychosis (Bonet et al., 2017). Although the results of this review suggested that apps are feasible and well accepted by patients with psychosis, and apps can capture symptoms with good correlation to traditional metrics, a lack of clinical integration was notable across nearly all studies. Thus, to better understand how to design an app optimized for clinical integration, we next conducted a survey study of patient interests and preferences. We designed a survey based on previous publications (Borzekowski et al., 2009; Gay, Torous, Joseph, Pandya, & Duckworth, 2016; INE, 2016; Miller, Stewart, Schrimsher, Peeples, & Buckley, 2015; NAMI, 2014; Robotham, Satkunanathan, Doughty, & Wykes, 2016; Trefflich, Kalckreuth, Mergl, & Rummel-Kluge, 2015) and administered it to a sample of 113 patients with psychosis. We aimed to evaluate the actual feasibility of e-health interventions in a potential sample of patients with psychosis in our target population and to evaluate the interest of these patients in e-health interventions (Bonet et al., 2018). The results highlighted that apps must offer improved communication with clinicians.

Next, we codesigned an e-health app called ReMindCare with a team of clinicians, patients and developers. Our main objective of this process was to ensure the usability of the app. In this regard, both the patients and prior work in this space led us to focus on displaying information in the app graphically to easily allow a quick overview of the results and analysis of relevant information. We used a set of information technologies that simplified the development and communication between different parts of the platform. This included utilizing free and open source software tools such as the MongoDB database (MongoDB, GNU AGPL v3.0) to ensure flexibility and scalability, a Node.js server (Node.js, MIT Licence) to power the app, Docker containers (Docker, Apache Licence 2.0.) to protect privacy and frameworks such as Meteor and Bootstrap to build responsive user interfaces. This development of the app was conducted in a test environment outside the hospital network. Early efforts in this phase were focused on proper functioning of the database, the website and the mobile application.

With a functional first version of the ReMindCare app, we next focused on the challenges related to integration of the app into the hospital system. First, we had to study the current digital infrastructure of the hospital and adapt the platform to achieve its integration into the system while ensuring the performance of the app remained as designed, and patient data privacy was maintained. User authentication around the identification of both physicians and patients was a barrier that we faced. This identification was carried out through the

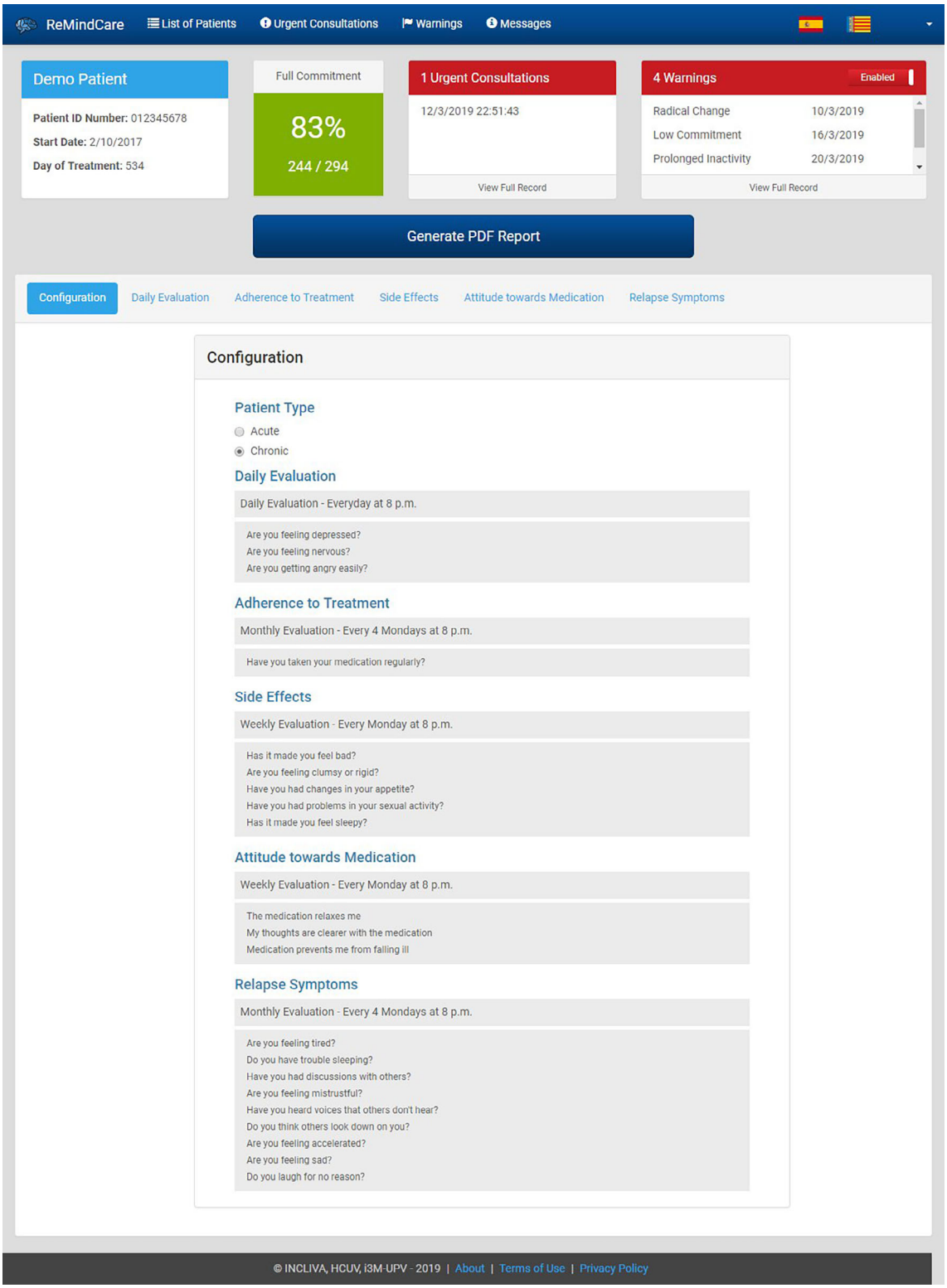

FIGURE 1 Screen shot of the ReMindCare dashboard (App for patients). Example of daily evaluation questions

Lightweight Directory Access Protocol (LDAP), which allows access to an organized and distributed directory service for an information search. The identification of patients and the report uploading was realized using Health Level Seven (HL7), which is an international set of standards to facilitate the electronic exchange of clinical information. This development process and installation of the app took approximately 2 years, with the most time spent on the clinical integration of the app into the hospital electronic system.

Although the process of integration was underway, we conducted a pilot study to test the validity and usability of the platform. This pilot trial involved four patients with psychosis for a period of 3 months, during which no negative effects associated with app use were found. The rates of compliance to surveys within the app were between 90% and 97%. Based on user feedback, we conducted further modifications to ensure the accurate functioning of the app in regards clinicians access to the app website, privacy of data registration and technical and electronic adjustments to achieve the automatic synchronization of ReMindCare with Android updates to ensure the appropriate performance of the app among different Android versions and smartphones.

2.5.2 | ReMindCare app

ReMindCare is a free and user-friendly app that conducts daily evaluations of the health status of patients with psychosis by offering quick questionnaires. Two types of questionnaires are presented (Figure 1):

- *Daily questionnaires*: Three daily questions that assess levels of anxiety, sadness and irritability.
- *Weekly questionnaires*: Eighteen weekly questions aimed to assess adherence to medication (1), the presence of side-effects to antipsychotic medication intake (5), the attitude towards medication intake (3) and the presence of prodromal psychosis symptoms (9).

To use this clinical tool, clinicians enrol their patients via a private portal. Once the patients are registered into the portal, they can

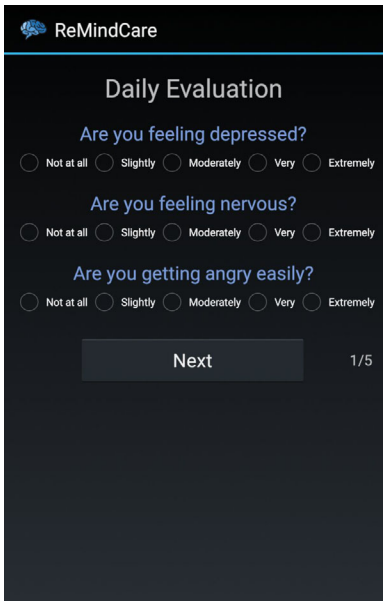

FIGURE 2 Screen shot of the ReMindCare dashboard (Website for clinicians). List of questions presented to patients

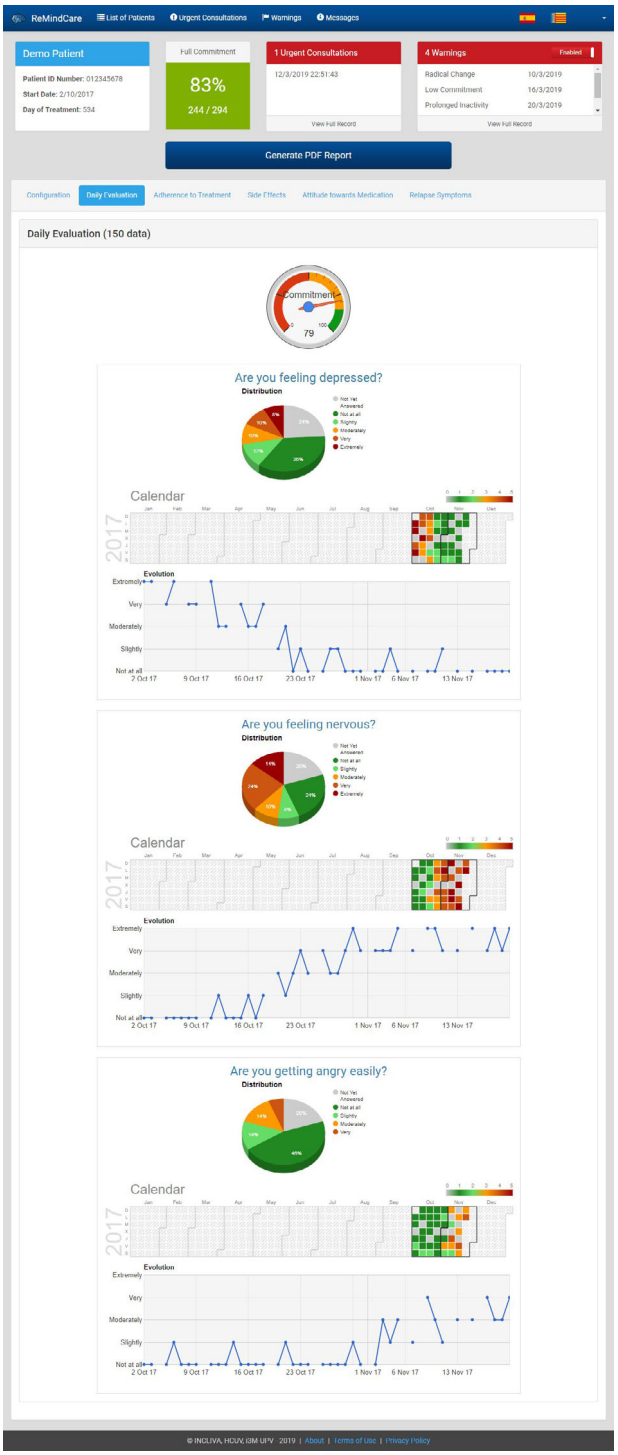

FIGURE 3 Screen shot of the ReMindCare Dashboard (for clinicians). Example of daily evaluation graphics

download the app, which is available on "Google Play," log into the app and begin to use it. Patients are instructed on how to download and log into the app, and they are informed regarding how their app data are used.

The information gathered by the app is accessible to clinicians on the portal, and it is exclusively used to orient clinicians for upcoming visits with patients, to help both patients and clinicians have a shared vision of the status of the patient and to discuss and establish together the therapeutic approaches. In addition, as displayed in Figures 2 and 3, on this portal, clinicians can not only visualize the information but also generate a PDF report that summarizes this information. These reports can be uploaded to the electronic medical record (EMR) of the patient because we enabled a function in the electronic hospital system that allows the inclusion of the ReMindCare app reports as another type of clinical report (eg, similar to results from a blood pressure test or glucose test). Moreover, if patients do not respond to notifications or abrupt variation in their answers occurs, the system automatically generates "alarms or warnings." These alarms notify the clinician by e-mail and are also displayed in the profile of the patient on the website. Moreover, patients are

TABLE 1 Study measures and assessment times

	ReMindCare intervention					
	Baseline	Intervention			Follow-up	
Timepoint	t_0	t_1	t_2	t_3	t_4	$t_{5\text{-}8}$
Enrolment						
Eligibility screen	X					
Informed consent	X					
Assessments						
Baseline assessment						
Clinical Global Impression Scale (CGI) (Busner & Targum, 2007)	X				X	X
Global Assessment of Functioning (GAF) (Endicott, Spitzer, Fleiss, & Cohen, 1976)	X				X	X
Positive and Negative Syndrome Scale (PANSS) (Peralta & Cuesta, 1994)	X				X	X
Premorbid Adjustment Scale (PAS) (Cannon-Spoor, Potkin, & Wyatt, 1982)	X				X	X
Drug Attitude Inventory (DAI-10) (Hogan, Awad, & Eastwood, 1983)	X				X	X
Beck Cognitive Insight Scale (BCIS) (Beck, Baruch, Balter, Steer, & Warman, 2004)	X				X	X
Sociodemographic information (Age, sex, ethnicity, marital status, level of education, living situation and employment status)	X					
Clinical information (Diagnose, years of illness, pharmacological treatment, suicidal attempts, history of illness)	X		X		X	X
Outcome measures						
Simplified Medication Adherence Questionnaire (SMAQ) (Morisky, Green, & Levine, 1986)	X		X		X	X
Number of relapses	X		X		X	X
Number of visits to urgent care units at the hospital	X		X		X	X
Number of hospital admissions	X		X		X	X
ReMindCare measures						
Answers to questionnaires		X	X		X	X
Quantity of "urgent consultation" requests		X	X		X	X
Quantity of alarms generated		X	X		X	X
Satisfaction Questionnaire†				X		X

Note: t_1 = introduction of the ReMindCare app into clinical practice; t_2 = first-year preliminary data assessment; t_3 = focus group, first year; t_4 = second-year follow-up; $t_{5\text{-}8}$ = fifth-year follow-up; Satisfaction questionnaire† = App feedback questionnaire made for the purpose of this research.

able to contact their clinician using an "Urgent Consultation" tab displayed on the app if they detect a significant worsening in their health status. By clicking this button, clinicians receive a notification e-mail and have to contact the patient within a maximum period of 48 hours. Further information about the use of the app and the webpage is available in the user manual included in Appendix A.

2.6 | Data collection and measures

An overview of all included measures and assessment points is included in Table 1.

Baseline surveys, including clinical and sociodemographic information and clinical standardized questionnaires, were administered before the enrolment of the patient in the study. As shown in Table 1, data regarding the main outcomes, such as adherence to medication, number of relapses, number of visits to the hospital urgent care units and number of hospital admissions, will be collected and analysed at the end of the first, second and fifth years of the intervention. Moreover, information generated for patients through the use of the app will also be analysed at the same timepoints. Finally, to analyse the feedback of patients regarding the use of the app, we plan to conduct focus groups at the end of the first year of the intervention, and we have also designed a "satisfaction questionnaire" (SQ) that patients will complete at the end of the first year of the intervention or before discontinuing the use of the app (if discontinuation occurs before the first year of app usage). This SQ was made for the purpose of this research study and is based on previous satisfaction and usability questionnaires, such as the user version of the Mobile Application Rating Scale (uMARS) (Stoyanov, Hides, Kavanagh, & Wilson, 2016), the System Usability Scale (SUS) (Brooke, 1996), EnLight: a tool for mobile and web-based eHealth interventions (Baumel, Faber, Mathur, Kane, & Muench, 2017) and the App Quality Evaluation (AQEL) (DiFilippo, Huang, & Chapman-Novakofski, 2017). This questionnaire is displayed in Appendix B.

2.7 | Planned data analysis

Descriptive analyses of sociodemographic and clinical variables will be conducted. A multivariate data analysis will be carried out to explore relationships between sociodemographic and clinical variables and adherence to treatment and ReMindCare measures. An ANOVA model of repeated measures will be used for the main research outcomes. All analyses will be conducted with an alpha set at $P < 0.05$.

These preliminary quantitative data analyses and the preliminary results regarding patient compliance, retention rate and perceived satisfaction with the use of the ReMindCare app are expected by the end of the first year of using the app (March 2020). At that time, qualitative analyses of data are also planned.

Subsequent analysis of the data will be conducted at the end of the second and fifth years of use of the app.

2.8 | Ethics, data privacy and participant safety

The ReMindCare app project has received full approval from the Research Ethics Committee of the faculty of Medicine at the University of Valencia and from the Research Ethics Committee of the Sanitary Research Institute (INCLIVA) of the Clinical Hospital of Valencia, Spain.

To protect the data sent by patients, communications to the platform are encrypted with a transport layer security certificate from the Generalitat Valenciana and are sent through the HTTPS (Hypertext Transfer Protocol Secure) protocol. This process ensures that all transmitted data are completely private and without a chance of being manipulated. Moreover, the hospital infrastructure is protected through a reverse proxy, which enhances security by establishing a single access point to it and hiding all inner infrastructures. Moreover, the integration of the app into the hospital systems is subjected to the LOPD-GDD (Organic Law 3/2018: protection of personal data and digital rights guarantee, December 5th), the Spanish organic law adaptation of the GDPR (General Data Protection Regulation).

3 | RESULTS

The ReMindCare app was systematically introduced into clinical practice in October 2018, and 57 patients have been enrolled in the study since then. Updates of the app and improvements in its functioning will be conducted as requested by feedback obtained from patients and clinicians and in accordance with Android and iOS developments.

4 | DISCUSSION

ReMindCare is an e-health intervention aimed at improving the quality of the current programme for early treatment of patients with psychosis. Although there are an increasing amount of apps being studied for early course psychosis (Camacho, Levin, & Torous, 2019), to our knowledge, this is the first pragmatic and prospective integration of an app into real world clinical care. The study is thus designed to generate data beyond just how the app may improve care but also how it can be implemented into clinical care, leading to the ability to augment quality existing health services (Bonet et al., 2017).

4.1 | Anticipated results

On the basis of previous studies (Bonet et al., 2017; Firth et al., 2016; Gitlow et al., 2017) that confirmed the interest of patients with psychosis in e-health interventions and based on the high interest in owning an e-health app that we found in our survey study (Bonet et al., 2018), we expect an acceptable retention rate (beyond 70%).

Moreover, based on previous studies (Ben-Zeev et al., 2014; Ben-Zeev, Kaiser, & Krzos, 2014; Brenner & Ben-Zeev, 2014; Kimhy,

Vakhrusheva, Liu, & Wang, 2014; Macias et al., 2015) that found rates of response to the communications of e-health apps to be higher than 70%, we also expect moderate compliance with the app's communications (beyond 70%).

Furthermore, as previous studies have stated that electronic assessments are valid and reliable measures (Brenner & Ben-Zeev, 2014; Kimhy et al., 2014; Palmier-Claus et al., 2013; Spaniel et al., 2008), and based on preliminary perceptions obtained from the first 7 months of the current intervention, we expect that the use of the ReMindCare app would produce the following differences in the treatment of psychotic disorders:

- *Improved quality of treatment delivery for clinicians*: Graphics of daily and weekly questionnaires allow clinicians to rapidly assess the status of the patient and to specifically orient their interactions with the patient to problematic areas. An improvement in the quality of evaluation is also expected. Perceptions of the clinicians regarding these issues will be qualitatively assessed in focus groups.
- *Improved insight about the illness and mental health status for patients*: Sharing with patients their responses to the app is expected to increase accuracy of information and to decrease bias in this process. Moreover, it is expected that, by discussing their app responses with the patients, insight about their illness and their health status will increase. These perceptions will be mainly assessed by the "satisfaction questionnaire" (SQ), and they will also be assessed qualitatively in focus groups. Moreover, changes in insight between baseline and 1 year of intervention will be assessed by using the BCIS (Beck et al., 2004).
- *Improved quality of communication between patient and clinician*: It is expected that patients will feel more understood as a result of improvements in evaluation and quality of their interactions with the clinician, which could lead to an enhancement of the overall quality of communication and alliance between patient and clinician. Again, this will be assessed by the SQ and the focus groups.
- *Improved adherence to treatment for patients*: As a result of improvements in insight about the illness and improvements in alliance with clinicians, an enhancement of adherence to treatment is also anticipated. Significant differences are expected in the SMAQ (Hogan et al., 1983) scores of patients between baseline and 1 year of intervention. Moreover, the number of relapses, treatment dropouts and rates of compliance and adherence to ReMindCare tests will also be analysed in this regard. It is expected that the more patients use ReMindCare (high rates of engagement and compliance), the fewer treatment dropouts and relapses there will be.
- *Improved early relapse detection and hospital admission reduction*: Again, higher rates of engagement with ReMindCare are expected to produce lower hospital admissions, early detection of relapses and fewer visits to urgent care units. Moreover, rates of relapses, changes in medication and visits to urgent care units will be compared among patients who used the "urgent consultation" function and those who do not. We expect that using this function will improve the quality of early detection.
- *Improved quality of communication between health care providers and improved quality of treatment decisions*: Due to general access of health care professionals to ReMindCare reports on the EMR, we expect improved communication between health professionals and, because of this, improved quality of treatment. Perceptions of clinicians on this issue will be qualitatively assessed in focus groups.

4.2 | Strengths and limitations

The main strength of our approach is the simplicity of the app and the direct integration of ReMindCare into daily clinical practice. As stated before, one of the most important factors regarding the sustainability of e-health interventions relies upon good integration into the workflow of health systems (Abbott, Foster, Marin Hde, & Dykes, 2014; Appelbaum & Wohl, 2000; Cresswell & Sheikh, 2013; Granja, Janssen, & Johansen, 2018). The ReMindCare app was designed with the main objective of being useful not only for patients but also for health providers. In this regard, the user-friendly design of the app, its integration into the public hospital workflow and the free access to the app for patients are major strengths that aim to ensure the use of the app by both patients and clinicians and to improve, as a result, the quality of treatment that patients receive and the quality of health services that clinicians provide.

Another main strength of our study is that the development of the app was based on two previous studies (Bonet et al., 2017, 2018), which allowed us to be confident about the theoretical framework of the intervention and to truly address the necessities of the patients. As we found in our study (Bonet et al., 2018), patients claimed improvements in communication with clinicians, which was one of our main objectives when we designed the app.

The graphical display of information can be regarded as another major strength. The integrated graphics provide a quick overview of the health status of the patient, which is extremely useful in the context of a busy public health system (Arango et al., 2018). Specifically, these graphics can help clinicians detect side-effects of medication that are not usually commented on by patients, such as sexual dysfunctions. This is relevant, as medication side-effects are one of the most important factors affecting medication dropouts (García et al., 2016).

Finally, the ReMindCare app has been developed in three languages, Spanish, English and Catalan, which allows the use of the app in different countries and autonomous communities.

However, some limitations must be taken into consideration. First, because of the characteristics of this real-world intervention, our study is not randomized or controlled. However, we plan to compare the main outcomes of the use of the app between users and age-matched controls, although the groups may differ in some characteristics. Another limitation is that ReMindCare has only been designed for Android systems, although an iOS version of the app is being designed.

To our knowledge, this is one of the earliest e-health interventions for patients with psychosis implemented as a standard care tool

integrated into clinical practice in the public hospital workflow. Real-time health information is being collected and used to work together with patients to improve the quality of real-world health care delivery.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in [repository name e.g "figshare"] at http://doi.org/[doi], reference number [reference number]

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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5.2. Resultados clínicos de la introducción de ReMindCare en la unidad de PEP del Hospital Clínico Universitario de Valencia. [**Objetivo 6**].

a. Estudios preliminares:

En un primer análisis de los resultados, realizado entre los meses de Septiembre de 2018 a Marzo de 2019, se observó que de los 81 pacientes en seguimiento en la unidad, el 16% (13/81) no pudo hacer uso de la app porque cumplía criterios de exclusión, siendo la principal causa el no disponer de un dispositivo móvil propio (4/13) o presentar un déficit cognitivo severo (4/13). A su vez, el 26% (21/81) no quiso utilizar la app, debido principalmente a su baja adherencia e implicación en el tratamiento en general (15/21). Al comparar a este grupo de no participantes frente al 58% (47/81) de los pacientes que accedieron a utilizar la app, no observamos diferencias significativas a nivel demográfico, no obstante, existía un mayor porcentaje de pacientes que accedieron a utilizar la app con antecedentes de suicidio (X^2= 4.42, P=0.036) mientras que los no usuarios, presentaron mayores puntuaciones en la escala CGI_SI (X^2= 6.62, P=0.037). Estos datos pueden consultarse en el **Apéndice V** (Bonet et al., 2019).

En un segundo análisis realizado entre los meses de Septiembre de 2018 a Marzo de 2020. Se analizó de forma preliminar los beneficios del uso de la consulta urgente en los pacientes de que accedieron a usar el dispositivo. En este periodo de tiempo, 57 pacientes eran o habían sido usuarios de la app. Y de ellos, el 26% (15/57) solicitaron una o más consultas urgentes. Al comparar este grupo de pacientes frente al 74% (42/47) que no solicitó una consulta urgente, observamos que los solicitantes presentaban una mayor cumplimentación de los cuestionarios de la app (X^2= 6.3, P=0.04) así como un mayor número de visitas a las unidades de urgencias hospitalarias (X^2= 4.4, P=0.03). A su vez, solo el 13,3% de los solicitantes, hizo uso de la consulta urgente para informar de una recaída psicótica. Estos datos pueden consultarse en el **Apéndice VI** (Bonet et al., 2020 (b)).

b. *Análisis exhaustivo tras 19 meses de introducción de ReMindCare en la práctica clínica.* (**Bonet et al., 2020 (c)**):

En Mayo de 2020, se procedió al análisis de los resultados clínicos de la introducción de ReMindCare en la *unidad de PEP del Hospital Clínico Universitario de Valencia*. Se analizaron los datos procedentes de 90 pacientes, de los que 59 eran o habían sido usuarios de la app (Grupo RC), frente a 31 pacientes que pese a cumplir los criterios de inclusión, rechazaron su uso y por lo tanto, siguieron el tratamiento normativo (Grupo TAU).

Tras 19 meses de intervención, se encontraron diferencias significativas entre los grupos en el número de recaídas, hospitalizaciones y visitas a urgencias. Así, solo el 20% (12/59) de los pacientes del grupo RC tuvieron recaídas, frente al 58% (18/31) de los pacientes del grupo TAU (X^2=13.7, *P*=0.001). A su vez, los pacientes del grupo RC tuvieron menos visitas a las unidades de urgencias hospitalarias (X^2=7.4, *P*=0.006) y menor número de hospitalizaciones (X^2=4.6, *P*=0.03).

Finalmente, se observó un alto compromiso de los pacientes del grupo RC con la app. La media de meses utilizando la app fue de 11.6 (SD=6-5; min/max: 0-19) mientras que la tasa de respuesta a los avisos de la app fue de 84.5 (SD=16.0) con el 61% (36/59) de pacientes con un compromiso de respuesta entre el 85-100%. Estos datos, se exponen en la publicación que se muestra a continuación (Bonet et al., 2020 (c)).

Original Paper

ReMindCare App for Early Psychosis: Pragmatic Real World Intervention and Usability Study

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Abstract

Background: eHealth interventions are widely used in clinical trials and increasingly in care settings as well; however, their efficacy in real-world contexts remains unknown. ReMindCare is a smartphone app that has been systematically implemented in a first episode of psychosis program (FEPP) for patients with early psychosis since 2018.

Objective: The objective of this study was to assess the efficacy of ReMindCare after 19 months of use in the clinic and varying use by individual patients.

Methods: The integration of the ReMindCare app into the FEPP started in October 2018. Patients with early psychosis self-selected to the app (ReMindCare group) or treatment as usual (TAU group). The outcome variables considered were adherence to the intervention and number of relapses, hospital admissions, and visits to urgent care units. Data from 90 patients with early psychosis were analyzed: 59 in the ReMindCare group and 31 in the TAU group. The mean age of the sample was 32.8 (SD 9.4) years, 73% (66/90) were males, 91% (83/90) were White, and 81% (74/90) were single.

Results: Significant differences between the ReMindCare and TAU groups were found in the number of relapses, hospitalizations, and visits to urgent care units, with each showing benefits for the app. Only 20% (12/59) of patients from the ReMindCare group had a relapse, while 58% (18/31) of the TAU patients had one or more relapses (χ^2=13.7, *P*=.001). Moreover, ReMindCare patients had fewer visits to urgent care units (χ^2=7.4, *P*=.006) and fewer hospitalizations than TAU patients (χ^2=4.6, *P*=.03). The mean of days using the app was 352.2 (SD 191.2; min/max: 18-594), and the mean of engagement was 84.5 (SD 16.04).

Conclusions: To our knowledge, this is the first eHealth intervention that has preliminarily proven its benefits in the real-world treatment of patients with early psychosis.

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KEYWORDS

app; clinical practice; mental health; psychosis; real-world intervention; telemedicine

Introduction

High interest in eHealth services and now digital and mobile health has been noted in many recent studies among patients with psychotic disorder diagnoses [1,2]. With COVID-19, this interest in digital health has surged, and the need to expand access to care through smartphones has become patent. Smartphone apps have been proposed as tools to mitigate social isolation, lack of access to care, and other triggers caused by the pandemic [3-5]. Researchers have already demonstrated that access to and use of technology among people with psychosis is nearly equivalent to that in the general population [6-8], but less is known about the actual efficacy of apps in care.

Apps have already seen growth in care for patients with early course psychosis. Many studies are using real-time ecological momentary assessment (EMA) surveys to monitor symptoms and experiences and identify early indicators of relapse [9]. Beyond relapse prediction, these EMA data can offer novel information on the longitudinal health status of patients, which could improve treatment and shared decision making between patient and physician [10]. Finally, eHealth services may be a major resource to enhance the benefits of the first episode of psychosis programs (FEPPs) for early psychosis, which can foster recovery [11] and reduce the risk of hospitalization and relapse [12,13].

Specific apps targeting schizophrenia have already been created and offer promising results. Examples of these innovative interventions are the Actissist [14] and the ExPRESS [15] interventions, which demonstrated potential in improving the quality of treatment of patients with early psychosis. Another example is the CrossCheck app [16], which demonstrated potential for identifying and dismantling dysfunctional beliefs that contribute to maintenance and distress associated with psychotic symptoms. Despite the widespread use of these eHealth interventions and high rates of efficacy reported in clinical trials, the efficiency and actual efficacy of these interventions in real-world clinical practice remains unknown [17].

One reason for the lack of initial success of health apps in clinical settings is lack of engagement. Often engagement in academic studies does not translate into real-world use [18,19]. Indeed, some studies found a negative correlation between the time spent using eHealth apps and the engagement of patients [20,21]. In addition, many clinicians expressed their concern that if these systems integrate seamlessly with clinical workflow, they will result in an increase in the clinicians' workload [22,23], which might affect their engagement with the app.

Other concerns have also limited efforts to integrate these apps into care settings. In our previous study [8], we found that 20% to 23% of patients felt anxious, suspicious, or paranoid concerning the internet, and almost 25% of patients perceived that use of the internet was directly related to one of their relapses. In addition, some studies indicated that excessive eHealth communications could be regarded as intrusive or irritating [24,25] or could increase worries about illness [25]. These potential harms of eHealth interventions must also be taken into consideration.

Considering these factors, it is clear that eHealth interventions shown to be feasible must now be assessed for effectiveness, efficacy, and efficiency [26] in real-world settings. With this objective in mind and to improve the daily treatment of patients with psychosis, we designed the ReMindCare app. The protocol followed for the design process and implementation of the app is published elsewhere [27]. In this protocol, we introduced ReMindCare as a smartphone app plus a clinician dashboard, developed to be implemented in a FEPP for patients with early psychosis.

To the best of our knowledge, ReMindCare is the first eHealth intervention for patients with early psychosis that has been systematically integrated into daily clinical practice, finally filling the gap between research and clinical practice [2,17].

The aim of this study was to assess the efficacy and clinical outcomes of the use of the app after 19 months in terms of adherence to ReMindCare, relapse prevention, hospital admissions, and visits to urgent care units compared with treatment as usual (TAU) without the app.

Methods

Study Setting

The app was systematically integrated into the daily clinical workflow in a FEPP at the University Clinic Hospital of Valencia, Spain. This FEPP started in 2010 with the objective of improving early detection, evaluation, and personalization of treatment. It covers a total of 330,000 inhabitants included in Area 5 of Valencia city. The incidence of novel psychotic disorders in this area has gradually increased during the 10 years since the program started. Currently, the FEPP in the clinic hospital has a mean of 30 to 35 new patients with psychosis per year.

The implementation of the ReMindCare app into the FEPP and into clinical practice started in October 2018 and is still in use today. In this study, we present the results from the first 19 months of use of the app.

Neither patients nor physicians received any remuneration or compensation for participating in the program or using the app. The use of the app was offered as an extra free service to the patients in the program.

Participants

Recruitment and Enrollment

The patient's psychiatrist of reference offered the use of the ReMindCare app to every outpatient from the FEPP who met the criteria for inclusion. Once patients enrolled in the study, they were encouraged to use the app as long as they remained in the program (maximum period of 5 years). To use the app, all patients signed an informed consent form and completed baseline assessments.

Eligibility Criteria

To be considered for this intervention, patients met the following criteria: (1) diagnosis of psychotic disorder following DSM-5 (*Diagnostic and Statistical Manual of Mental Disorders, 5th Edition*) criteria, interview conducted by a licensed clinician,

(2) aged between 17 and 65 years, (3) smartphone ownership with an internet connection that allows for the proper installation and functioning of the app, and (4) less than 5 years of illness duration. However, it must be stated that some patients remained in the program for more than 5 years. These patients remained in the FEPP to prevent potential relapses, as they experienced severe fluctuations in their symptoms.

Criteria for exclusion were (1) lack of ability to use and master a mobile device and the internet, (2) refusal to sign an informed consent form, and (3) level of Spanish or English not fluent enough to maintain a conversation or understand the app questionnaires.

Intervention

ReMindCare App

ReMindCare is a free and user-friendly app that conducts daily evaluations of the health status of patients with early psychosis by offering quick questionnaires (Figure 1).

Two types of questionnaires were included:

- Daily questionnaires: 3 daily questions assessing levels of anxiety, sadness, and irritability (Figure 2)
- Weekly questionnaires: 18 weekly questions aimed at assessing adherence to medication (1), the presence of side effects from antipsychotic medication intake (5), the attitude toward medication intake (3), and the presence of prodromal psychosis symptoms (9)

Figure 1. Screenshot of the ReMindCare app home screen.

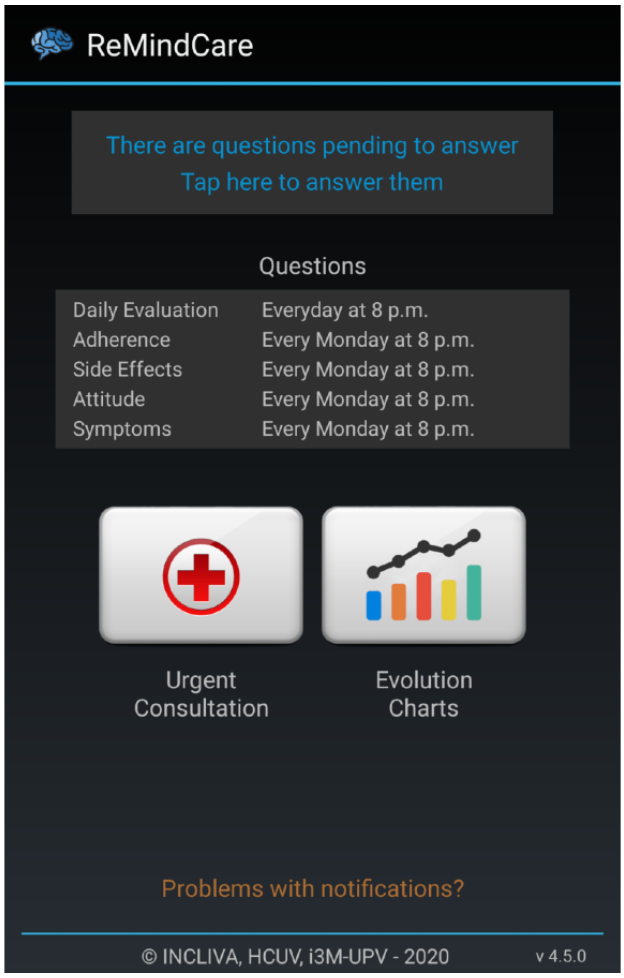
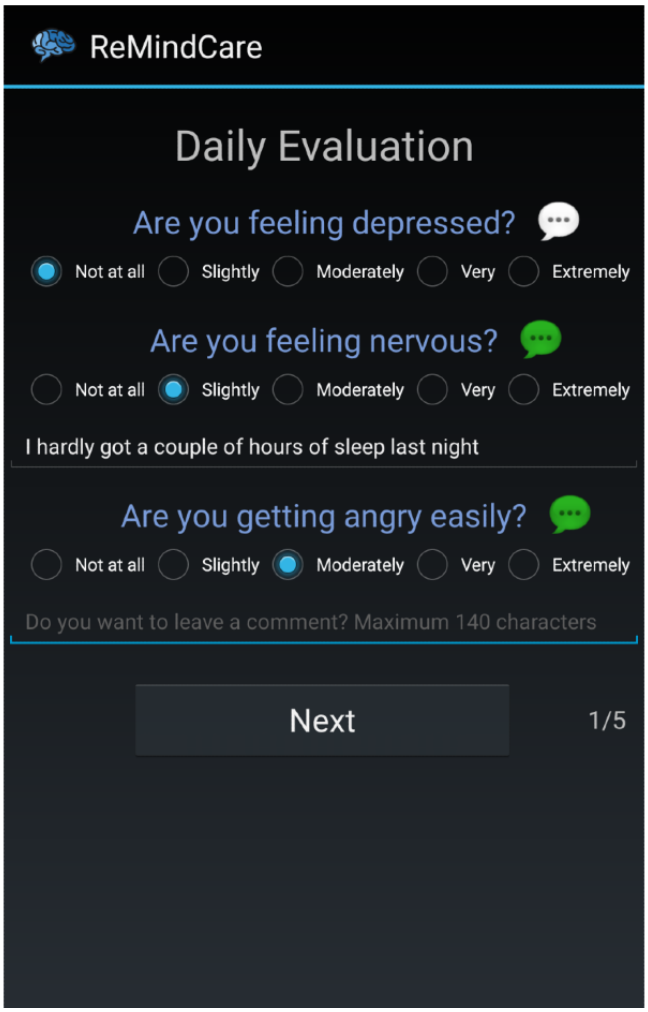


Figure 2. Screenshot of the ReMindCare daily questionnaire.



In addition, the app offered preset alerts in case of low engagement or abrupt changes in survey responses. Low engagement alerts were set off if patients did not respond to the surveys for 7 days or more, while abrupt changes were considered when there was a difference of 2 points (Likert scale 1 to 5) or more between each question in the last 2 surveys answered. These alerts notified physicians by email and were also displayed in the profile of the patient on the app's website portal.

All data captured by the app were accessible for physicians on a password-protected dashboard. Moreover, physicians could download a summary pdf of these data from the dashboard and attach it to the electronic clinical record of the patient in the hospital database.

The app is available in 3 languages (Spanish, English, and Catalán), although we are open to developing new language versions of the app. Our aim is to extend the use of the app to other countries, and adaptation of the app to different languages would be necessary to ensure patient engagement. Further information about the design process of the app and its characteristics can be found in the ReMindCare app study protocol [27].

Patients who used the app (ReMindCare group) did not experience any changes in their usual clinical appointments.

Treatment as Usual

The TAU group comprised patients who met the criteria but rejected using the app. In this group of patients, 42% (13/31) were patients with low adherence to treatment, 26% (8/31) did not perceive any benefit from using the app, and 26% (8/31) were suspicious about technology and their privacy. Additionally, 6% (2/31) were included in this group because they only used the app for 2 days. These patients continued with their usual psychiatric treatment at the FEPP and were not adversely affected by their rejection of participation.

Procedure

Once patients enrolled in the FEPP, after an interview with their psychiatrist of reference, they were asked to complete some baseline assessments. Subsequently, they were offered the use of the ReMindCare app. The ReMindCare app was described as an extra tool developed by the FEPP that could help them manage their symptoms and help clinicians better understand their illness evolution. The main characteristics of the app were listed. After receiving this information, patients decided whether they were willing to use the app. If they were not interested, they were placed in the TAU group. If patients were interested, they were informed in more detail by an expert clinician about the installation process, characteristics of the app, and ethics and data privacy information.

Patients could use the ReMindCare app to contact their psychiatrist of reference directly in case of symptoms worsening by using the urgent consultation request tab on the home screen of the app. If they clicked the urgent consultation request, their clinician would contact them by phone within 48 hours (patients who did not use the app could call the department of psychiatry at the hospital and be referred to their psychiatrist or attend an urgent care unit). In addition, clinicians contacted patients by phone in response to preset alarms. As a result of these phone calls and the information that patients provided to the clinician, urgent care visits could be scheduled if necessary. With these services, we aimed to improve the detection of early psychotic symptoms and reduce the visits to urgent care units at the hospital, as these prodromal symptoms will be primarily treated by a phone call or in the outpatient services. If patients did not make an urgent consultation request and no preset alarms were set off, they continued with their scheduled clinical appointments.

Furthermore, the use of the ReMindCare app changed the dynamics of the clinical appointment at the outpatient services. Once patients arrived at the clinical appointment, physicians accessed their profile on the ReMindCare's physician dashboard and used the information provided for patients to guide them through the interview. Clinicians used shared decision making with patients and discussed their responses.

Data Collection and Measures

Baseline

After patients were enrolled in the FEPP, the following data were collected:

- Sociodemographic information: age, gender, country, ethnicity, marital status, education level, employment status, and cohabitation
- Clinical information: antipsychotic medication, injectable medication, length of illness, associated illnesses, suicidal attempts, Clinical Global Impression Severity of Illness scale (CGI-SI) [28], Global Assessment of Functioning (GAF) [29], Positive and Negative Syndrome Scale (PANSS) [30], Premorbid Adjustment Scale (PAS) [31], date discharged from FEPP

Outcome Measures

- Efficacy: number of relapses, number of visits to the hospital urgent care units, and number of hospital admissions in the ReMindCare group compared with the TAU group
- Feasibility: number of patients who agreed to use the app compared with the patients who did not use it (TAU)
- Compliance and engagement: number of times patients answered the questionnaires when presented and number of months using the app, patients dropouts, plus number of urgent consultation requests

Data Analysis

Data were analyzed with the statistical program SPSS Statistics version 22 (IBM Corp). The cohort was divided into two groups: ReMindCare group patients agreed to use the app and used it for at least 1 month; the TAU group patients did not use the app or used it for less than 1 month. To consider that patients in the ReMindCare group had a relapse while using the app, patients had to be actively using the app. Relapses of patients who did not use the app for more than 2 months were not considered as relapses while using the app. Descriptive statistics (mean, standard deviation, frequency, and percentage) were determined, and chi-square test analysis was performed to compare the differences between the ReMindCare group and the TAU group.

Ethics, Data Privacy, and Participant Safety

The ReMindCare app project received approval from the research ethics committee of the faculty of medicine at the University of Valencia and from the research ethics committee of the Sanitary Research Institute of the University Clinic Hospital of Valencia, Spain.

To protect the data sent by patients, communications to the platform were encrypted with a transport layer security certificate from the Generalitat Valenciana and were sent through the https protocol. The hospital infrastructure is protected through a reverse proxy, which enhances security by establishing a single access point to it and hiding all inner infrastructures. Moreover, the integration of the app into the hospital systems was subjected to Organic Law 3/2018: protection of personal data and digital rights guarantee, December 5th, the Spanish organic law adaptation of the General Data Protection Regulation.

Results

Data from 90 patients were analyzed: 59 used or are using the app (ReMindCare group) and 31 did not agree to use the app (TAU group). Characteristics of both groups are displayed in Tables 1 and 2.

Table 1. Sociodemographic data.

Characteristic	Total	RC[a] group	TAU[b]	χ^2 (*P* value)
Age in years, mean (SD)	32.8 (9.4)	32.1 (1.2)	34.3 (1.7)	1.5 (.57)
24 and younger, n (%)	19 (21)	12 (20)	7 (23)	—[c]
25-44, n (%)	58 (64)	40 (68)	18 (58)	—
45 and older, n (%)	13 (14)	7 (12)	6 (19)	—
Gender (male), n (%)	66 (73)	40 (68)	25 (81)	1.7 (.19)
Native country (Spain), n (%)	79 (87)	48 (81)	30 (97)	4.2 (.04)
Race (White), n (%)	83 (91)	51 (86)	31 (100)	4.6 (.33)
Marital status, n (%)	—	—	—	5.2 (.16)
Single	74 (81)	50 (85)	23 (74)	—
Married	11 (12)	5 (9)	6 (19)	—
Other	85 (7)	4 (7)	2 (7)	—
Educational level, n (%)	—	—	—	5.9 (.05)
Primary	2 (2)	0 (0)	2 (7)	—
Secondary	45 (50)	27 (46)	18 (58)	—
College or higher	43 (48)	32 (54)	11 (36)	—
Employment status, n (%)	—	—	—	5.6 (.24)
Employed	29 (32)	16 (27)	13 (42)	—
Student	21 (23)	16 (27)	4 (13)	—
Not employed	38 (42)	25 (42)	13 (42)	—
Unable to work	3 (3)	2 (3)	1 (3)	—
Cohabitation, n (%)	—	—	—	2.3 (.51)
Alone	6 (7)	3 (5)	3 (10)	—
Family_birth	60 (66)	39 (66)	20 (65)	—
Family_own	11 (12)	6 (10)	5 (16)	—
Other	14 (15)	11 (19)	3 (10)	—

[a]RC: ReMindCare.

[b]TAU: treatment as usual.

[c]not applicable.

Table 2. Baseline clinical information.

Characteristics	Total	RC[a] group	TAU[b]	χ^2 (*P* value)
Injectable medication, n (%)	18 (20)	8 (14)	10 (32)	4.4 (.03)
Length of illness in years, mean (SD)	10.5 (2.8)	3.9 (0.4)	5.7 (0.5)	12.3 (.002)
0-1, n (%)	13 (14)	13 (22)	0 (0)	—[c]
2-5, n (%)	43 (48)	30 (51)	13 (42)	—
More than 6, n (%)	34 (38)	16 (27)	18 (58)	—
Associated illnesses, n (%)	29 (32)	18 (31)	11 (36)	0.2 (.63)
Suicidal attempts, n (%)	16 (18)	12 (22)	3 (10)	2.1 (.15)
CGI-SI[d], mean (SD)	4.2 (0.9)	4.1 (0.1)	4.4 (0.1)	2.7 (.26)
Mild (1-3), n (%)	13 (16)	10 (19)	3 (11)	—
Moderate (4-5), n (%)	66 (83)	42 (81)	24 (86)	—
Severe (>5), n (%)	1 (1)	0 (0)	1 (4)	—
GAF[e], mean (SD)	60.7 (10.9)	61.3 (1.7)	59.8 (1.7)	1.3 (.52)
Mild (71-100), n (%)	8 (10)	4 (8)	4 (14)	—
Moderate (51-70), n (%)	51 (65)	35 (69)	16 (57)	—
Severe (<50), n (%)	20 (25)	12 (24)	8 (29)	—
PANSS[f], mean (SD)	65.9 (18.8)	64.5 (2.2)	68.7 (4.6)	52.1 (.28)
Positive	18.4 (6.5)	18.7 (5.8)	18.7 (6.8)	23.9 (.58)
Negative	18.9 (6.9)	15.4 (5.1)	17.9 (9.3)	28.2 (.17)
N5. Difficulty in abstract thinking	2.3 (1.3)	2.0 (0.2)	2.8 (1.5)	12.8 (.03)
N6. Lack of spontaneity and flow conversation	1.7 (1.3)	1.6 (1.1)	1.9 (1.7)	12.9 (.02)
General	32.3 (8.2)	66.1 (14.7)	70.5 (22.2)	32.2 (.41)
G5. Mannerism and posturing	1.1 (0.7)	1.1 (0.4)	1.3 (0.7)	9.9 (.01)
PAS[g], mean (SD)	10.5 (2.8)	10.7 (0.5)	10.14 (0.6)	9.1 (.70)
Relapses_Baseline, n (%)	—	—	—	4.3 (.12)
0	53 (59)	38 (64)	15 (48)	—
1	21 (23)	14 (24)	7 (23)	—
≥2	16 (18)	7 (12)	9 (29)	—
UCU[h] visits_Baseline, n (%)	—	—	—	0.9 (.61)
0	26 (29)	19 (32)	7 (23)	—
1	36 (40)	23 (39)	13 (42)	—
≥2	28 (31)	17 (29)	11 (36)	—
Hospitalizations_Baseline, n (%)	—	—	—	4.6 (.10)
0	19 (21)	16 (27)	3 (10)	—
1	50 (56)	32 (54)	18 (58)	—
≥2	21 (23)	11 (19)	10 (32)	—

[a]RC: ReMindCare.

[b]TAU: treatment as usual.

[c]not applicable.

[d]CGI-SI: Clinical Global Impression Severity of Illness scale

[e]GAF: Global Assessment of Functioning.

[f]PANSS: Positive and Negative Syndrome Scale.

[g]PAS: Premorbid Adjustment Scale.

[h]UCU: urgent care units.

Sociodemographic Analysis

The mean age of the sample was 32.8 (SD 9.4) years, 73% (66/90) were males, 91% (83/90) were White, and 81% (74/90) were single. No significant differences were found between the ReMindCare and TAU groups in any of the sociodemographic information analyzed except for the native country. We found that nearly every immigrant considered for inclusion agreed to use the app (ReMindCare group 19% [10/11], TAU group 3% [1/11]; χ^2=4.2, *P*=.04). Further information regarding sociodemographic analysis of the data is displayed in Table 1.

Baseline Clinical Analysis

Significant differences were found between the ReMindCare group and TAU group in some clinical factors. With regard to injectable medication, 32% (10/31) of TAU patients were taking injectable medication, while only 14% (8/59) of the ReMindCare took it (χ^2=4.4, *P*=.04). Every new patient in the FEPP (length of illness: 0-1 year) agreed to use the app (13/90, 22%), and 58% (18/31) of the TAU group had their illness for 6 or more years (χ^2=12.3, *P*=.002). Moreover, the TAU patients showed higher scores on the PANSS N5 and N6 negative subscales and G5 in the general subscales (χ^2=12.8, *P*=.03; χ^2=12.9, *P*=.02; χ^2=9.9, *P*=.01, respectively).

Considering medication, 20% (18/90) of patients were taking injectable medications, 32% (29/90) of the patients suffered from another illness, and 18% (17/90) had a prior suicidal attempt. The mean of the CGI-SI was 4.2 (SD 0.9), the GAF mean=60.7 (SD 10.9), PANSS mean 65.9 (SD 18.8), and PAS mean 10.5 (SD 2.8). Finally, 12% (11/90) of patients were discharged from the FEPP. No significant differences were found between the groups in any of these factors. Moreover, no significant differences were found between the ReMindCare group and TAU group in terms of the number of relapses (χ^2=4.3, *P*=.12), visits to urgent care units (χ^2=0.9, *P*=.61), or the number of hospitalizations (χ^2=4.6, *P*=.10) at baseline. Further clinical information is available in Table 2.

ReMindCare Outcomes

The mean of days using the app was 352.2 (SD 191.2), which corresponds to 11.6 months. The mean of compliance was 84.5 (16.04), and 61.1% of the ReMindCare group had a compliance rate between 85% and 100%.

Of the 59 ReMindCare patients, 31% (18/59) requested an urgent consultation, 20% (12/59) had a relapse while using the app, and 8% (2/59) developed a delusion involving the app and the research group.

After 19 months of intervention, 63% (37/59) of patients continued using the app, while 12% (7/59) stopped using the app because they were discharged from the FEPP and 25% (15/59) opted to stop using ReMindCare. Reasons for discontinuation: 33% (5/15) of patients felt suspicious about technology (among these patients, 4 had a relapse while using the app); 40% (6/15) perceived the app as boring and did not perceive any benefit; and 27% (4/15) of patients left treatment and did not continue in the program. This information is shown in Table 3.

Table 3. Use of ReMindCare.

Characteristic	RC[a] group (n=59)	Min-max
Days using app, mean (SD)	352.2 (191.2)	18-594
Months using app, mean (SD)	11.6 (6.5)	0-19
Engagement, mean (SD)	84.5 (16.0)	42-100
85%-100%, n (%)	36 (61)	—[b]
UCU[c], n (%)	18 (31)	—
Relapses using app, n (%)	12 (20)	—
Relapses related to app, n (%)	2 (8)	—
Status of use after 19 months, n (%)		
Patients using app	37 (63)	—
Patients not using app	22 (37)	—
Discharged from FEPP[d]	7 (32)	—
Dropouts	15 (68)	—

[a]RC: ReMindCare.

[b]not applicable.

[c]UCU: urgent care units.

[d]FEPP: first episode of psychosis program.

With regard to the clinical outcomes, after 19 months of ReMindCare's integration into the clinical workflow, only 20% (12/59) of patients from the ReMindCare group had a relapse, while 58% (18/31) of TAU patients had one or more relapses (χ^2=13.7, *P*=.001). Moreover, ReMindCare patients had fewer visits to urgent care units (χ^2=7.4, *P*=.006) and fewer hospitalizations than TAU patients (χ^2=4.6, *P*=.03). Information regarding these clinical outcomes is displayed in Table 4.

Table 4. Clinical outcomes after 19 months of the ReMindCare intervention.

Characteristic	Total, n (%)	RC[a] group, n (%)	TAU[b], n (%)	χ^2 (*P* value)
Relapses	—[c]	—	—	13.7 (.001)
0	60 (67)	47 (80)	13 (42)	—
1	29 (32)	12 (20)	17 (55)	—
≥2	1 (1)	0 (0)	1 (3)	—
UCU[d] visits	20 (22)	8 (14)	12 (39)	7.4 (.006)
Hospitalizations	9 (10)	3 (5)	6 (19)	4.6 (.03)

[a]RC: ReMindCare.

[b]TAU: treatment as usual.

[c]not applicable.

[d]UCU: urgent care units.

Discussion

Principal Findings

The results obtained from these analyses of the first 19 months of ReMindCare use highlight the potential benefits of this eHealth intervention for patients with early psychosis. Patients who used the app not only had fewer relapses than the TAU group, but they also had fewer visits to the urgent care unit and fewer hospitalizations.

Results related to the efficacy of the app are in line with previous results obtained in clinical trials [14-16]. However, as far as we know, this is the first study to identify the benefits of the use of an app as a tool systematically integrated into daily clinical practice in a FEPP.

With regard to the feasibility of the app, no significant differences were found between the ReMindCare group and the TAU group in terms of sociodemographic characteristics except for native country. The feasibility of this intervention aligns with the results obtained in our previous study [8], where we found no differences in terms of sociodemographic characteristics and interest in using eHealth interventions.

With regard to the clinical characteristics of the samples and their impact on the effect of ReMindCare, there were some differences between groups. We found that patients who did not use the app were more likely to be taking injectable medication, have a longer history of illness, and have higher scores on the PANSS N5 and N6 negative subscales and G5 in the general subscales. These results might suggest that the use of ReMindCare was not indicated for chronic patients. However, we did not find differences in other clinical scales such as the CGI-SI, GAF, and PAS scales or even on the PANSS total scale. More importantly, we did not find any differences between groups in terms of baseline relapses, hospitalizations, or visits to urgent care units.

These results are in line with the ones we obtained in our previous study [8], where we found that interest in using eHealth apps was equivalent between chronic and early psychosis patients. In this regard, we suggest that differences obtained in terms of the clinical characteristics of the patients could be more related to the history of treatment than to clinical characteristics. As we found, every new patient who joined the FEPP (length of illness less than 1 year) was interested in using the app (22% of users), while patients who had a longer history of treatment (length of illness more than 6 years) were more likely to reject its use (58% of TAU group). This could highlight the relevance of introducing these new technologies at the very beginning of treatment so early psychosis patients consider these apps to be just another tool included in their daily clinical treatment and not an extra service, especially since our results suggested that use of the app had a significant impact in improving the course of the illness.

Finally, with regard to compliance and engagement with the app, we found that 61% of patients had compliance rates between 85% to 100%. Rates of engagement were also high, as 63% of patients still use the app after almost 1 year. These results of compliance and long-term engagement are contrary to previous studies [20,21] and suggest that the use of an app in a long-term approach is feasible and beneficial.

However, we would like to highlight that 20% of patients had a relapse while using the app and 8% developed a delusion involving the use of the app and the research group. These negative results should be cautiously considered.

Technology could be a major resource to improve the quality of treatments, but as we found in a previous study [8], it can also play an important role as a trigger for psychotic symptoms. In this regard, in a 3-case study in 2011 conducted by Nitzan et al [32], they stated that the use of the internet and computers might contribute to a gradual break with reality and development of psychotic symptoms. They suggested that given that patients

with psychotic diagnoses have greater difficulties in filtering and understanding signals and symbols, they are also more likely to misinterpret digital messages. However, no specific studies regarding the potential harms of the use of new technologies have been undertaken until the present.

In our study, we found that the ReMindCare app was related to beneficial clinical effects for the vast majority of patients who used it. However, despite the general positive effects found in this study, there are still some barriers and negative effects that must be taken into consideration. The main barrier found in our study relates to the 34% of the approached patients who did not want to use the app and who also tended to be the more chronic patients. Moreover, the main negative effect we found related to the 8% of patients who developed a delusion involving the app. As a result, we would like to point out that this app is not a panacea to prevent relapses. However, it is clear that the app positively affected the course of the illness, as only 5% of those who relapsed required hospitalization compared with 19% of patients who relapsed in the TAU group.

Limitations and Strengths

There were some limitations that must be taken into consideration. First, not every outpatient from the FEPP was eligible for inclusion, as some patients did not have their own smartphone with an internet connection or did not have the ability to use the app or understand it due to language barriers. Developing strategies to prevent digital exclusion should be a priority to ensure that every patient could benefit from these technologies [33]. Second, as a real-world study, this study was not randomized. Despite the groups not differing in the vast majority of clinical or demographic characteristics, there were some factors such as personality that could influence our results.

The main strength of our study was the fact that ReMindCare is the first app that has been systematically integrated into the clinical FEPP workflow. To our knowledge, there are no previous studies that used an app as a tool to improve the daily treatment of patients with early psychosis. All the studies we found were conducted in academic research settings that did not emulate real-world environments [17,34].

Another strength is in regard to the development of the ReMindCare app. First, it was based on two previous studies [2,8] and co-designed with patients [27]. Second, we conducted a pilot study and focus groups to ensure the involvement of both patients and care providers [27] in the design and improvement process of the app.

Finally, we would like to highlight the long-term approach of this intervention. As stated before, ReMindCare is now integrated into clinical practice and it was used for 19 months. These results align with previous studies [16] that found that people with psychosis have the abilities and interest required to engage in long-term eHealth interventions.

Implications for the Future

As a result of these analyses, we highlighted the benefits that the use of ReMindCare app produced on early psychosis patients in a FEPP. Our aim is to continue improving the app in response to the needs and suggestions provided by patients and clinicians. As Ross et al [22] claimed in their meta-review, in order to ensure the use of these eHealth technologies over time, there are three challenges that should be overcome. First, the apps must be able to adapt to the characteristics of the environment and patients. Second, the apps should be easy to use. Third, the apps should be integrated into clinical practice, adjusting the characteristics of the app in order to ensure it is user-friendly and efficient for patients and clinicians. It is our aim to address these issues to maintain the positive results obtained in this study.

However, we would like to point out a major issue that must guide future eHealth interventions. As stated before, 8% of patients developed a delusion related to the use of the app, 25% of patients deliberately stopped using the app, and 34% of patients approached did not want to use the app in the first place. These results suggest that there are still significant numbers of patients not willing to use eHealth interventions, and there are some patients who could be adversely affected by the use of these technologies. Studying the characteristics of these patients should guide future research in order to ensure that the use of digital technologies only provides benefits to the patients [8].

Finally, we would like to underline that given the exceptional situation that the world is facing at the moment with COVID-19 and in order to address the requirements of interventions that could improve the telematic treatment of patients and prevention of hospital collapses [4,35], ReMindCare could be used as an effective and efficient tool. Since quarantining in Spain began March 13, 2020, patients have not been permitted to come in person to their clinical appointments and have received their clinical evaluations by phone. Since that moment, the use of ReMindCare has been extremely useful to improve the evaluation and adherence of early psychosis patients. However, future analysis will be conducted in regard to this aspect.

As the conclusion of this study, we would like to point out that, to the best of our knowledge, ReMindCare is not only the first app to be integrated into the clinical practice, it is the first eHealth intervention with evidence that it improves the outcomes of early psychosis patients in a real-world care setting.

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Authors' Contributions

LB and JS recruited and evaluated the patients. JS treated the patients, and LB supervised the app performance and the patients' responses and alarms. DA and IB developed the app and supervised its functioning, and they also drafted and discussed the paper. LB wrote the paper and analyzed the data. JS designed and supervised the project. JS and JT reviewed the data and supervised the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CGI-SI: Clinical Global Impression Scale-Severity Illness
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
EMA: ecological momentary assessment
FEPP: first episode of psychosis program
GAF: Global Assessment of Functioning
PANSS: Positive and Negative Syndrome Scale
PAS: Premorbid Adjustment Scale
TAU: treatment as usual

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c. *Resultados clínicos comparativos entre los pacientes usuarios de la app y los no usuarios durante los meses de pandemia (Marzo 2020- Marzo 2021):*

Finalmente, en los últimos meses del presente trabajo, se realizó un estudio en el que se analizaron los efectos del primer año de pandemia y confinamiento por el COVID-19, sobre la salud mental de los pacientes y como esto, podía estar mediado por el uso de la aplicación ReMindCare.

Para ello, se compararon diferentes variables clínicas entre los meses de Marzo 2019 a Febrero 2020 y los meses de Marzo 2020 a Febrero 2021, meses correspondientes al inicio y transcurso de la pandemia.

Como resultado de este análisis, se observó un aumento del 26.6% (X^2=6.29, *P*=0.012) en el número de pacientes en seguimiento en la unidad, así como, un incremento del 107.14% (X^2=4.10, *P*=0.04) en la incidencia de nuevos pacientes. No obstante, al comparar las dos franjas temporales, no se observaron diferencias significativas a nivel de recaídas (X^2=1.67, *P*=0.19) o rehospitalizaciones (X^2=0.32, *P*=0.57) en los pacientes ya en seguimiento por la unidad.

En cuanto al uso de ReMindCare, 53 pacientes hicieron uso de la app durante el periodo comprendido entre los meses de Marzo 2020 y Febrero de 2021. Estos pacientes presentaron un menor número de recaídas (X^2=5.46, *P*=0.019) y hospitalizaciones (X^2=5.63, *P*=0.018) que los que siguieron el tratamiento normativo.

Estos datos, pueden ser consultados en el **Apéndice VII.**

6. DISCUSIÓN:

Como se expuso en la introducción y objetivos de la tesis, ReMindCare es una aplicación diseñada con el fin de constituir una herramienta útil en la práctica clínica que mejore la atención sanitaria de los pacientes en las unidades de primeros episodios psicóticos. Se trata de una intervención que no solo ha obtenido altas tasas de adherencia a largo plazo, sino que ha mostrado sus beneficios en la reducción de recaídas, hospitalizaciones y visitas a urgencias, incluso durante el periodo de cuarentena impuesto por la pandemia del Covid-19.

Como ya se comentaba al inicio del texto, tras el inminente e imprevisible cambio en nuestra cotidianidad que ha impuesto la pandemia, han sido muchos los estudios que han señalado el efecto negativo que esta excepcional situación ha producido y está produciendo en la salud mental de los pacientes con psicosis (Rodríguez et al., 2020; García-Álvarez et al., 2020). Sólo en nuestra unidad, hemos visto incrementado el número de pacientes en seguimiento un 26.6% desde que empezó la pandemia en el mes de Marzo de 2020 con respecto al año anterior, y hemos observado un aumento de la incidencia del 107.14% con respecto al año previo. Este hecho subraya, la ya aclamada necesidad, de potenciar el acceso de los pacientes a los servicios de salud mental, así como de aumentar su flexibilidad y adaptación a las nuevas necesidades (Donogue et al., 2020; Galea et al., 2020). Es por ello, que los efectos clínicos obtenidos por los usuarios de la app frente a los no usuarios durante este último año son significativamente relevantes. Y proporcionan apoyo a los diferentes autores que ven en las intervenciones *mHealth* una forma eficaz y eficiente de paliar los efectos perniciosos de la pandemia (Donogue et al., 2020; Torous et al., 2020).

Estos beneficios clínicos obtenidos por el uso de la aplicación, están en línea con los resultados obtenidos en numerosos estudios previos. Intervenciones como *Express app* (Eisner et al., 2019) o *Actissist Intervention* (Bucci et al., 2018) han mostrado la validez de los registros mediante dispositivos móviles a la hora de evaluar el estado clínico del paciente, y a su vez, han encontrado potenciales beneficios en cuanto a la reducción de sintomatología psicótica. Por otra parte, intervenciones como *FOCUS* (Ben-zeev et al., 2019) o *Clintouch app* (Lewis et al., 2020) ambas con una duración de doce semanas, consiguieron ya no solo mejorar el estado clínico de los pacientes, sino que obtuvieron altas tasas de cumplimentación de los registros durante el periodo de intervención. No obstante, cabe destacar que todas estas intervenciones proporcionaban recompensas económicas a los participantes tanto por hacer uso de los aplicativos, como por cada cuestionario completado.

Es por ello que el aspecto más destacable de nuestro estudio no hace referencia a la aplicación en sí misma, sino a la metodología que la acompaña.

En primer lugar, ReMindCare fue desarrollada en base a dos estudios previos (Bonet et al. 2017-2018 (a)) con el fin de garantizar que este aplicativo se ajustara a las demandas de los usuarios. Además, tras 12 meses de intervención, se realizaron dos grupos focales y se administró un cuestionario de feedback a 28 pacientes, (cuyos datos están pendientes de publicación, pero pueden consultarse en el **APÉNDICE VIII**). En estos estudios, se obtuvieron altas tasas de satisfacción con el aplicativo (96,4%, 27/28) y el 100% de los pacientes afirmó que lo recomendaría a otros pacientes. Es por ello, que frente a intervenciones previas, en el desarrollo de ReMindCare ha sido fundamental el contar con el punto de vista del paciente, para ya no solo mejorar el aplicativo, sino para responder a las necesidades de los usuarios. Puesto que como diferentes estudios señalan, el implicar a los pacientes en el desarrollo de los dispositivos, resulta fundamental para garantizar el éxito de las intervenciones (Batra et al., 2017; Granja et al., 2018).

Otra característica distintiva de ReMindCare, hace referencia a la perspectiva de uso a largo plazo con la que fue diseñada. Y es que, pese a la gran cantidad de apps disponibles en la actualidad, la gran mayoría son diseñadas para llevar a cabo estudios experimentales cuya duración varía entre las dos horas y el año, siendo muy pocas las que exceden este periodo de tiempo (Camacho et al., 2019; Miralles et al., 2020).

No obstante, la característica más innovadora de este aplicativo, hace referencia a su integración sistemática en la práctica clínica diaria. Y es que, pese a que recientemente se han publicado diferentes protocolos de intervenciones *eHealth* para pacientes con psicosis que buscan ser integradas en la práctica clínica, tales como el *Momentum Trial en Dinamarca* (Vitger et al., 2019), la aplicación *App4Independence* (A4i) en Canadá (Kidd et al., 2019) o el programa multidisciplinar *HORYZONS* en Australia (Álvarez-Jiménez et al., 2019), no hemos podido encontrar datos de ninguna intervención que haya sido sistemáticamente implementada en la práctica clínica y que haya sido testeada durante un periodo superior a los 28 meses. Este aspecto resulta fundamental, ya que como diferentes estudios han señalado, el éxito de las intervenciones de tipo *eHealth* solo puede garantizarse en la medida que estas intervenciones se integren de forma efectiva en la práctica clínica (Granja et al., 2018; Vukovik et al., 2018).

Esta integración en la práctica clínica, que la diferencia del resto de intervenciones previas, se refleja en tres aspectos fundamentales:

En primer lugar, se trata de una aplicación que permite la incorporación de informes pdf a la historia clínica electrónica, característica que no hemos encontrado en ningún estudio previo (Bonet et al., 2017), y que permite a todos los clínicos implicados en el tratamiento del paciente, acceder a estos informes.

En segundo lugar, puesto a que se trata de una aplicación desarrollada con el fin de ser utilizada en un contexto real, ningún paciente fue recompensado económicamente ni por hacer uso de la app ni por permanecer en el estudio. Este aspecto hace que, frente a las intervenciones de mayor relevancia actual (Ben-zeev et al., 2019; Bucci et al., 2018; Eisner et al., 2019; Lewis et al., 2020), las altas tasas cumplimentación de los registros y de compromiso de uso a largo plazo obtenidas con ReMindCare, resulten más válidas que las obtenidas en estudios previos.

Y en tercer lugar, la integración clínica permite que los datos recogidos por la app sean usados tanto para mejorar la evaluación del paciente y la detección de posibles empeoramientos clínicos, como para dirigir la entrevista con el paciente y trabajar de forma colaborativa en consulta. Como diferentes estudios han señalado, la eficacia de las intervenciones *mHealth* aumenta cuando se acompaña de feedback personalizado (Hassen et al., 2019; Linardon et al., 2019). Esta característica ha supuesto un cambio radical en la dinámica de la entrevista y la atención del paciente, y busca no sólo mejorar la adherencia del paciente sino mejorar la eficiencia y eficacia del tratamiento que recibe (Bonet et al. 2020 (a)).

Como se indicaba al principio de este escrito, intervenciones orientadas a la mejora de la detección precoz de la psicosis y la mejora del tratamiento que estos pacientes reciben, debe ser una prioridad (Arango et al., 2018; Pelayo-Terán et al., 2018; MSCBS, 2019). Y en este sentido, consideramos que ReMindCare puede ser una buena herramienta que ayude a alcanzar estos objetivos. Porque ya no solo ha obtenido altas tasas de adherencia tanto en lo referente al uso a largo plazo de la app, como en la implicación de los pacientes en sus respuestas, sino que cuando comparamos la evolución clínica de los pacientes usuarios de la aplicación frente a los que no, se han observado importantes beneficios que refuerzan su uso.

7. LIMITACIONES E IMPLICACIONES PARA EL FUTURO:

7.1. Limitaciones

La principal limitación con la que contamos en nuestro estudio, hace referencia al hecho de que no todos los pacientes de la unidad hicieron uso de la app. Por una parte, porcentajes próximos al 16% no pudieron hacer uso de la aplicación puesto que no disponían de un dispositivo de tipo smartphone propio y con acceso a internet, porque presentaban barreras de lenguaje o porque disponían de sistemas iOS, para los cuáles aún estamos pendientes de finalizar la versión compatible.
Por otra parte, existe un porcentaje de pacientes, que en este estudio los hemos considerado como el grupo TAU, que rechazaron el uso de la app sin que existieran barreras que lo justificaran. Como se muestra en el apartado de análisis de datos, se trata de un grupo de pacientes, en ocasiones, con una mayor gravedad psicopatológica, la cual se ha relacionado con un peor ajuste funcional a largo plazo (Tabares-Seisdedos et al., 2008). Esto provoca que, quizá siendo los pacientes que mayor beneficio podrían obtener del uso de la app, al no acceder a su uso, no puedan beneficiarse de las potenciales mejoras observadas en aquellos que sí que la utilizan (Bonet et al., 2020 (c)).

En segundo lugar, otra limitación a tener en cuenta se refiere a la propia naturaleza del estudio, que impide el control absoluto de las variables implicadas en los resultados. Se trata de un estudio naturalístico en el que no se pudo realizar ni asignación aleatoria de los pacientes ni se pudieron llevar a cabo otros procedimientos de control característicos de los ensayos clínicos. No obstante, al comparar las características clínicas y demográficas de los pacientes usuarios y no usuario de la app no obtuvimos grandes diferencias significativas entre ambos grupos (Bonet et al., 2020 (c)). Aun así, podrían existir determinadas variables de personalidad o relacionadas con el vínculo terapéutico entre paciente y clínico o a la percepción del propio paciente a cerca de la enfermedad, que podrían estar influyendo en los resultados obtenidos.

7.2. Implicaciones para el futuro

En base a lo expuesto anteriormente, queremos señalar las principales direcciones que deben guiar la investigación futura.

En primer lugar, dado el creciente uso de las nuevas tecnologías en el ámbito de la atención al paciente de salud mental (Miralles et al., 2020) cuyo uso está siendo aún más promovido desde que la pandemia comenzó (Torous et al., 2020; Wang et al., 2020), resulta imprescindible realizar estudios que garanticen, ya no solo un acceso global de todos los pacientes a estos servicios, sino que aseguren la seguridad de los mismos. Puesto que no podemos olvidar, ese porcentaje próximo al 40% de pacientes que afirmaron haber padecido experiencias negativas vinculadas al uso de internet o ese 30% que afirmaron haber padecido recaídas directamente relacionadas con su uso (Bonet et al., 2018 (a)).

Por otra parte, si bien el uso de nuestro aplicativo resulto mayoritariamente beneficioso, el 8% de los usuarios de ReMindCare desarrollaron un delirio directamente relacionado con su uso (Bonet et al., 2020 (c)). Resulta fundamental, por lo tanto, realizar estudios que ayuden a identificar que pacientes pueden beneficiarse de estos servicios y potenciar su acceso a los mismos, así como identificar qué características del paciente pueden afectar de forma negativa a su salud y prevenir así los posibles efectos negativos que puedan surgir (Botella et al., 2009; Greer et al., 2019).

En segundo lugar, es imprescindible seguir realizando avances en la actualización del software del dispositivo y en sus características, con el fin de asegurar en cada momento, su correcto funcionamiento y su adaptación a las demandas y necesidades de pacientes y clínicos (Batra et al., 2017; Granja et al., 2018).

Además, también estamos explorando la posibilidad de utilizar técnicas de machine learning con las que analizar los datos de los pacientes y poder elaborar algoritmos de predicción, como ya empiezan a hacer en algunos estudios (Pérez-Arribas et al., 2018; Rozet et al., 2019). Para ello, estamos trabajando en colaboración con el Instituto de Instrumentación para la imagen molecular (i3M) de la Universidad Politécnica de Valencia y la profesora y especialista María José Castro Bleda de la Universidad Politécnica de Valencia.

Finalmente, y en base a los beneficiosos resultados obtenidos en nuestras últimas publicaciones (Bonet et al., 2020 (c)-2021) y a la creciente demanda de intervenciones mHealth impuesta por la pandemia (Kannarkat et al., 2020; Torous et al., 2020; Wang et al., 2020) nos gustaría extender la implementación de ReMindCare en otras unidades PEP tanto a nivel nacional como internacional.

En la actualidad, estamos pendientes de tres líneas de expansión en este sentido: En primer lugar, estamos trabajando desde el 2019 con la unidad PEP del Hospital de Basurto en el

País Vasco, donde la implementación definitiva de ReMindCare en la práctica clínica, se llevará a cabo entre los meses de Abril y Mayo de 2021.

Por otra parte, estamos trabajando en colaboración con el Doctor John Torous, director de la división de psiquiatría digital del *Instituto Beth Israel Deaconess de la Facultad de Medicina de Harvard*, cuyo asesoramiento a lo largo del proceso de difusión de la aplicación ha sido fundamental y con el que esperamos desarrollar posibles colaboraciones en el futuro.

Finalmente, recientemente hemos establecido comunicación con la empresa *ALFATEC*, dedicada a la consultoría, desarrollo y mantenimiento de sistemas informáticos en entornos sanitarios. En la actualidad, se está valorando la posibilidad de, a partir de un proyecto piloto potencialmente co-financiado por alguna convocatoria competitiva, extender el uso de ReMindCare a diferentes consejerías y ministerios de salud de Latino América.

No obstante, es importante destacar que para poder garantizar los beneficiosos resultados que hemos obtenido en la unidad PEP, resulta imprescindible prevenir el mal uso de la app y disponer de un personal formado y que pueda proporcionar el feedback adecuado a las respuestas de los pacientes, puesto que como hemos visto, este feedback resulta fundamental para garantizar el adecuado compromiso de los pacientes a largo plazo (Hassen et al., 2019; Linardon et al., 2019).

A nuestro parecer, siempre y cuando se garantice una adecuada integración de la app en los servicios hospitalarios y una adecuada implicación tanto por parte de clínicos y pacientes, se trata de una intervención altamente novedosa que verdaderamente puede suponer ese salto tan demandado en el ámbito *eHealth,* que permita unir la investigación experimental con la mejora de la práctica clínica.

8. CONCLUSIONES

Las principales conclusiones de esta tesis se exponen a continuación:

1. Existen múltiples intervenciones *mHealth* con potenciales beneficios expuestos a nivel experimental, pero no existe evidencia que replique estos resultados en la práctica clínica diaria.

2. Globalmente, el acceso y uso de internet y dispositivos móviles de los pacientes con psicosis es equivalente al observado en la población general.

3. El uso de internet puede impactar de forma negativa en la salud mental de los pacientes con psicosis y precipitar nuevos episodios.

4. Los pacientes con psicosis se muestran interesados en los sistemas *mHealth*, sobre todo en servicios que puedan aumentar la rapidez de comunicación con el clínico.

5. ReMindCare es la primera app para pacientes con psicosis sistemáticamente implementada en la práctica clínica diaria e integrada en la historia clínica electrónica. Concretamente en la *Unidad de Primeros Episodios Psicóticos del Hospital Clínico Universitario de Valencia*.

6. Los pacientes usuarios de la aplicación ReMindCare frente a los pacientes que deciden no utilizar el dispositivo, presentan un menor número de recaídas (X^2=13.7, *P*=0.001), hospitalizaciones (X^2=4.6, *P*=0.03) y visitas a urgencias (X^2=7.4, *P*=0.006).

7. Los usuarios de ReMindCare muestran una tasa media de cumplimentación de los registros del 84.5% (SD=16.0) y la media de meses utilizando la app fue de 11.6 (SD=6-5; min/max: 0-19).

8. La pandemia por COVID-19 ha aumentado un 26.6% (X^2=6.29, *P*=0.012) la incidencia de pacientes en la *Unidad de Primeros Episodios Psicóticos* del *Hospital Clínico Universitario de Valencia*. Y los usuarios de ReMindCare, han mostrado una mejor evolución clínica que los no usuarios durante este periodo de pandemia, con menor un menor número de recaídas (X^2=5.46, *P*=0.019) y hospitalizaciones (X^2=5.63, *P*=0.018).

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10. APÉNDICES

APÉNDICE I

Bonet L, Llacer B, Hernandez M, Arce D, Blanquer I, Cañete C et al. S249. Is internet harmful for psychotic patients? *Schizophr Bull*. 2018;44(Suppl 1):S424.

in the general population. Furthermore, other findings support the role of childhood trauma as a socio-environmental risk factor for psychotic symptoms, and research on the potential etiological relationship between trauma/stressful events in childhood/adolescence and psychotic disorders is evolving. The aim of the current study was to examine relations among all items and domains of childhood trauma and schizophrenic symptoms in patients with schizophrenia. The relationship between types of trauma and their association with psychotic symptoms was analysed.

Methods: In this study, we collected data from 50 schizophrenic patients (39 males and 11 females). All patients met the DSM 5 criteria for schizophrenia. Psychotic symptoms were measured by the Positive and Negative Syndrome Scale (PANSS). Trauma and stressful events in childhood and adolescence were assessed using the Childhood Trauma Questionnaire (CTQ).

Results: We found significant correlations between emotional and sexual abuse, emotional neglect and denial scale in CTQ with positive symptoms of the PANSS ($p<0,05$).

Meanwhile, no correlations were found between CTQ domains neither with negative symptoms nor with general psychopathology scale of the PANSS.

Discussion: This study showed that childhood trauma could be a predictor factor for developing positive symptoms in schizophrenia. Most studies found similar results, showing a correlation between childhood trauma and hallucinations in schizophrenia. A correlation between childhood trauma and agressive behaviours was also described in litterature. These results went along with the stress sensitization model where the HPA axis is overactive and excessively reactive to the subsequent environemental stressors causing positive symptoms of the disease.

S249. IS INTERNET HARMFUL FOR PSYCHOTIC PATIENTS?

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Background: Developments in electronic health (e-Health) interventions for psychotic patients have been possible since the growing access and use of internet and electronic devices in past 10 years (Bonet et al. 2017). However, before proceeding further on develop these interventions; limited knowledge exists about the impact of internet and new technologies on the mental health of these psychotic patients. The aim of this study is to assess the benefits and risks of new technologies usage in a survey of patients diagnosed with psychotic disorders. We analyzed the relationship between experiences and opinions about internet and demographic and clinical characteristics of the sample and patterns of use of these technologies.

Methods: Structured questionnaire was designed. This questionnaire was divided in three parts: 1) clinical and demographic information, 2) access and use of technologies, and 3) experiences and opinions about internet. In total, 97 patients diagnosed with psychotic disorder participated in this cross-sectional study. Mean age of the sample was 37.06 (SD=12.9), 72.2% of participants were male, 84.5% were single and 60.8% had achieved secondary education. Main diagnoses in the sample were First Episode of Psychosis (45.4%) and Schizophrenia (34%) and 64.9% of patients had a length of illness lower than 72 months

Results: The percentage of patients who daily acceded to internet was 63.9% while 21.6% weekly acceded. 90.7% of participants owned a mobile phone and 68% had a social media account. Related to feelings about internet, 60.8% of patients felt socially linked due to internet usage and 78.4% felt informed. However, 22.7% felt frustrated and 19.6% felt suspicious. Internet was considered as a benefit for mental health for 46.4% of patients, while 38.1% have had unpleasant experiences related to its usage, 24.7% have had internet-related relapses and 26.8% expended excessive time online. Significant association was found between feeling informed and frequency of access to internet ($\chi2= 6.17$ $p=0.05$), however any other significant association was found between feelings about internet and clinical or demographic characteristics or patterns of use of technology. According to experiences, significant associations were found between internet-related relapses and length of illness ($\chi2= 4.74$ $p=0.03$), frequency of internet access ($\chi2= 9.76$ $p<0.01$) and social media ownership ($\chi2= 5.55$ $p=0.02$). Expending excessive time on internet was found significant associated to age of the sample ($\chi2= 6.57$ $p=0.04$), employment status ($\chi2= 10.73$ $p=0.03$), frequency of access to internet ($\chi2= 10.15$ $p<0.01$) and social media ownership ($\chi2= 9.62$ $p<0.01$). Association between stop taking medication because of information read on the internet and level of education was also found ($\chi2= 9.03$ $p=0.01$).

Discussion: Despite the general positive feelings about internet usage, percentages between 38-19% of patients had a negative vision of internet. Furthermore, frequency of access to internet and social media ownership have been found associated to internet-related relapses and potential pathological use of internet (excessive time on it). Younger patients, recent diagnosis of psychosis and being in a non-active employment situation seem to be related to these pathological results too. To our knowledge, this is the first study to describe the potential risks about internet usage in patients diagnosed with psychotic disorders, however further studies are needed.

Reference:

1. Bonet L, et al Use of mobile technologies in patients with psychosis: A systematic review. Rev Psiquiatr Salud Ment. 2017; 10 (3): 168–178

S250. RELATION BETWEEN PSYCHOPATHOLOGY AND QUALITY OF LIFE IN SCHIZOPHRENIA PATIENTS BEFORE AND AFTER FIRST ANTIPSYCHOTIC TREATMENT

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Background: It is common knowledge that antipsychotic treatment improves the symptomatology in schizophrenia, especially for the psychotic and general symptoms. It is also a fact that patients with schizophrenia often report a reduced quality of life compared to healthy controls. In this study we aim at examining the relation between self-reported quality of life (QLS), psychopathological symptoms and level of function before and after antipsychotic treatment. We hypothesize that there will be a correlation between QLS and severity of symptoms before treatment. Further we expect an improvement in QLS after treatment and that this improvement will correlate with improvement in symptomatology.

Methods: As a part of a large multimodal study on antipsychotic naïve patients with schizophrenia, 69 patients were recruited. Their psychopathology was measured with the Positive and Negative Syndrome Scale (PANSS), level of function was estimated using Global Assessment of Function (GAF), and QLS was reported by answering a questionnaire. Patients were treated with individual doses of Amisulpride for six weeks, after which they were reexamined.

The questionnaire regarding QLS counts 21 questions, divided into four domains: Self and present life (i.e. "how satisfied are you with your present life"), social relations ("how satisfied are you with your current social life"), Living situation ("how much do you like the place you live") and Work situation ("How satisfied are you with the work you do"). Higher scores indicate higher satisfaction within the domain. Since the follow up period was only 6 weeks, we focused on self and present life (SPL) and

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Is internet harmful for patients with psychosis?

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INTRODUCTION:

Developments in electronic health (e-Health) interventions for patients diagnosed with psychosis have been possible since the growing access and use of internet and electronic devices in past 10 years (Bonet et al. 2017). However, before proceeding further with the development of these interventions, limited knowledge exists about the impact of internet and new technologies on the mental health of these patients.

OBJECTIVE:

The aim of this study is to assess the benefits and risks associated to the use of new technologies in a survey of patients diagnosed with psychotic disorders. We analyzed the relationship between experiences and opinions about internet and demographic and clinical characteristics of the sample and patterns of use of these technologies.

METHODS:

Structured questionnaire was designed. This questionnaire was divided in three parts: 1) clinical and demographic information, 2) access and use of technologies and 3) experiences and opinions about internet. In total, 97 outpatients diagnosed with psychotic disorder participated in this cross-sectional study.

Mean age of the sample was 37.06 (SD=12.9), 72.2% of participants were male, 84.5% were single and 60.8% had achieved secondary education. Main diagnoses in the sample were First Episode of Psychosis (45.4%) and Schizophrenia (34%) and 64.9% of patients had a length of illness lower than 72 months. Further clinical and demographic information is displayed in Table 1.

Table 1. Clinical and Socidemographic information

	Total, n (%)
	N=97
Diagnosis, n (%)	
Schizophrenia	33 (34)
Other Psychotic Disorder	67 (66)
Lenght of Illness (months), mean (SD)	105.3 (125.6)
< 72 months, n (%)	63 (64.9)
➢72 months, n (%)	34 (35.1)
Age (years), mean (SD)	37.06 (12.9)
17-30 years, n (%)	36 (37.1)
31-50 years, n (%)	42 (43.3)
50-73 years, n (%)	19 (19.6)
Gender (male) n (%)	70 (72.2)
Marital status, n (%)	
Single	82 (84.5)
Married	7 (7.2)
Widowed/ Divorced	8 (8.2)
Education, n (%)	
Primary School	17 (17.5)
Secondary Education	59 (60.8)
University Degree	21 (21.6)
Employment status, n (%)	
Employed	22 (22.7)
Not employed	26 (26.8)
Student	17 (17.5)
Unable to work	22 (22.7)
Others	13 (13.4)
Internet frequency of access, n/N (%)	
Daily	62 (63.9)
Weekly	21 (21.6)
< than once a week	14 (14.4)
Mobile ownership, n/N (%)	88 (90.7)
Social media ownership, n/N (%)	66 (68)

RESULTS:

The percentage of patients who daily acceded to internet was 63.9% while 21.6% weekly acceded. 90.7% of participants owned a mobile phone and 68% had a social media account.

As shown in table 2, in regard to feelings associated with the use of internet, 60.8% of patients felt socially linked due to internet usage and 78.4% felt informed. However, 22.7% felt frustrated and 19.6% felt suspicious. Significant association was found between feeling informed and frequency of access to internet (χ^2= 6.17 p=0.05). However, any other significant association was found between feelings about internet and demographic or clinical characteristics of the sample or patterns of use of technology.

Table 2. Feelings related to internet usage.

	Socially linked	Informed	Frustrated / Anxious	Suspicious / Paranoid
	p (χ^2, df)	p (χ^2, df)	p (χ^2, df)	p (χ^2, df)
Agreement [1], n (%)	59 (60.8)	76 (78.4)	22 (22.7)	19 (19.6)
Diagnosis	.14 (3.94, 2)	.06 (5.53, 2)	.19 (3.37, 2)	.75 (.58, 2)
Length of illness	.89 (.02, 1)	.06 (3.54, 1)	.96 (2.79, 1)	.72 (.13, 1)
Age	.39 (1.89, 2)	.08 (5.06, 2)	.46 (1.56, 2)	.68 (.77, 2)
Gender	.09 (2.75, 1)	.93 (.01, 1)	.54 (.37, 1)	.46 (.54, 1)
Marital status	.33 (2.22, 2)	.87 (.28, 2)	.22 (3.07, 2)	.74 (.59, 2)
Education				
Employment status	.08 (8.50, 4)	.31 (4.82, 4)	.73 (2.04, 4)	4.03 (4.02, 4)
Internet frequency of access	.32 (2.31, 2)	**.05 (6.17, 2)**	.77 (.53, 2)	.24 (2.82, 2)
Mobile ownership	.73 (.12, 1)	.97 (.00, 1)	.42 (.64, 1)	.83 (.04, 1)
Social media ownership	.2 (1.62, 1)	.23 (1.46, 1)	.29 (1.12, 1)	.26 (1.29, 1)

[1] Sum of individual scores in the questionnaire of "Strongly agree" and "Somewhat agree" in each factor.

RESULTS:

Internet was considered as a benefit for mental health for 46.4% of patients, while 38.1% have had unpleasant experiences related to its usage, 24.7% have had internet-related relapses and 26.8% expended excessive time online.

Significant associations were found between internet-related relapses and length of illness (χ^2= 4.74 p=0.03), frequency of internet access (χ^2= 9.76 p<0.01) and social media ownership (χ^2= 5.55 p=0.02). Expending excessive time on internet was found significant associated to age of the sample (χ^2= 6.57 p=0.04), employment status (χ^2= 10.73 p=0.03), frequency of access to internet (χ^2= 10.15 p<0.01) and social media ownership (χ^2= 9.62 p<0.01). Association between stop taking medication because of information read on the internet and level of education was also found (χ^2= 9.03 p=0.01). These results are displayed in Table 3.

Table 3. Experiences related to internet usage

	Internet as a benefit	Unpleasant experiences	Stop taking medication	Internet-relapse related	Excessive time on internet	Internet social isolation
	p (χ^2, df)	p (χ^2, df)	p (χ^2, df)	p (χ^2, df)	p (χ^2, df)	p (χ^2, df)
Agreement [1], n (%)	45 (46.4)	37 (38.1)	8 (8.2)	24 (24.7)	26 (26.8)	17 (17.5)
Diagnosis	.49 (1.43, 2)	.23 (2.99, 2)	.47 (1.53, 2)	.05 (5.84, 2)	.14 (3.99, 2)	.21 (3.15, 2)
Lenght of illness	.34 (.90, 1)	.67 (.18, 1)	.35 (.86, 1)	**.03 (4.74, 1)**	.14 (2.24, 1)	.59 (.29, 1)
Age	.25 (2.76, 2)	.42 (1.73, 2)	.32 (2.29, 2)	.48 (1.49, 2)	**.04 (6.57, 2)**	.64 (.89, 2)
Gender	.12 (2.49, 1)	.12 (2.37, 1)	.14 (2.13, 1)	.72 (.13, 1)	.53 (.40, 1)	.30 (1.07, 1)
Marital status	.75 (.58, 2)	.97 (.07, 2)	.09 (4.63, 2)	.39 (1.88, 2)	.44 (1.65, 2)	.40 (1.83, 2)
Education	.99 (.03, 2)	.87 (.28, 2)	**.01 (9.03, 2)**	.72 (.65, 2)	.42 (1.74, 2)	.61 (.98, 2)
Employment status	.06 (9.27, 4)	.63 (2.56, 4)	.26 (5.33, 4)	.99 (.32, 4)	**.03 (10.73, 4)**	.41 (4.01, 4)
Internet frequency of access	.96 (.09, 2)	.83 (.37, 2)	.61 (.98, 2)	**<.01 (9.76, 2)**	**<.01 (10.15, 2)**	.46 (1.54, 2)
Mobile ownership	.05 (3.93, 1)	.76 (.09, 1)	.11 (2.56, 1)	.32 (.99, 1)	.26 (1.25, 1)	.59 (.28, 1)
Social media ownership	.87 (.03, 1)	.09 (2.94, 1)	.66 (.19, 1)	**.02 (5.55, 1)**	**<.01 (9.62,1)**	.41 (.67, 1)

[1] Sum of individual scores in the questionnaire of "Strongly agree" and "Somewhat agree" in each factor.

CONCLUSIONS:

Despite the general positive feelings about internet usage, percentages between 38-19% of patients had a negative vision of internet. Furthermore, frequency of access to internet and social media ownership have been found associated to internet-related relapses and potential pathological use of internet (excessive time on it). Younger patients, recent diagnosis of psychosis and being in a non-active employment situation seem to be related to these pathological results too.

These findings suggest that although technology is widely accepted by patients, internet is a source of information that could be interpreted as a false alarm signal that may trigger paranoid symptoms (Torous et al. 2016;Treisman et al. 2016).

To our knowledge, this is the first study to specifically describe the potential risks about internet usage in patients diagnosed with psychotic disorders, however further studies are needed.

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APÉNDICE II

Aprobación del estudio del Comité de Ética del Instituto de Investigación Clínica y Sanitaria del Hospital Clínico Universitario de Valencia (INCLIVA).

Hoja de información al paciente y consentimiento informado.

INFORME DEL COMITE ETICO DE INVESTIGACION CLINICA DEL HOSPITAL CLINIC UNIVERSITARI DE VALENCIA

Don Diego V. Cano Blanquer, Secretario del Comité Ético de Investigación del Hospital Clínic Universitari de Valencia

CERTIFICA

Que en este Comité, en su reunión de fecha 22 de marzo de 2018, y según consta en el acta de la misma, se han analizado los aspectos éticos y científicos relacionados al proyecto de investigación que lleva por título:

Uso de un aplicativo móvil (ReMindCare App) en el tratamiento de pacientes con Trastorno Psicótico.

Mismo que será llevado a cabo en el Servicio de Psiquiatría y cuyo investigador principal es el Dr. Julio Sanjuán Arias, acordando que reúne las características adecuadas referentes a información a los pacientes y cumplimiento de los criterios éticos para la investigación médica y biomédica establecidos en la ***Declaración de Helsinki*** (Junio 1964, Helsinki, Finlandia) de la Asamblea Médica Mundial, y sus revisiones (Octubre 1975, Tokio, Japón), (Octubre 1983, Ve necia, Italia), (Septiembre 1989, Hong Kong), (Octubre 1996, Somerset West, Sudáfrica), (Octubre 2000, Edimburgo), (Octubre 2008 Seúl, Corea) y (Octubre 2013 Fortaleza, Brasil) y en la ***Declaración Universal sobre el Genoma Humano y los Derechos del Hombre de la UNESCO*** y los acuerdos del ***Protocolo Adicional del Consejo de Europa para la protección de los Derechos del Hombre y de la dignidad del ser humano frente a la aplicaciones de la biología y de la medicina*** (París 12-1-1998, ratificado el 23-7-1999).

Lo que certifico a efectos oportunos del desarrollo de la Tesis Doctoral de Doña Lucia Bonet.

Valencia, 22 de marzo de 2018.

Fdo. : Don Diego V. Cano Blanquer
Secretario del Comité Ético de Investigación Clínica

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Registro de Actividad de Tratamiento

Proyecto/Estudio de Investigación Biomédica

Nombre del proyecto

Uso de nuevas tecnologias en el tratamiento de Trastorno Mental Severo. RemindCare: App para pacientes de Primero Episodios Psicóticos.

Responsable del tratamiento / Corresponsables del tratamiento

Ip o IPs. Al menos uno debe ser personal del centro sanitario de origen de los datos o de los pacientes.

Nombre	CIF - DNI	Correo electrónico	Teléfono
Julio Sanjuán Arias	CIF - DNI	Julio.sanjuan@uv.es	666426998
Nombre y apellidos	CIF - DNI	De uso profesional	De uso profesional
Nombre y apellidos	CIF - DNI	De uso profesional	De uso profesional

Fines científicos del tratamiento de datos – Objetivo simplificado del proyecto/estudio

El objetivo de nuestro proyecto es el de desarrollar una aplicación móvil (ReMindCare App) que permita monitorizar la adherencia al tratamiento médico y psicosocial y la evolución clínica de los pacientes con psicosis.

Para lograr la traslación directa de los datos obtenidos por la app a la práctica clínica habitual, estamos trabajando para que los registros realizados por los pacientes puedan visualizarse en la Historia Clínica Electrónica.

Nuestra finalidad es la de analizar si el uso de la app incrementa la adherencia al tratamiento farmacológico y psicosocial, si mejora el estado clínico y si es aceptada por los pacientes y por los profesionales. Y con todo ello, demostrar que el uso de dicho aplicativo resulta coste-eficiente comparado con el tratamiento habitual.

Resultados esperados del tratamiento de datos – Proyecto/Estudio

☒ Mejoras en la eficacia/calidad de los servicios sanitarios	☒ Publicaciones en revistas científicas
☒ Mejoras en protocolos de actuación clínica asistencial local	☒ Presentación en congresos
☐ Mejoras en protocolos de actuación clínica asistencial nacional o internacional	☒ Tesis doctoral
☒ Mejora de la eficiencia o reducción de costes de los servicios sanitarios	☒ Trabajos de posgrado (TFM)
☐ Validación de la seguridad/eficiencia de métodos clínicos, medicamentos o dispositivos sanitarios	☒ Trabajos de grado (TFG)
☒ Registro de datos cuyo objetivo es servir como base para futuros proyectos/estudios	☐ Otros. Defina: Pulse aquí para escribir texto.

Caracterización de la población -Colectivos de interesados

La intervención esta dirigida a los pacientes de la Unidad de Primeros Episodios Psicóticos del área de Psiquiatría en el Hosptal Clínico de Valencia.

Se trata de pacientes con diagnóstico de Trastorno Psicótico (Esquizofrenia, T. Esquizofreniforme T. Delirante, T.Bipolar, T.Psicótico no especificado) según criterios DSM-5. De edades comprendidas entre 18 y 70 años y que dispongan de un móvil propio con conexión a internet así como de las habilidades mínimas para utilizar este dispositivo.

No se incluiran pacientes con: (1)Retraso mental severo, (2) Falta de habilidades en el uso y manejo de dispositivos móviles e internet, (3) Sin castellano-valenciano-ingles fluido.

Categorías de datos personales que se utilizarán en el proyecto

Seleccione las casillas que correspondan y defina los datos que se requieren, en su caso.

☒ Identificativos	☐ Genéticos
☒ Relativos a la salud	☐ Vida sexual u orientación sexual
☐ Fisiológicos	☐ Características personales - Antropométricas
☐ Sociológicos	☐ Profesionales
☒ Vida y hábitos personales - comportamiento	☐ Geográficos
☒ Demográficos	☐ Otros. Defina: Pulse aquí para escribir texto.

Se debe anexar a este documento el listado de variables que se utilizarán para el proyecto/estudio

Categorías de destinatarios de datos personales

No

Transferencia internacional de datos (Fuera de la UE)

Seleccione una opción y en su caso, complete la información que corresponda

☒ En el marco o como consecuencia de este proyecto/estudio, no se realizarán transferencias de datos fuera de la EU.

☐ Sí, están previstas. En el caso de Describa y se gestionarán a través de Describa.

Plazo de supresión

Los datos se mantendrán bloqueados durante un periodo de 5 años, posteriores a la finalización del proyecto/estudio con la finalidad de cumplir con posibles reutilizaciones de los datos para futuros proyectos.

Base jurídica del tratamiento

Seleccione al menos una opción y en su caso, complete la información que corresponda.

- ☒ RGPD: 6.1.A) Se contará con el **consentimiento** de las personas de quienes se tratarán datos personales.
- ☐ RGPD: 6.1.C) El tratamiento es necesario para el cumplimiento de una **obligación legal**. Específicamente la incluida en Citar artículo y nombre de la ley.
- ☐ RGPD: 6.1.E) El tratamiento es necesario para el cumplimiento de una **misión en interés público** o en el ejercicio de poderes públicos conferidos al responsable del tratamiento. Específicamente Justificar el interés público del tratamiento o los poderes que facultan al responsable para su realización.
- ☐ RGPD: 6.1.F) El tratamiento es necesario para la satisfacción de **interéses legítimos del responsable** del tratamiento. Específicamente justificar. Se ha realizado una ponderación en la cual el interés legítimo prevalece sobre los intereses, derechos y libertades fundamentales de los interesados, principalmente debido a Haga clic o pulse aquí para describir y justificar de manera breve. Se adjunta a este documento el análisis realizado.

Medidas de seguridad de los datos personales[1]

- Minimización en las variables utilizadas y en la cantidad de participantes en el proyecto/estudio
- Uso de datos seudonimizados
- Medidas legales de confidencialidad al equipo investigador y terceros
- Compromiso de no reidentificación por el equipo investigador y terceros
- Datos depositados en un equipo institucional, con control de acceso físico y lógico
- Acceso a los datos y a los equipos que los contienen exclusivamente al equipo investigador y, en su caso, a terceros con contratos que regulen el acceso
- Uso de medidas de encriptación y/o cifrado de los datos, al custodiarse y/o transferirse
- Medidas de autenticación de usuarios de la App de manera inequivoca y fiable (personal médico y pacientes)
- Indicar otras medidas de seguridad que se tomarán en el proyecto
- Indicar otras medidas de seguridad que se tomarán en el proyecto

Derechos de los participantes en el proyecto/estudio

Derecho de:		Tomando en cuenta:
Acceso a la información del tratamiento de datos	Sí ☒ No ☐	Cuando asisten a consulta, se le muestra y/o entrega un informe resumen de la información que captura al App.
Rectificación de datos inexactos	Sí ☐ No ☒	El paciente no tiene opción de rectificar las respuestas que realiza en la app. En caso de que el caiente quisiera rectificar respuestas lo puede indicar al médico, quien tomará registro de ello, sin modificar en ningún caso la respuesta original. Buena práctica clínica.
Supresión de datos	Sí	En los casos previstos en el artículo 17 del Reglamento (UE) 2016/679 – RGPD.
Limitación del tratamiento	Sí ☐ No ☒	El participante no tiene la opcion de contestar solo una parte de los cuestionarios, ni utilizar solo algunas funcionalidades que ofrece. Tiene que usarla como lo indica el manual de usuario.
Portabilidad de datos[2]	Sí ☒ No ☐	Los datos, distintos al informe que se entrega en consulta por el médico, no pueden ser utiliados por ningún otro sistema informático ya que se han generado por la aplicación en desarrollo.
Oposición al tratamiento[3]	Sí ☐ No ☒	La base legal es el consentimiento.

Los participantes del proyecto/estudio, podrán solicitar el ejercicio de sus derechos en el siguiente medio de contacto: El psiquiatra de referencia de cada paciente, en consulta.

[1] Las medidas predefinidas forman parte de la política de privacidad y seguridad de la información de INCLIVA, mismas que deben ser incluidas en los proyectos/estudios de investigación que se desarrollan bajo su gestión.
[2] Derecho de aplicación obligatoria, si la base legal es el consentimiento. No aplica en el caso de tratamiento necesario para el cumplimiento de una misión de interés público.
[3] Derecho solo aplicable, si la base legal del tratamiento es una misión de interés público o satisfacción de intereses legítimos del responsable.

Nota informativa al IP.

Es responsabilidad del IP, o de los IPs, del proyecto/estudio:

a) generar y conservar los registros para tener capacidad de aportar evidencias del cumplimiento de la normativa aplicable y de la aplicación permanente de las medidas de seguridad establecidas.
b) la aplicación de las medidas de seguridad para los datos personales implicados, así como garantizar su confidencialidad, integridad, disponibilidad y resiliencia permanentemente.
c) garantizar que todas las personas implicadas respetarán la confidencialidad de cualquier información acerca de los sujetos del ensayo, así como la protección de sus datos de carácter personal
d) actualizar el presente documento cuando se identifique un cambio o un aspecto no contemplado en la versión vigente, en cualquier momento de la vida del proyecto, mismo que deberá ser coherente con el protocolo del proyecto/estudio.

En caso de que ocurriese una violación de seguridad, en un plazo no mayor de 48 horas, deberá comunicarlo al Delegado de Protección de Datos para su valoración y, en su caso, comunicación a la autoridad de control de acuerdo a lo establecido en el Art. 33 del Reglamento General de Protección de Datos.

Se entiende por "violación de la seguridad de los datos personales":

Toda violación de la seguridad de los datos que les ocasione:

a) Destrucción,
b) pérdida,
c) alteración accidental o ilícita
d) transmisión inadecuada
e) conservación inadecuada
f) tratamiento inadecuado
g) comunicación no autorizada
h) acceso no autorizado.

Dichas violaciones se gestionan por la Fundación INCLIVA a través del procedimiento *PR-IN-ViPD Gestión de violaciones de seguridad de datos personales*, disponible en www.incliva.es/proteccion-datos-personales. Para minimizar la ocurrencia de estas circunstancias, el proyecto debe realizarse de acuerdo a la *Política de privacidad y seguridad de la información de INCLIVA*, disponible en la misma página web.

Versión: 1
Fecha de actualización: 24/10/2019

Firma del Responsable del tratamiento, o Corresponsables del tratamiento[4]

Declaro que toda la información suministrada es veraz

[4] Necesaria firma autógrafa o con certificado digital

Fecha/firma de revisión por el Delegado de Protección de Datos

Entidad donde se desarrolla el proyecto:

Departamento de salud clínico-malvarrosa
Hospital Clínico Universitario de Valencia
Av. de Blasco Ibáñez, 17, 46010 Valencia
Delegado de Protección de Datos: dpd@gva.es

Entidad gestora del proyecto:

Fundación INCLIVA
CIF: G96886080
Av. Menéndez y Pelayo 4, acc. 46010, Valencia.
Delegado de Protección de Datos: protecciondatos@incliva.es

HOJA DE INFORMACIÓN AL PACIENTE

TÍTULO DEL ESTUDIO: Uso de un aplicativo móvil (ReMindCare App) en el tratamiento de pacientes con Trastorno Psicótico.	
CÓDIGO DEL ESTUDIO	2018/059.
VERSIÓN Y FECHA	**Inicio del estudio 26/09/2018**
PROMOTOR	
INVESTIGADOR PRINCIPAL	JULIO SANJUÁN ARIAS
SERVICIO	PSIQUIATRIA
CENTRO	HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA

Nos dirigimos a usted para informarle sobre un estudio de investigación en el que se le invita a participar. El estudio ha sido aprobado por el Comité de Ética de la Investigación de su centro, de acuerdo a la legislación vigente, Ley 14/2007, de 3 de julio, de Investigación biomédica. Nuestra intención es que usted reciba la información correcta y suficiente para que pueda decidir si acepta o no participar en este estudio. Lea esta hoja de información con atención y nosotros le aclararemos las dudas que le puedan surgir. Además, puede consultar con las personas que considere oportuno.
Así mismo, podrá solicitar cualquier explicación que desee sobre cualquier aspecto del estudio y sus implicaciones a lo largo del mismo contactando con la investigadora encargada del proyecto **Lucia Bonet Mora**, en el **teléfono 963 983 190** (De Lunes a Viernes de 8:00h a 14:00h).

1. Participación voluntaria:

Le invitamos a participar en el estudio porque ha sido diagnosticado de Trastorno Psicótico. Debe saber que su participación en este estudio es voluntaria y que puede decidir NO participar. Si decide participar, puede cambiar su decisión y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con su médico ni se produzca perjuicio alguno en su atención sanitaria.

2. Justificación y Objetivo del estudio:

El uso de nuevas tecnologías en el tratamiento de pacientes con trastorno psicótico, puede suponer una mejora con respecto al tratamiento tradicional al permitir una evaluación sintomatológica de mayor fiabilidad.

Por ello, el objetivo de nuestro estudio es introducir el uso de una app móvil en la práctica clínica cotidiana, con el fin de facilitar la comunicación entre paciente y psiquiatra, mejorar la prevención de recaídas y disminuir los ingresos hospitalarios. Todo ello encaminado a la recuperación funcional y social del paciente.

3. Descripción del estudio:

El estudio consiste en el uso de la app ReMindCare que hemos diseñado desde la Unidad de Primeros Episodios Psicóticos del Hospital Clínico. El uso de esta aplicación, se ofrecerá a todos los pacientes de la unidad que dispongan de un móvil propio con conexión a internet. Se estima que un total de 100 pacientes de la unidad hagan uso del mismo.

Descarga y uso de ReMindCare app:

Para empezar a utilizar la app, deberá descargarla de forma gratuita del App Store Google Play. Una vez descargada la aplicación y con ayuda de su psiquiatra o psicólogo/a de referencia, será registrado en la aplicación y podrá comenzar su uso.

El uso de la aplicación, consiste en responder a una serie de cuestiones que se le presentarán, orientadas a evaluar su estado clínico. Es importante que responda a la totalidad de las preguntas con la mayor sinceridad que pueda, puesto que el objetivo de la app es el de disponer de un registro de su estado de salud lo más ajustado a la realidad posible. Esto permitirá mejorar el ajuste de la medicación de forma individualizada.

Alarmas y avisos al clínico:

En caso de que el programa detecte alguna variación importante en su estado de salud, su médico de referencia recibirá un aviso y contactará con usted dependiendo de la gravedad del problema. Por otra parte, usted dispondrá de un botón denominado “Consulta Urgente” en el que podrá avisar a su médico de que no se encuentra bien y que necesita ponerse en contacto con él lo antes posible. Al pulsar este botón de “Consulta Urgente” su médico se podrá en contacto con usted en un plazo máximo de 48h.

4. Actividades del estudio:

Usted podrá hacer uso de la aplicación durante todo el periodo de tiempo que permanezca como paciente de la unidad. Su uso, no supondrá un aumento de la periodicidad de sus citas con el clínico, salvo que usted solicite una “consulta urgente” o que el dispositivo detecte grandes variaciones en su estado de salud, que requieran adelantar la cita programada con su médico.
El uso de la app, supone el responder a tres cuestiones diarias y a dieciocho cuestiones que se presentan únicamente los lunes.

5. Riesgos y molestias derivados de su participación en el estudio:

Las molestias previsibles asociadas al uso de la App son mínimas. El tiempo que invertirá en responder a los avisos del aplicativo de forma diaria es inferior a 1 minuto y el tiempo que invertirá en responder a la evaluación semanal nunca será superior a los 3 minutos. Por otra parte, no existe ningún tipo de riesgo asociado al uso del aplicativo móvil.

6. Posibles beneficios:

Mediante esta investigación esperamos mejorar la calidad de los servicios de atención temprana a pacientes de la Unidad de Primeros Episodios Psicóticos. En concreto, si usted participa en este estudio los beneficios esperados son:

1. *Mejora de la evaluación de su estado de salud y de las decisiones que el clínico tome acerca de su tratamiento:* Gracias al registro diario de su estado de salud con la App, su psiquiatra o psicólogo/a podrá disponer de una idea más valida de cuál ha sido su estado clínico a lo largo del tiempo. Gracias a ello podrá ajustarle el tratamiento de manera más adecuada con particular atención a la eficacia y a los efectos secundarios del mismo.

2. *Mejora de la detección de variaciones en su estado de salud y posibles recaídas:* Mediante el registro de su estado de salud y el sistema de alarmas, podremos detectar posibles empeoramientos en su estado de salud de forma más temprana pudiendo prevenir que su estado avance a estados de gravedad superiores.

3. *Mejora de la comunicación con su psiquiatra o psicólogo/a de referencia:* Gracias a los registros de salud y el sistema de avisos, su médico podrá estar informado en cada momento de cual está siendo su estado de salud de forma que ambos puedan tener una visión de su evolución más ajustada a la realidad.

7. Protección de datos personales:

El investigador y el centro son responsables respectivamente del tratamiento de sus datos y se comprometen a cumplir con la normativa de protección de datos en vigor, la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y Garantía de los Derechos Digitales, el Real Decreto que la desarrolla (RD 1720/2007) y el Reglamento (UE) 2016/679 del Parlamento europeo y del Consejo de 27 de abril de 2016 de Protección de Datos (RGPD).

Los datos recogidos para el estudio estarán identificados mediante un código, de manera que no incluya información que pueda identificarle, y sólo su médico del estudio/colaboradores podrá relacionar dichos datos con usted y con su historia clínica. Por lo tanto, su identidad no será revelada a persona alguna salvo excepciones en caso de urgencia médica o requerimiento legal.

El acceso a su información personal identificada quedará restringido al médico del estudio/colaboradores, autoridades competentes, al Comité de Ética de la Investigación y personal autorizado por el promotor (monitores del estudio, auditores), cuando lo precisen para comprobar los datos y procedimientos del estudio, pero siempre manteniendo la confidencialidad de los mismos de acuerdo a la legislación vigente.

De acuerdo a lo que establece la legislación de protección de datos, usted puede ejercer los derechos de acceso, modificación, oposición y cancelación de datos, para lo cual deberá dirigirse a su médico del estudio. Si usted decide retirar el consentimiento para participar en este estudio, ningún dato nuevo será añadido a la base de datos, pero sí se utilizarán los que ya se hayan recogido.

Además, puede limitar el tratamiento de datos que sean incorrectos, solicitar una copia o que se trasladen a un tercero (portabilidad) los datos que usted ha facilitado para el estudio. Para ejercitar sus derechos, diríjase al investigador principal del estudio o al Delegado/a de Protección de Datos del centro/institución en dpd@gva.es. Así mismo tiene derecho a dirigirse a la Agencia de Protección de Datos si no quedara satisfecho.

Los datos codificados pueden ser transmitidos a terceros y a otros países, pero en ningún caso contendrán información que le pueda identificar directamente, como nombre y apellidos, iniciales, dirección, nº de la seguridad social, etc. En el caso de que se produzca esta cesión, será para los mismos fines del estudio descrito o para su uso en publicaciones científicas, pero siempre manteniendo la confidencialidad de los mismos de acuerdo a la legislación vigente.

El investigador adoptará las medidas pertinentes para garantizar la protección de su privacidad y no permitirá que sus datos se crucen con otras bases de datos que pudieran permitir su identificación.
Si investigador no puede confirmar esta demanda, el paciente deberá ser informado del riesgo de re-identificación derivado de la reutilización de sus datos en futuros estudios no definidos en este momento.

CONSENTIMIENTO INFORMADO POR ESCRITO

TÍTULO DEL ESTUDIO: Uso de un aplicativo móvil (ReMindCare App) en el tratamiento de pacientes con Trastorno Psicótico.	
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Yo, _____ <<nombre y apellidos del participante>>

He leído la hoja de información que se me ha entregado sobre el estudio.
He podido hacer preguntas sobre el estudio.
He recibido suficiente información sobre el estudio.
He hablado con _____<<nombre del investigador>>

Comprendo que mi participación es voluntaria.

Comprendo que puedo retirarme del estudio:
- Cuando quiera.
- Sin tener que dar explicaciones.
- Sin que esto repercuta en mis cuidados médicos.

Presto libremente mi conformidad para participar en el estudio.

Consiento al uso y tratamiento de mis datos personales para esta investigación en las condiciones explicadas en esta hoja de información.

Recibiré una copia firmada y fechada de este documento de consentimiento informado

Firma del participante
Fecha: ____/____/____

Firma del investigador
Fecha: ____/____/____

APÉNDICE III:

Manual de usuario de la aplicación ReMindCare para el clínico

REMINDCARE APP

MANUAL DE USUARIO

Versión para el clínico

Actualizado para ReMindCare 6.6.0 (8 febrero 2021)

Manual de uso de la app ReMindCare para clínicos

App desarrollada por la Unidad de Psiquiatría del Hospital Clínico de Valencia en colaboración con la Universidad Politécnica de Valencia.

Dirigida a pacientes con diagnóstico de Trastorno Psicótico con el fin de mejorar la evaluación del estado clínico del paciente y la comunicación entre paciente y médico.

ReMindCare es una app que recoge información sobre el estado clínico de los pacientes con trastorno psicótico mediante breves evaluaciones diarias y semanales.

Esta información puede consultarse en una página web de acceso restringido, en la que los clínicos pueden visualizar los datos de los pacientes, así como generar un informe PDF en el que se resumen los principales datos obtenidos por la app. Estos informes pueden ser subidos como un archivo adjunto a la historia clínica electrónica del paciente, de forma que pueden ser consultados por cualquier clínico involucrado en el tratamiento del mismo.

A su vez, la app produce todo un sistema de alertas con las que notificar al clínico sobre variaciones en el estado del paciente o del cese de uso de la app. Por otra parte, los pacientes pueden generar un aviso para solicitar una consulta urgente con el clínico, pulsando un botón denominado "Consulta Urgente".

El proceso de diseño e implementación de la app, puede ser dividido en las siguientes fases:

En primer lugar, se realizó una revisión sistemática de publicaciones previas (Bonet et al. 2017). El objetivo era obtener una visión general de las tendencias actuales en el diseño de apps para pacientes con psicosis. Los análisis se centraron en estudios que valoraban la usabilidad y calidad de las apps, la mejora en la evaluación del paciente y en la adherencia a la medicación y la reducción de los síntomas clínicos y las hospitalizaciones.

Como resultado de este primer análisis, se observó que las intervenciones en pacientes con psicosis mediante el uso de apps son viables y bien aceptadas. Además, disponen de una buena correlación con medidas de evaluación tradicionales y pueden suponer una mejora en el tratamiento de la enfermedad. No obstante, se observó una gran limitación en estos estudios. Todos ellos hacían referencia a ensayos clínicos con una duración determinada, nunca superior a 2 años, lo que impedía el análisis de los resultados a largo plazo. Por otra parte, al tratarse de estudios aislados, no permitían analizar los efectos de la integración de estos sistemas en la práctica clínica cotidiana.

La segunda fase, consistió en el diseño y pase de una encuesta a una muestra de pacientes con psicosis (Bonet et al. 2018). El objetivo de este estudio fue analizar la viabilidad de implementar una intervención mediante el uso de una app móvil en una muestra de pacientes con psicosis en nuestra localidad de referencia. A su vez, se buscaba analizar el interés de esta muestra en disponer de una app que les ayudara en el manejo de la enfermedad, así como conocer su interés en diferentes funciones y servicios que podría realizar esta app.

El análisis de los datos obtenidos mediante esta encuesta, permitió confirmar que la muestra de pacientes disponía de un acceso y uso de tecnologías equivalente al de la población general. A su vez, se obtuvieron altas tasas de interés en disponer de una app, sobre todo en aquellos servicios que implicaban una mejora de la comunicación y

cercanía con el clínico. No obstante, también se observó potenciales efectos adversos de un uso excesivo de las tecnologías.

En la tercera fase, en base a la información obtenida en los estudios previos, se procedió al diseño y elaboración de la app y la página web. El objetivo que guio este proceso fue el de elaborar una app sencilla, que pudiera ser directamente implementada en la práctica clínica y que dispusiera de funciones que permitirán al paciente comunicar con mayor fiabilidad y rapidez las variaciones en su estado clínico.

Se optó por una base de datos MongoDB (GNU AGPL v3.0) para la recogida de datos de los pacientes, hecho que garantiza la flexibilidad y escalabilidad de las medidas. Por otra parte, se seleccionó un servidor web Node.js (MIT License) con encriptación mediante HTTPS para garantizar la privacidad de las comunicaciones. Tanto la base de datos como el servidor web se encuentran aislados en contenedores Docker (Apache License 2.0).

Finalmente, la aplicación móvil fue diseñada con compatibilidad a Android e iOS para garantizar su buen funcionamiento.

Todos estos sistemas, excepto iOS son gratuitos y disponen de licencias de uso libres.

Finalmente, en la cuarta fase, se realizó un ensayo piloto en el que se analizó la validez y usabilidad de la app. En este estudio participó un total de 4 pacientes durante un periodo de tres meses. Las tasas de cumplimiento de los avisos de la app fueron de entre el 97% al 90%. No obstante, cabe destacar que un paciente abandonó el estudio a los 5 días de empezar por empeoramientos en su estado clínico.

Como resultado de este estudio piloto, se realizaron algunas modificaciones en referencia al acceso de los clínicos a la página web, el registro de los datos de los pacientes y algunas cuestiones técnicas de carácter informático. Y a su vez, se garantizó la validez y viabilidad de implementación del uso de la app.

Bonet L, Izquierdo C, Escartí MJ, Sancho JV, Arce D, Blanquer I et al. Utilización de tecnologías móviles en pacientes con psicosis: una revisión sistemática. Rev Psiquiatr Salud Ment 2017 Jul-Sept; 10(3): 168-78. PMI: 28258835

Bonet L, Llácer B, Hernandez-Viadel M, Arce D, Blanquer I, Cañete C et al. Differences in the Use and Opinions About New eHealth Technologies Among Patients With Psychosis: Structured Questionnaire. JMIR Ment Health. 2018 Jul;5(3):e51. PMID: 30045835

ÍNDICE

0. DESCRIPCIÓN DE LA APP

ReMindCare es una app para smartphone que realiza registros diarios del estado de salud de pacientes con trastorno psicótico con el fin de mejorar la evaluación de su estado clínico y la comunicación entre paciente y médico. Esta app ha sido desarrollada por la Unidad de Psiquiatría del Hospital Clínico de Valencia (INCLIVA) en colaboración con la Universidad Politécnica de Valencia.

1. FUNCIONAMIENTO

0. FUNCIONAMIENTO GENERAL

Para empezar a hacer uso de la plataforma, en primer lugar, los clínicos deben registrarse en la web de ReMindCare. Seguidamente, deben dar de alta a cada uno de los pacientes dentro del sistema. Una vez hayan sido dados de alta por el clínico, los pacientes deben descargarse la app en su dispositivo e iniciar sesión. Será entonces cuando los pacientes empezarán a recibir de forma diaria unas notificaciones para responder a evaluaciones de su estado de salud.

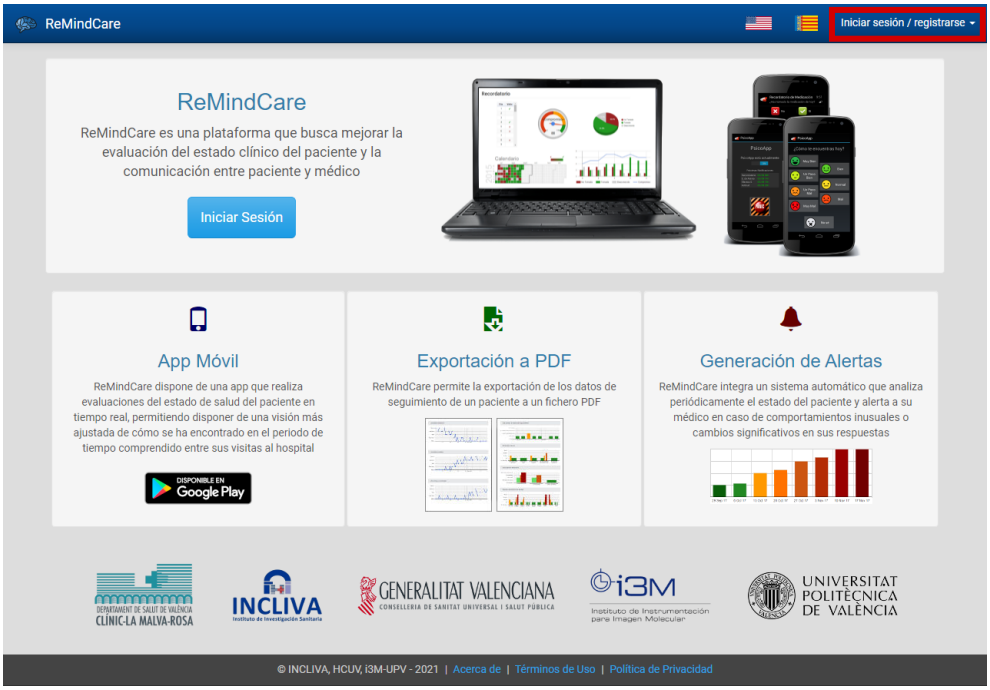
La información recogida por el aplicativo en base a estas evaluaciones podrá ser visualizada por el clínico desde la página web de ReMindCare y podrá producir alertas en caso de que se detecten variaciones bruscas en las respuestas del paciente. A su vez, el paciente dispone de una opción, dentro de la app, que le permite informar a su clínico de referencia de un posible empeoramiento en su estado de salud.

La información recogida por el dispositivo sobre cada paciente, así como los avisos que puedan generarse a raíz de su uso, únicamente se muestran en el perfil del clínico que lo haya registrado y con quien haya decidido compartirlo.

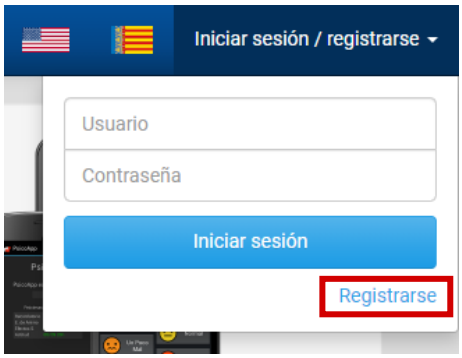
1. REGISTRO DEL CLÍNICO EN EL SISTEMA

Si la plataforma se encuentra integrada en el sistema hospitalario, el clínico debe:

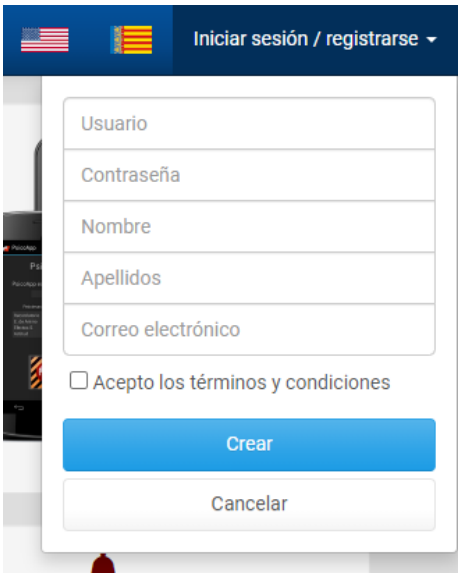
1. Pulsar en “Iniciar sesión / registrarse”, situado en la parte superior derecha.
2. Pulsar en “registrarse”.
3. Introducir los datos solicitados, siendo el usuario y contraseña los mismos que el de su sistema hospitalario. La dirección de email será a la que se enviarán las solicitudes de consulta urgente y alertas de actividad del paciente.
4. Pulsar en Crear



Página principal de la web



Panel de Inicio de Sesión



Panel de Registro

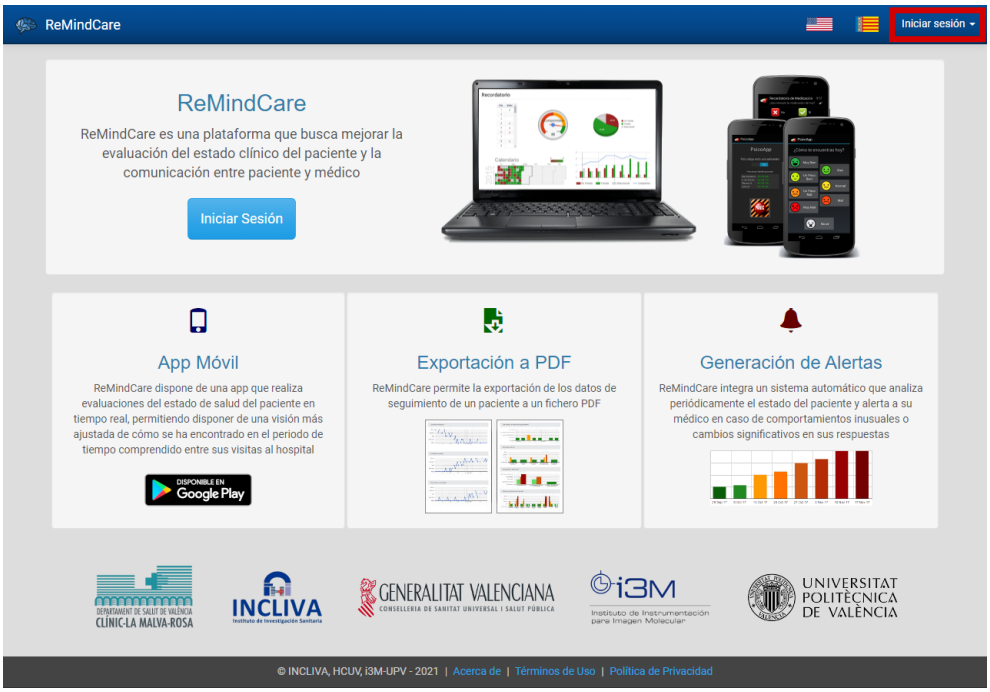
Si la plataforma no se encuentra integrada en el sistema hospitalario, el registro será realizado por el servicio informático encargado de administrar ReMindCare, y se le proporcionará una contraseña temporal.

Mediante este proceso, garantizamos que únicamente el personal médico autorizado pueda tener un perfil en el sistema.

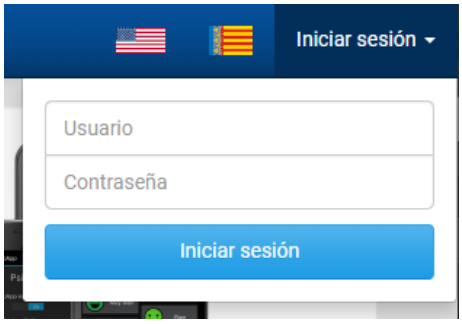
2. ACCESO AL PERFIL DEL CLÍNICO

Para acceder a su perfil, el clínico debe:

1. Pulsar en “Iniciar sesión”, situado en la parte superior derecha.
2. Introducir DNI y contraseña.
3. Pulsar en Iniciar sesión



Página principal de la web



Panel de Inicio de Sesión

Una vez iniciada la sesión, el clínico dispone de cuatro pestañas que serán siempre accesibles en el encabezamiento de la web:

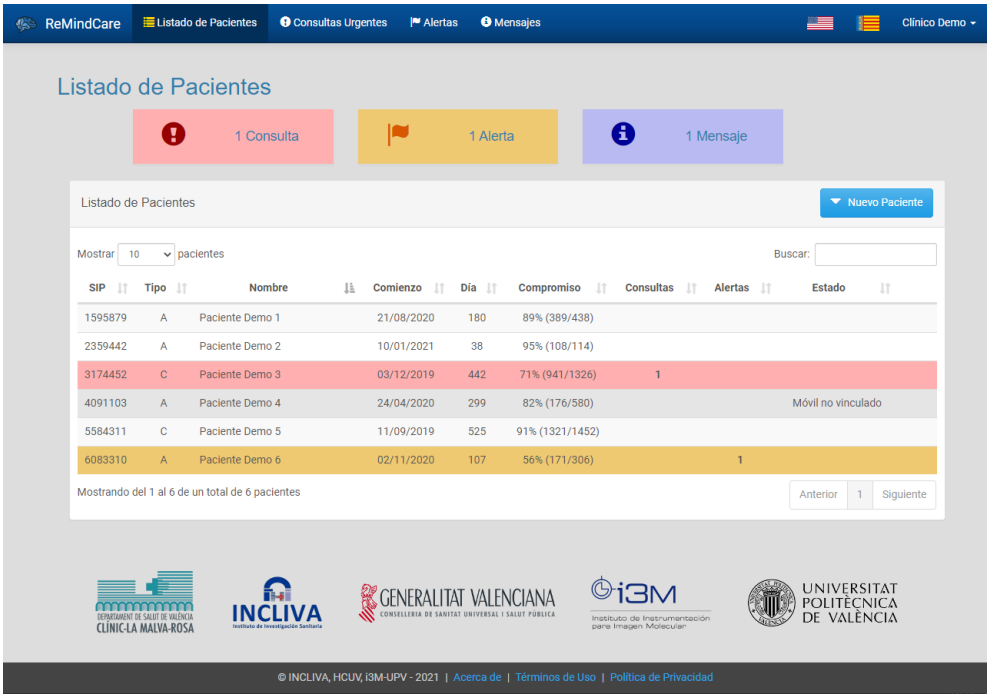
Encabezamiento de la web

2.1. Listado de pacientes

Se muestra el listado de pacientes introducidos por el clínico y el resumen de sus principales características:

- Número SIP del paciente
- Nombre del paciente
- Fecha de comienzo de uso del aplicativo.
- Días de tratamiento o de uso del aplicativo.
- Cumplimiento o porcentaje de respuesta global a las evaluaciones del aplicativo.
- Número de peticiones de consulta urgente generadas por el paciente.
- Número de alertas o generadas automáticamente por el aplicativo.
- Estado de la app del paciente (pendiente de vinculación, etc.)

El listado dispone de funcionalidades como búsqueda de pacientes, ordenación por columnas o paginación.



Listado de Pacientes

2.2. Consultas urgentes

Esta pestaña permite acceder a información sobre las peticiones de consulta urgente que el paciente ha generado de forma voluntaria. En ella se muestra información relativa al paciente que ha generado la petición y su fecha y hora.

Consultas Urgentes

2.3. Alertas

Permite acceder a información relativa a las alertas que el sistema ha generado de forma automática, que pueden ser de tres tipos:

- Inactividad prolongada
- Cambio drástico
- Compromiso bajo

Alertas

2.4. Mensajes

Permite crear y acceder a mensajes que los clínicos o el administrador de la plataforma haya querido incluir como relevantes.

Mensajes

3. REGISTRO DEL PACIENTE

Para registrar al paciente en el sistema se debe disponer previamente de su SIP, y seguir los siguientes pasos:

1. Acceder al espacio personal del clínico (véase apartado 2. Acceso al perfil del clínico).
2. Ir al listado de pacientes.
3. Pulsar en Nuevo Paciente
4. Introducir el SIP en el campo “SIP Paciente”.
5. Pulsar en Verificar SIP

Si la plataforma está integrada en el sistema hospitalario, se comprobará que el SIP introducido existe en la base de datos del hospital y aparecerá automáticamente el nombre del paciente, el cual no podrá ser modificado.
En caso contrario, se aceptará cualquier SIP con formato válido y el clínico deberá introducir también el nombre del paciente.

6. Introducir el nombre del paciente si procede.
7. Seleccionar el tipo de paciente (agudo o crónico).
8. Seleccionar los clínicos que se desea que tengan acceso al paciente.
9. Pulsar en Crear Paciente

Nuevo paciente

4. CAPTURA DE LOS DATOS DEL PACIENTE

Una vez que el paciente haya sido registrado y comience a hacer uso de la aplicación móvil (véase apartado 5. Instalación de la app en el smartphone del paciente), el clínico podrá visualizar los datos recogidos en la página web. Para visualizar los datos del paciente:

1. Ir al listado de pacientes.
2. Seleccionar el paciente cuyos datos se quieren visualizar.

Al pulsar en un paciente en concreto, se accede a su perfil, en el que puede visualizarse la siguiente información relativa a los datos recogidos por la app:

4.1. Paneles resumen de actividad

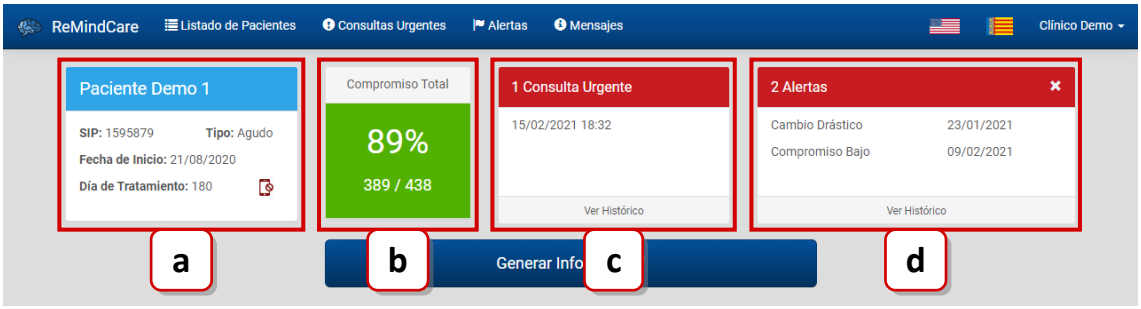
a. Panel de identificación del paciente: Contiene información relativa al paciente y a su registro en el sistema:

- Nombre del paciente.
- Número SIP.
- Tipo de paciente (agudo o crónico).
- Fecha de inicio de uso del dispositivo.
- Días de tratamiento o uso del dispositivo.
- Si el paciente ha desactivado las notificaciones de su dispositivo.

***b. Panel de compromiso total**:* muestra la cantidad de preguntas respondidas sobre las totales y su porcentaje.

c. Panel de consultas urgentes: muestra las peticiones recientes de consulta urgente con fecha y hora generadas por el paciente. Al hacer *click* en la consulta urgente se pueden visualizar más detalles. Al hacer *click* en "Ver Histórico", se puede acceder al historial de peticiones generadas por el paciente a lo largo del tiempo.

d. Panel de alertas: muestra las alertas generadas recientemente con fecha y hora. Al hacer *click* en la alerta, se puede visualizar más detalles de la alerta e ir a la gráfica asociada. Al hacer *click* en "Ver Histórico", se puede acceder al historial de alertas generadas a lo largo del tiempo.



Paneles resumen de actividad y botón Generar Informe PDF

4.2. Generar informe PDF

Generar un informe permite exportar los datos generados del paciente en un fichero PDF, además de sus consultas urgentes y sus alertas. Para generar un informe:

1. Acceder al espacio personal del clínico.
2. Ir al listado de pacientes.
3. Seleccionar el paciente cuyos datos se quieren exportar.
4. Pulsar en Generar Informe PDF, situado debajo de los paneles resumen.
5. En el panel que se abrirá, seleccionar el intervalo temporal de los datos a exportar.
6. Seleccionar si se desea incluir el historial de consultar urgentes y de alertas.

En caso de que la plataforma esté integrada con el sistema hospitalario, se permite subir el PDF al Historial Clínico Electrónico del hospital de manera automática. Si no estuviera integrado, la única opción posible es la de descargar el fichero PDF al disco duro para posteriormente subirlo de manera manual al Historial Clínico Electrónico.

7. Pulsar en Subir PDF o Descargar PDF según las circunstancias.

Generar Informe PDF

Un ejemplo de este informe puede encontrarse en el **ANEXO I**.

4.3. Pestañas de acceso a los datos

Los datos del paciente se encuentran divididos en 5 categorías, a las que se pueden acceder pulsando en las diferentes pestañas ubicadas debajo del botón de “Generar Informe PDF”.

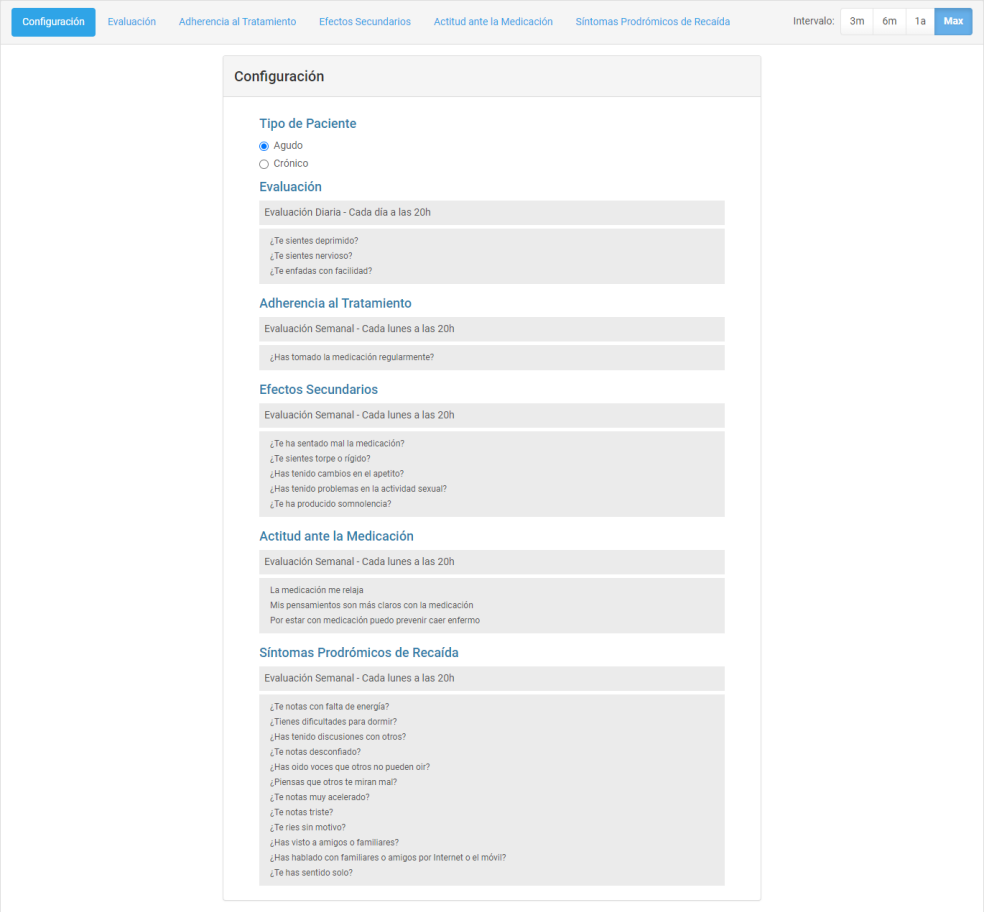
Los datos a visualizar pueden ser filtrados para mostrar los últimos 3 meses, 6 meses, 1 año o desde el principio, a través de los botones de “Intervalo”

Pestañas de acceso a los datos e Intervalo temporal

Configuración

En este apartado se tiene una vista general de todas las evaluaciones que se realizan al paciente, junto a su frecuencia y hora a la que se realizan.

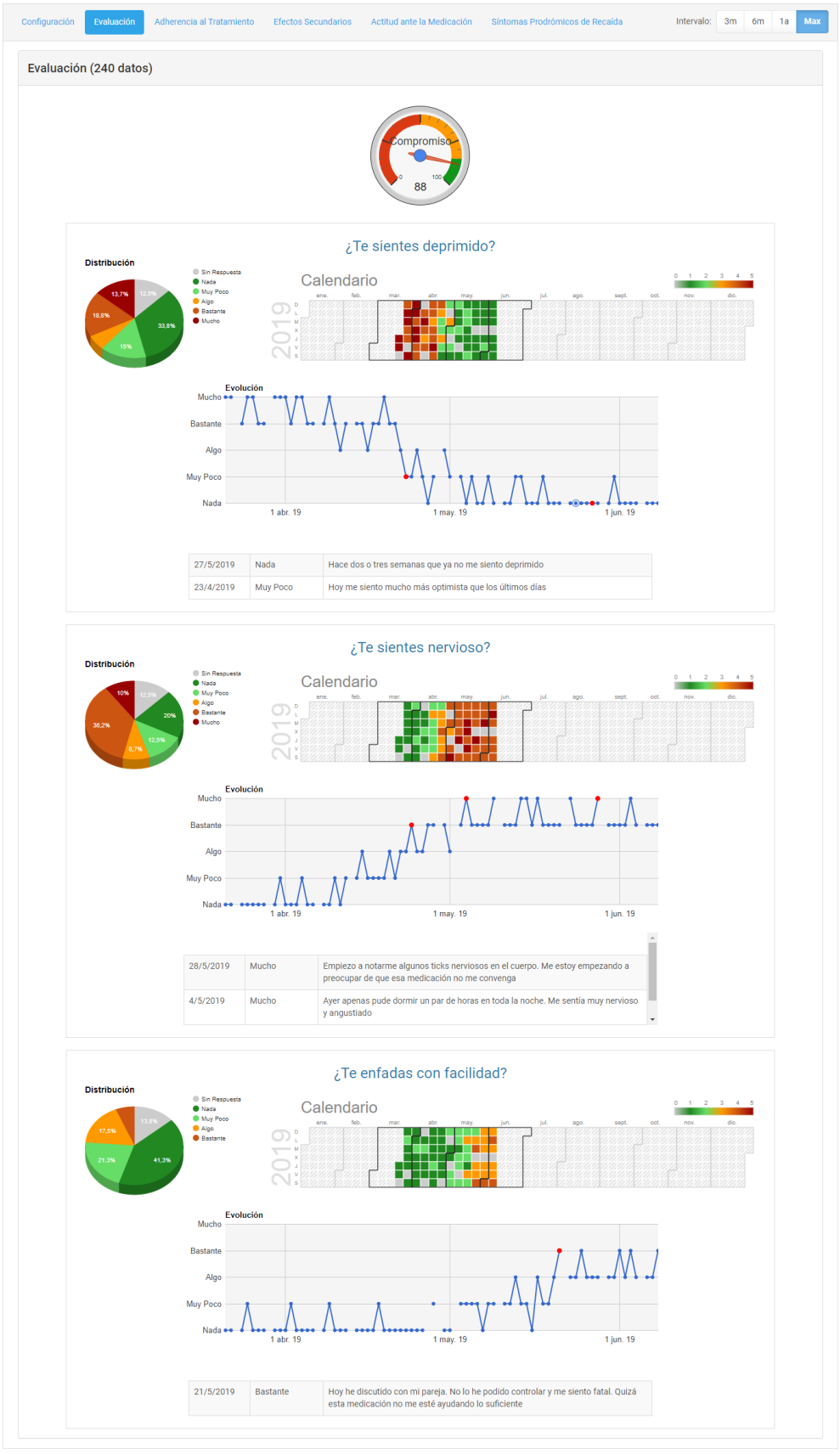
También se puede cambiar el tipo de paciente (agudo o crónico), cambiando la frecuencia de las evaluaciones.



Pestaña Configuración

Evaluación del estado de ánimo

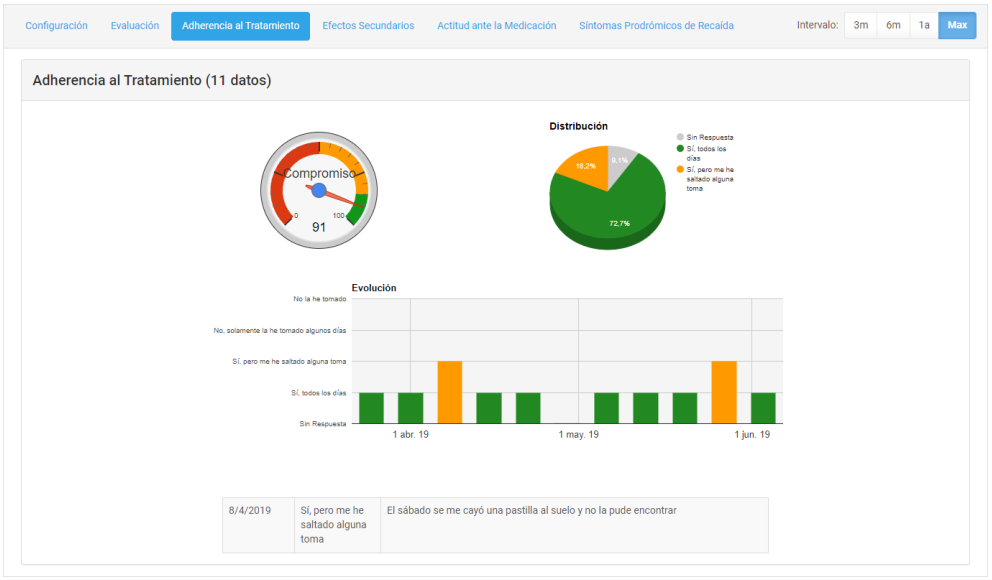
En este apartado se recogen todas las respuestas que ha generado el paciente y que comprenden la evaluación diaria (para agudos) y semanal (para crónicos). La representación de los datos se lleva a cabo mediante una gráfica circular, un calendario y una gráfica lineal. Además, los pacientes pueden voluntariamente añadir comentarios a cada una de sus respuestas, que se muestran en forma de tabla debajo de las gráficas, a la vez que añade un punto rojo en la gráfica lineal.



Pestaña Evaluación

Adherencia al Tratamiento

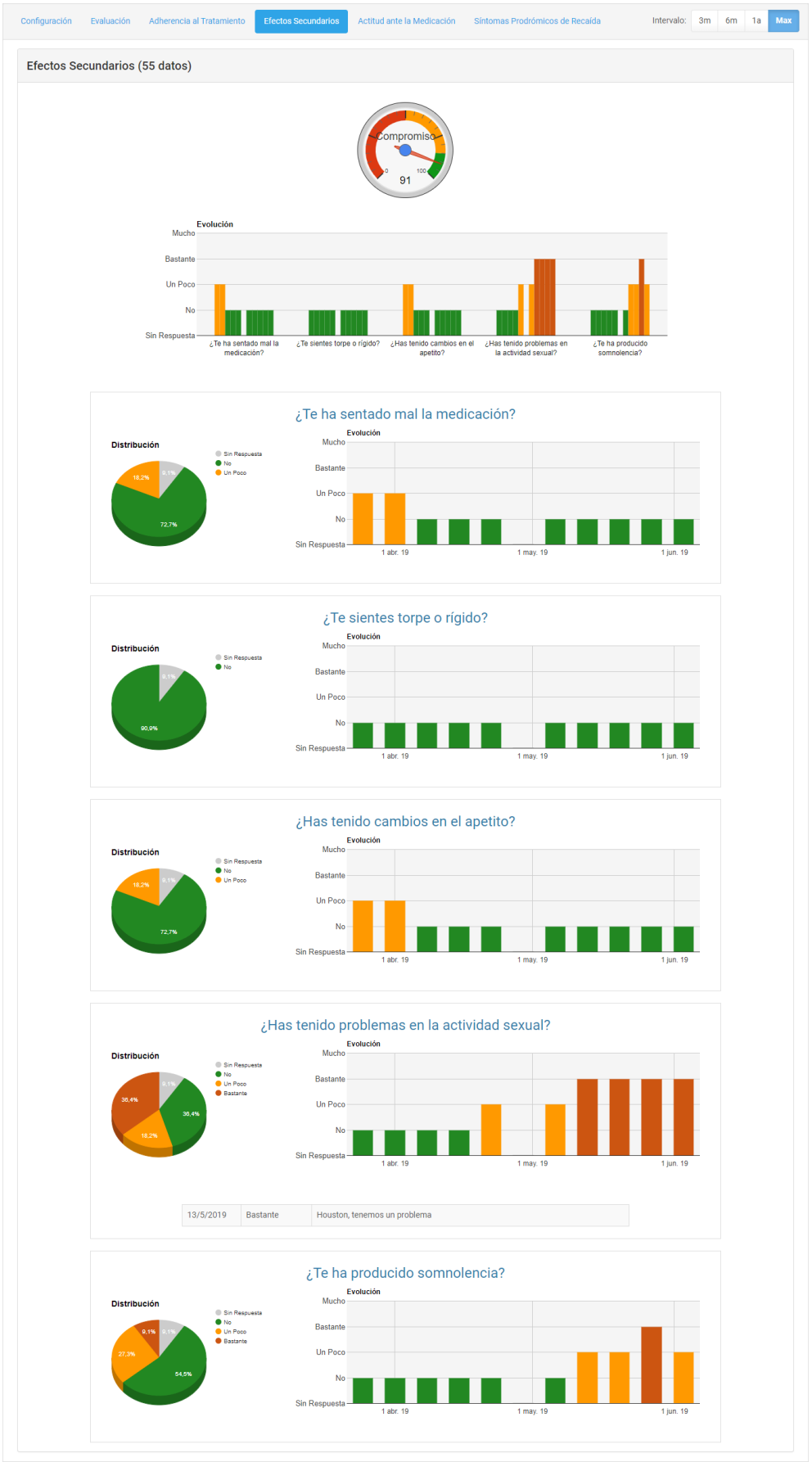
En este apartado se recogen todas las respuestas del paciente en relación a su adherencia a la medicación, cuya frecuencia puede ser semanal (para agudos) o mensual (para crónicos). Los datos son representados mediante una gráfica circular y una de columnas. También se incluyen los comentarios del paciente.



Pestaña Adherencia al tratamiento

Efectos secundarios

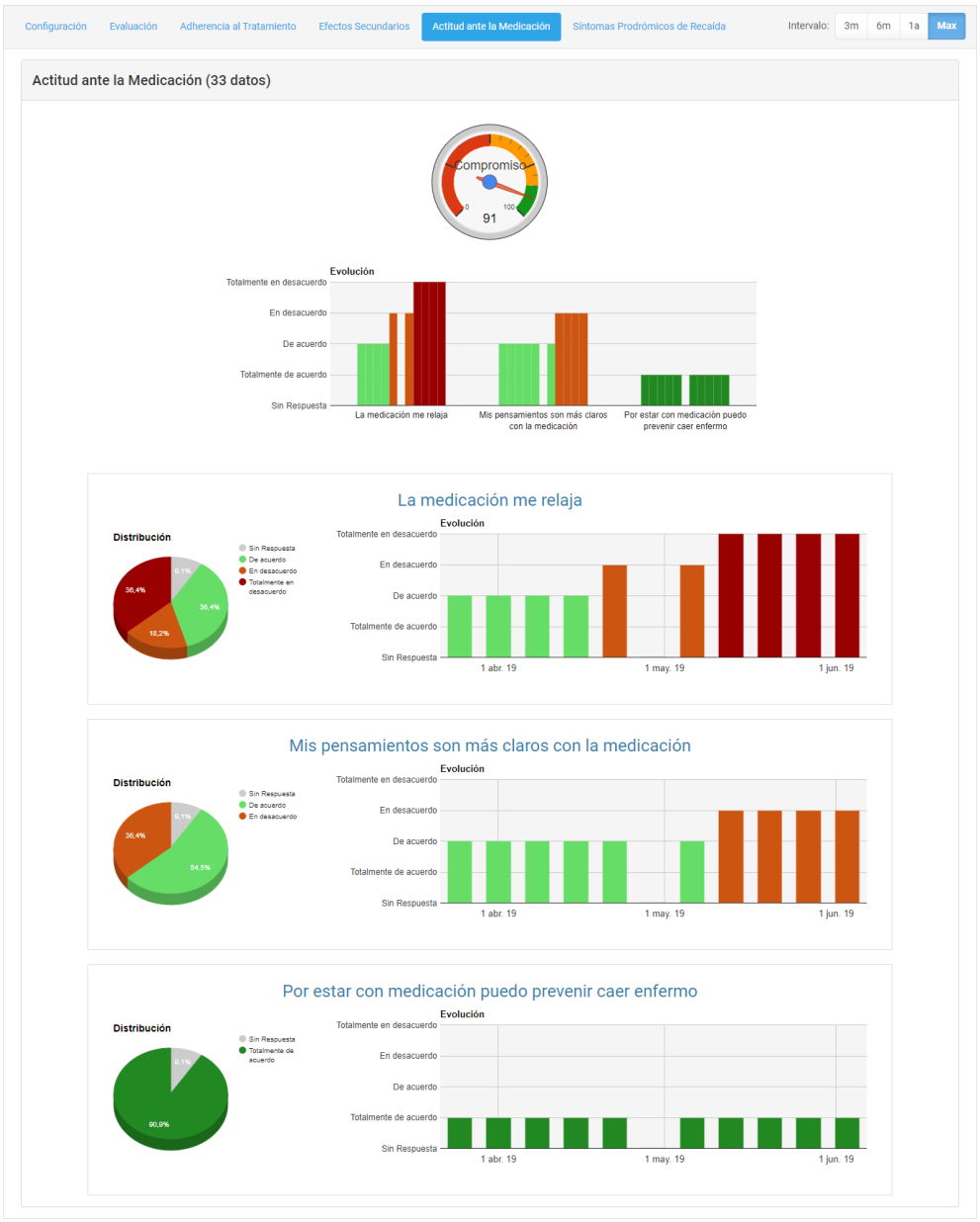
En este apartado se recogen todas las respuestas del paciente en cuanto a sus efectos secundarios, cuya frecuencia puede ser semanal (para agudos) o mensual (para crónicos). Los datos son representados mediante una gráfica circular y una de columnas, además de incluir otra gráfica adicional de columnas que engloba todas las respuestas. También se incluyen los comentarios del paciente.



Pestaña Efectos Secundarios

Actitud ante la medicación

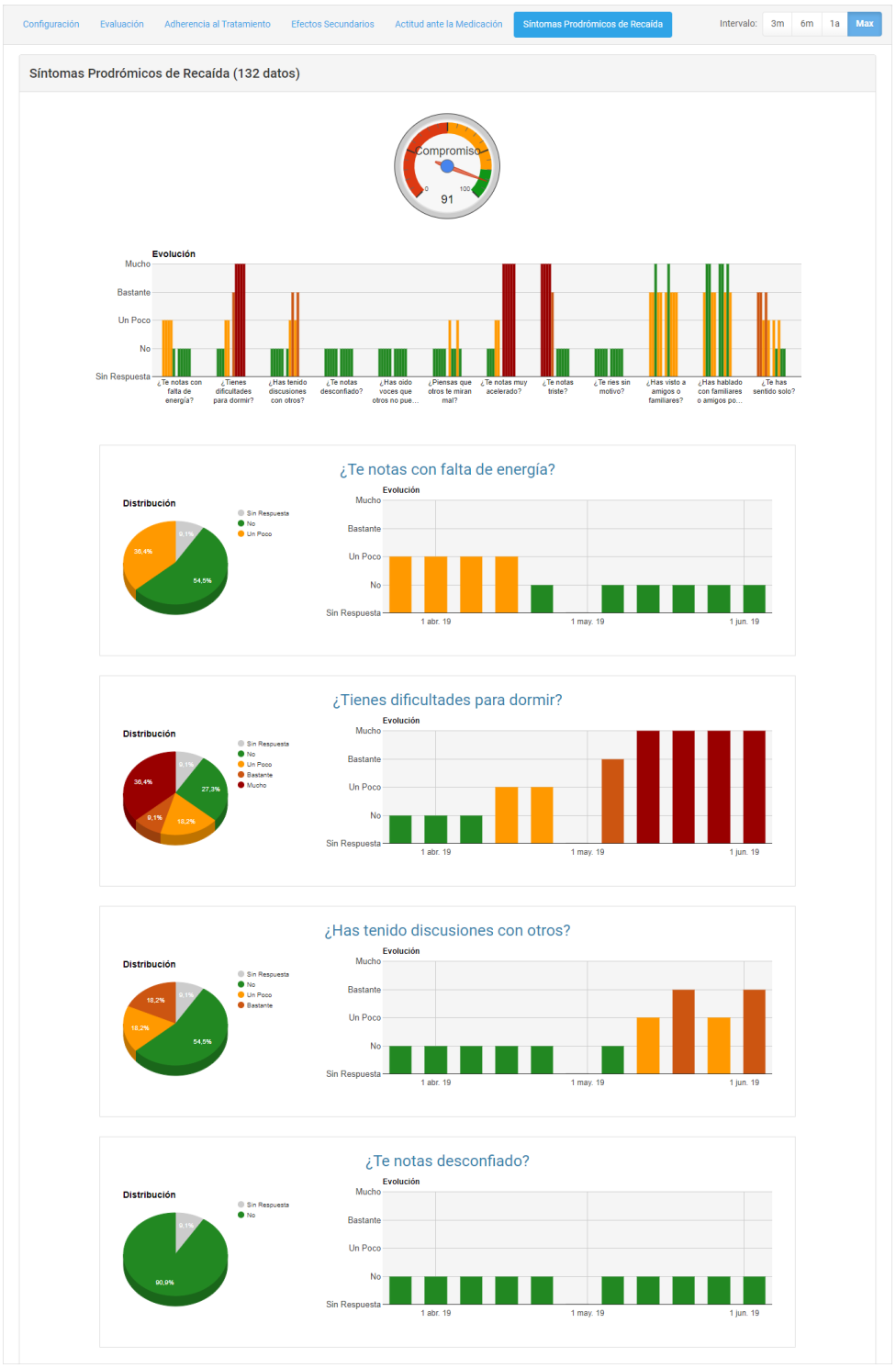
Aquí se recogen todas las respuestas del paciente en relación a su actitud ante la medicación, cuya frecuencia puede ser semanal (para agudos) o mensual (para crónicos). Los datos son representados mediante una gráfica circular y una de columnas, además de incluir otra gráfica adicional de columnas que engloba todas las respuestas. También se incluyen los comentarios del paciente.



Pestaña Actitud ante la medicación

Síntomas prodrómicos de recaída

Aquí se recogen todas las respuestas del paciente orientados a evaluar posibles síntomas de recaída psicótica o de empeoramiento en su estado clínico, cuya frecuencia puede ser semanal (para agudos) o mensual (para crónicos). Los datos son representados mediante una gráfica circular y una de columnas, además de incluir otra gráfica adicional de columnas que engloba todas las respuestas. También se incluyen los comentarios del paciente.



Pestaña Síntomas prodrómicos de recaída

5. DESVINCULACIÓN DEL DISPOSITIVO Y PACIENTE

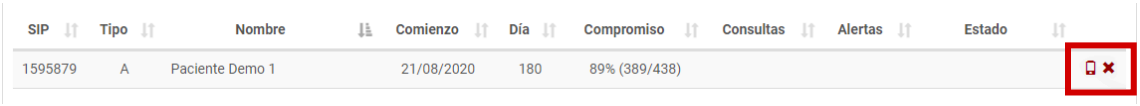
5.1. Desvinculación del dispositivo

Cada paciente en la página web solo puede estar vinculado con un dispositivo móvil, por lo que un segundo móvil no puede utilizar la app si ya está siendo utilizada por otro. Existe la opción de desvincular el dispositivo de un paciente, lo que hará que la app del paciente se desactive y deje de recibir los cuestionarios.

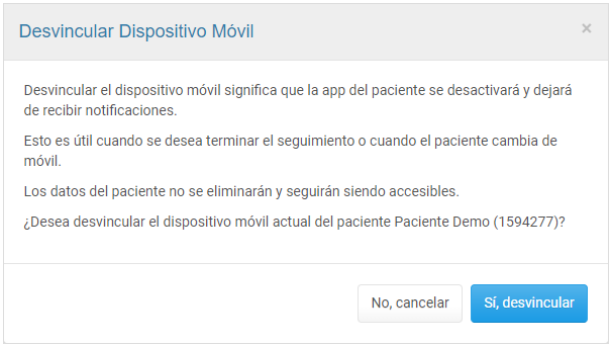
Resulta de utilidad cuando se desea pausar o terminar el seguimiento, o el paciente cambia de móvil, permitiendo al nuevo reanudar el seguimiento. Si no se desvincula primero, el nuevo móvil no podrá usar la app.

Para desvincular el dispositivo de un paciente:

1. Acceder al espacio personal del clínico.
2. Ir al listado de pacientes.
3. Situar el cursor sobre un paciente. Se mostrarán dos iconos en la parte derecha.



4. Pulsar en 
5. Confirmar la desvinculación del móvil pulsando en 



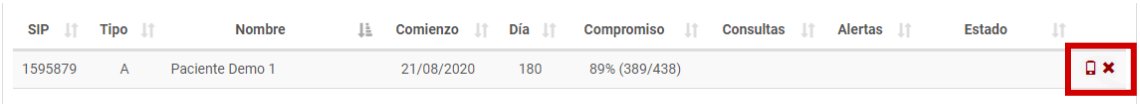
Desvincular dispositivo móvil

5.2. Desvinculación del paciente

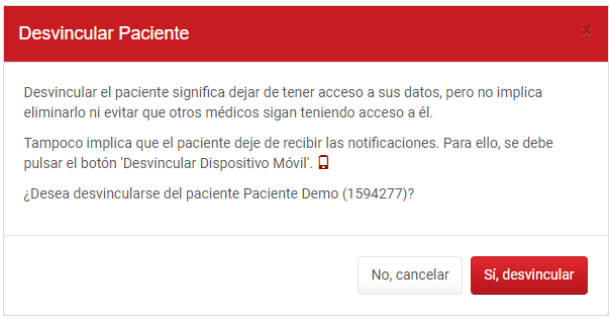
También se puede desvincular el propio paciente del clínico, haciendo que este ya no sea visible en su lista de paciente. Es importante destacar que esta acción no elimina los datos del paciente ni tampoco evita que el resto de clínicos deje de tener acceso a él.

Para desvincular el paciente:

1. Acceder al espacio personal del clínico.
2. Ir al listado de pacientes.
3. Situar el cursor sobre un paciente. Se mostrarán dos iconos en la parte derecha.



4. Pulsar en ✖
5. Confirmar la desvinculación del móvil pulsando en **Sí, desvincular**



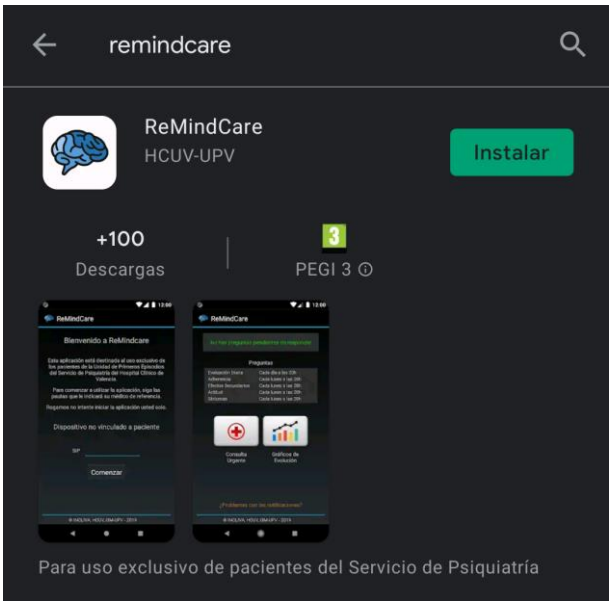
Desvincular paciente

Si se desvinculase un paciente por error, se puede volver a añadir a la lista de pacientes creándolo de nuevo (como se explica en 3. Registro del paciente).

6. INSTALACIÓN DE LA APP EN EL SMARTPHONE DEL PACIENTE

Tras el registro del paciente en el sistema por parte del clínico (ver Apartado 3. Registro del paciente), el paciente realizar los siguientes pasos en su smartphone:

1. Entrar el Google Play.
2. Buscar por “remindcare”.
3. Comprobar que la app encontrada es la correcta comparándola con la siguiente captura:



ReMindCare en Google Play

4. Instalar la app

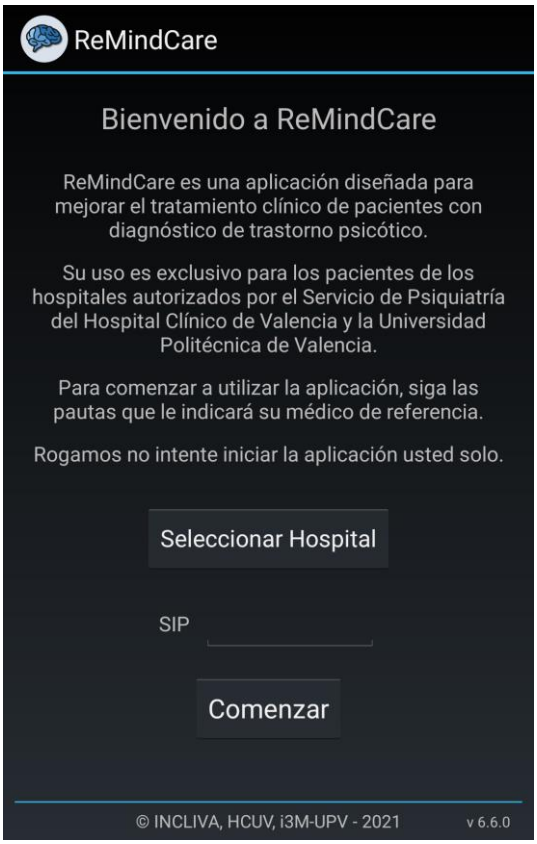
Como método alternativo, se puede instalar la app a través de un PC:

1. Abrir un navegador web
2. Ir al siguiente enlace: https://play.google.com/store/apps/details?id=com.grycap.remindcare
3. Instalar la app

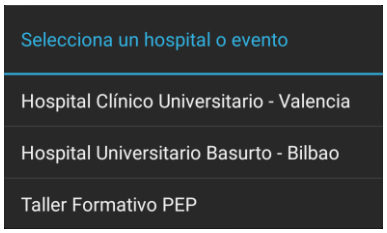
Una vez instalada la app en el dispositivo del paciente, se deberá iniciar sesión en la app. Para ello:

1. Abrir la app de ReMindCare
2. Pulsar en Seleccionar Hospital
3. Seleccionar el hospital adecuado.
4. Introducir el SIP del paciente en el campo SIP y pulsar el botón Comenzar

Es importante destacar que el paciente solo podrá iniciar sesión si su SIP ha sido registrado previamente por el clínico en la web.



Pantalla de bienvenida de la app



Selección del hospital

Una vez iniciada la sesión, el paciente accede a la pantalla principal de la app, en la que puede visualizarse:

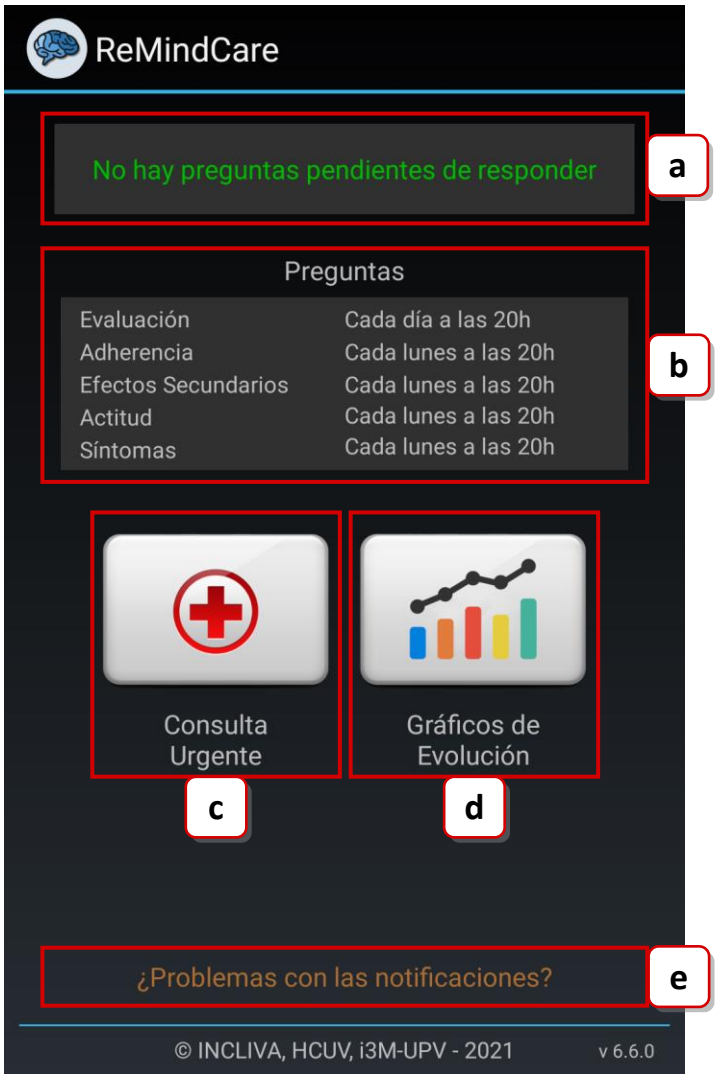
a. Estado de activación de las preguntas: indica si las preguntas están activas y pendientes de responder (sucede a partir de las 20h).

b. Resumen de preguntas: muestra el listado de los cuestionarios y con qué frecuencia se realizan.

c. Consulta urgente: botón que permite al paciente solicitar una consulta urgente.

d. Gráficos de evolución: permite al paciente visualizar todas sus respuestas en formato gráfico.

e. ¿Problemas con las notificaciones?: muestra explicaciones y soluciones en caso de tener problemas con las notificaciones en el dispositivo. Este aspecto se tratará en mayor detalle en el punto 6.1. Presentación de las notificaciones.



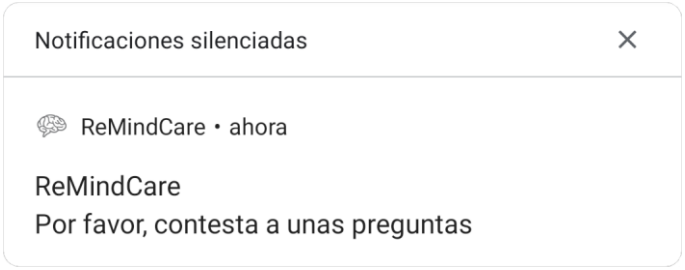
Pantalla principal

7. FUNCIONAMIENTO DE LA APP

Tras iniciar sesión en la app, el paciente empezará a recibir notificaciones para responder a los cuestionarios de forma automática.

7.1. Presentación de las notificaciones

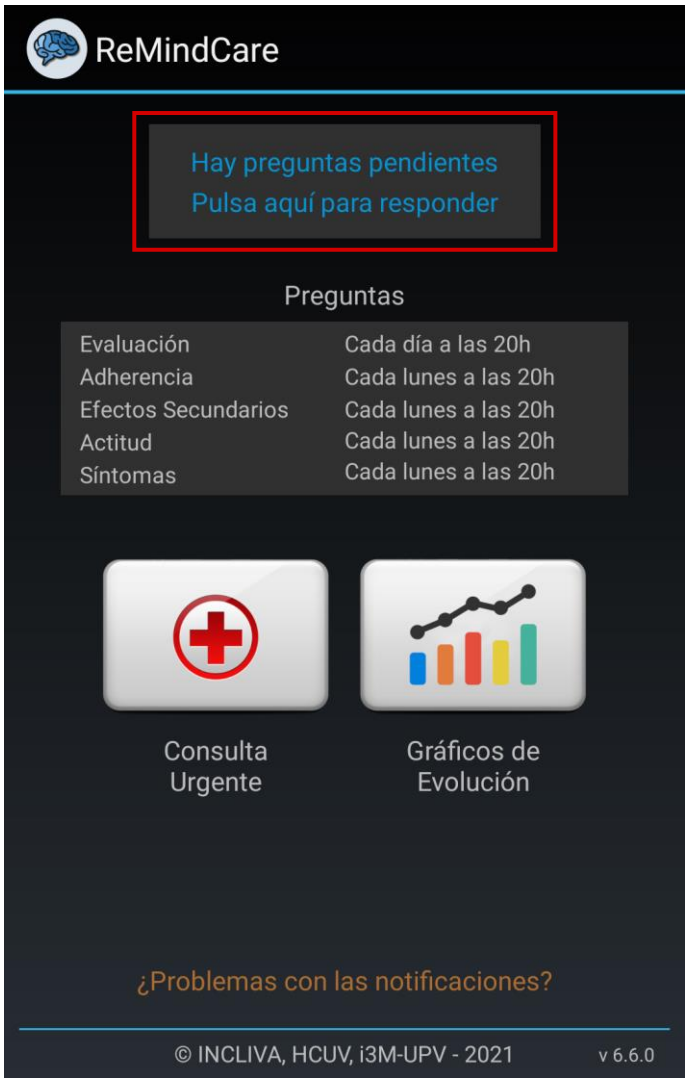
Las notificaciones son un recordatorio de que uno o varios cuestionarios se encuentran disponibles para ser contestados. Tienen el siguiente aspecto:



Los cuestionarios tienen una frecuencia distinta dependiendo de si el paciente es agudo o crónico. En todos los casos, las notificaciones se muestran a partir de las 20h.

Pacientes agudos: Un cuestionario diario y cuatro semanales.
Pacientes crónicos: Un cuestionario semanal y cuatro mensuales.

Para contestar las preguntas se puede pulsar en la notificación, o bien, entrando en la propia app, donde se podrá ver que un mensaje informando que hay preguntas activas.



Preguntas pendientes por responder

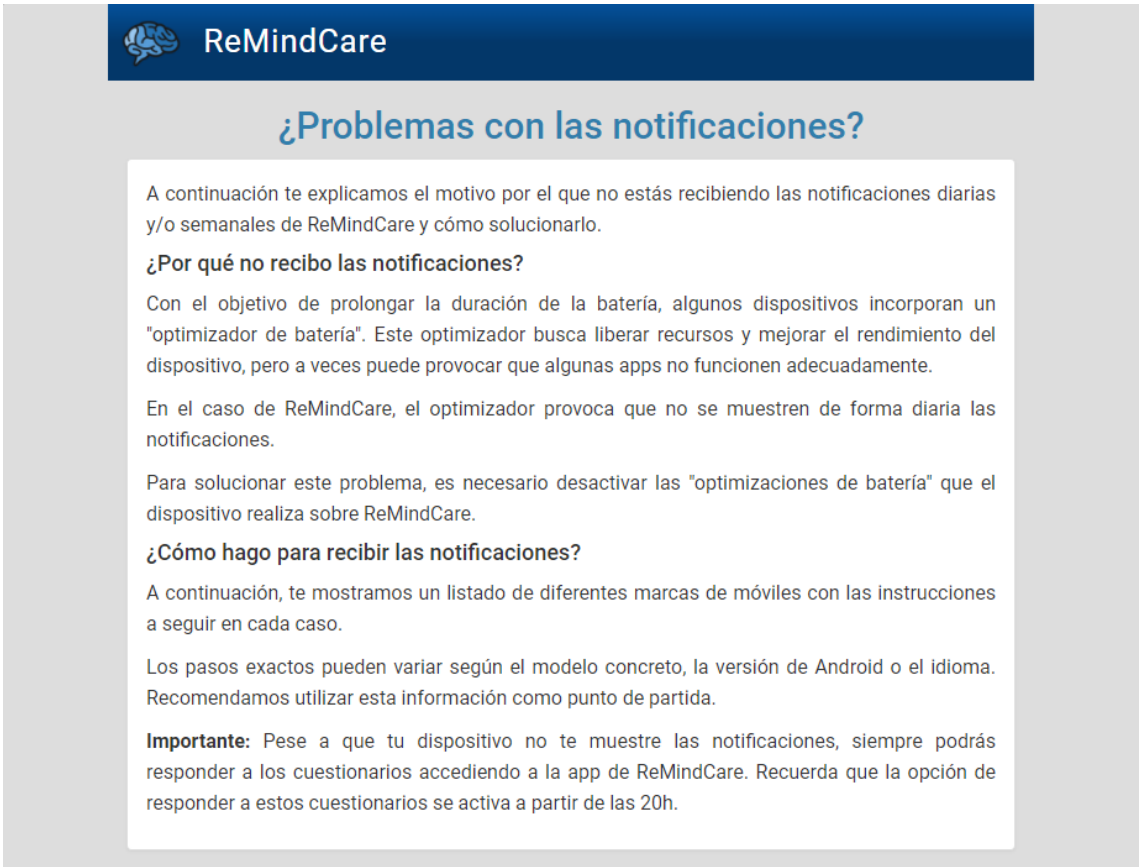
Es importante destacar que, debido a las características y restricciones de cada dispositivo móvil, puede que las notificaciones se retrasen o incluso que no lleguen a aparecer; por lo que es conveniente indicar a los pacientes que estas notificaciones son un mero recuerdo de que deben acceder a la app y que, pese a que no reciban, los cuestionarios se seguirán activando con normalidad a partir de las 20h.

Esto es debido a que estos dispositivos, con el fin de aumentar la duración de su batería y de mejorar su rendimiento, tratan de disminuir al máximo la sobrecarga del sistema. Para ello, limitan ciertas apps que el dispositivo no consideran importantes y quedan “dormidas” hasta que el paciente accede a ellas. Es por este motivo que, pese a que el paciente no reciba las notificaciones, en el momento en el cual accede a la app, esta se activa y permite al paciente responder.

En caso de que los pacientes presenten problemas con las notificaciones, existe un enlace en la pantalla principal de la app que lleva a una web con explicaciones y posibles soluciones.

¿Problemas con las notificaciones?

Al pulsar, se abrirá una web en donde se podrá consultar, para cada marca de móvil, las acciones concretas que son necesarias para solucionar el problema. No obstante, es importante indicar que se trata de un proceso que requiere cierto dominio de las tecnologías, por lo que sería interesante que los clínicos con mayor desenvoltura, ayudaran a los pacientes en el proceso.



Web ¿Problemas con las notificaciones?

7.2. Rango de respuesta

Cada cuestionario tiene un limite de tiempo para ser respondido, después del cual se desactiva y se considera no respondido.

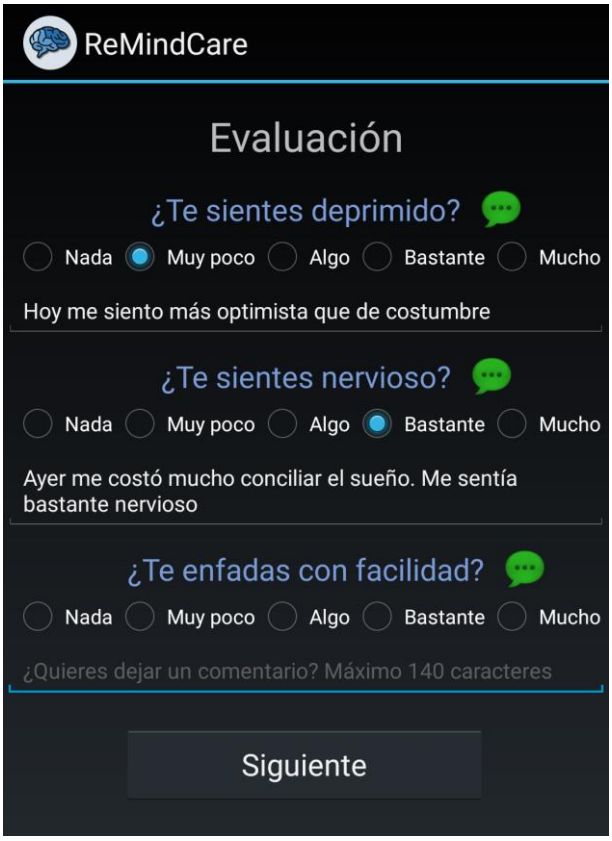
Cuestionarios diarios: Se dispone de 8h, desde las 20h hasta las 4h del día siguiente.
Cuestionarios semanales: Se dispone de 32h, desde las 20h hasta las 4h dos días después.
Cuestionarios mensuales: Se dispone de 80h, desde las 20h hasta las 4h cuatro días después.

7.3. Cuestionarios

En cada cuestionario, se muestran unas preguntas que el paciente deberá responder en la medida en que se ajusten a su propia experiencia. Las respuestas proporcionadas se presentan en una escala tipo Likert (1 al 5), donde:

1 ➞ Nada
2 ➞ Muy poco
3 ➞ Algo
4 ➞ Bastante
5 ➞ Mucho

Como apoyo a la propia respuesta, los pacientes pueden añadir comentarios a cada una de ellas mediante el icono 💬. El objetivo es que puedan justificar sus respuestas o añadir comentarios para trabajarlas con el clínico en consulta.



Comentarios a las respuestas

Los cuestionarios que se presentan al paciente son los siguientes:

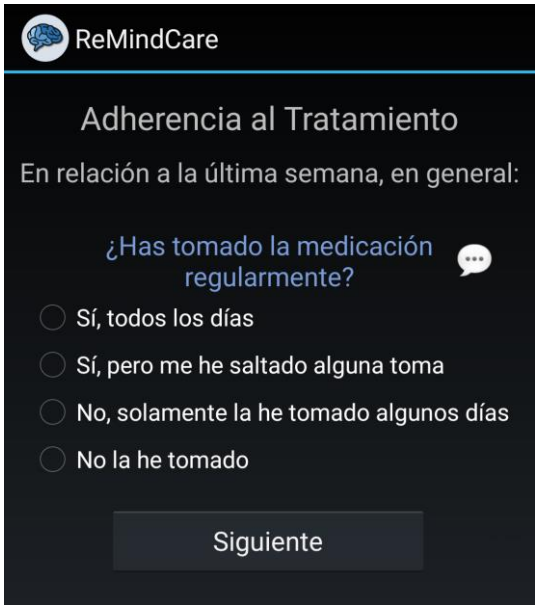
Evaluación del estado de ánimo

Cuestionario de frecuencia diaria (para agudos) o semanal (para crónicos). En él se presentan 3 cuestiones dirigidas a evaluar de forma breve su estado de salud mental general.

Evaluación

Adherencia a la medicación

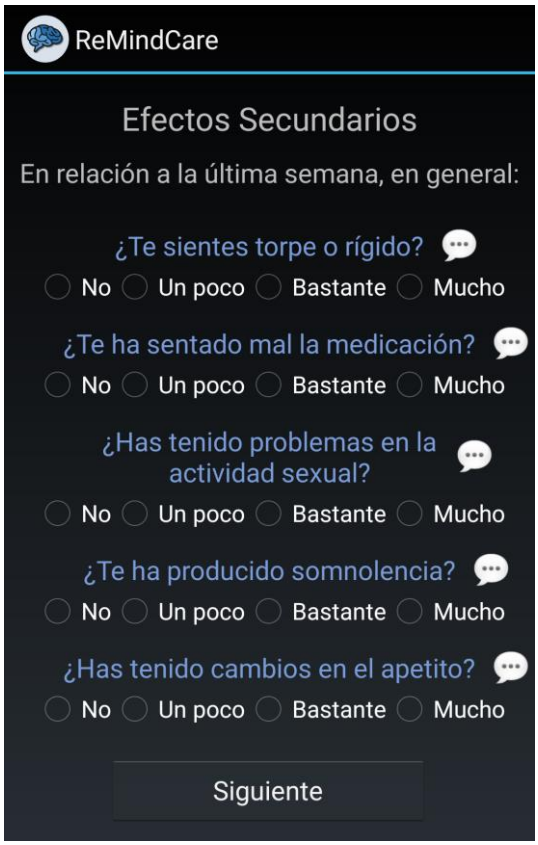
Frecuencia semanal (para agudos) o mensual (para crónicos). Es una única pregunta que evalúa la adherencia del paciente a la toma de medicación antipsicótica.



Adherencia al Tratamiento

Efectos secundarios a la toma de medicación

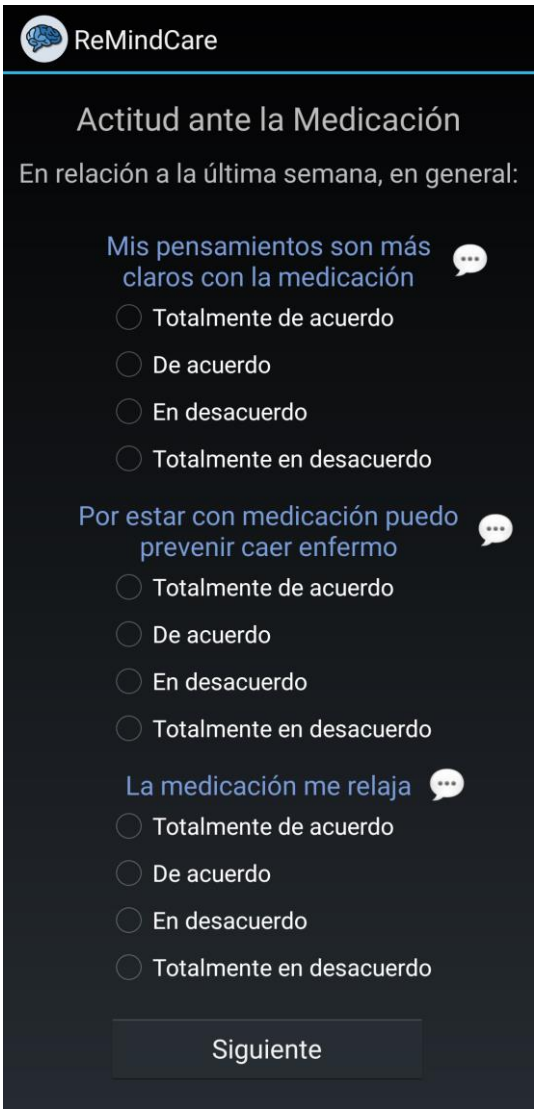
Frecuencia semanal (para agudos) o mensual (para crónicos). Evaluación de la presencia de síntomas secundarios a la toma de la medicación antipsicótica.



Efectos secundarios

Actitud hacia la medicación

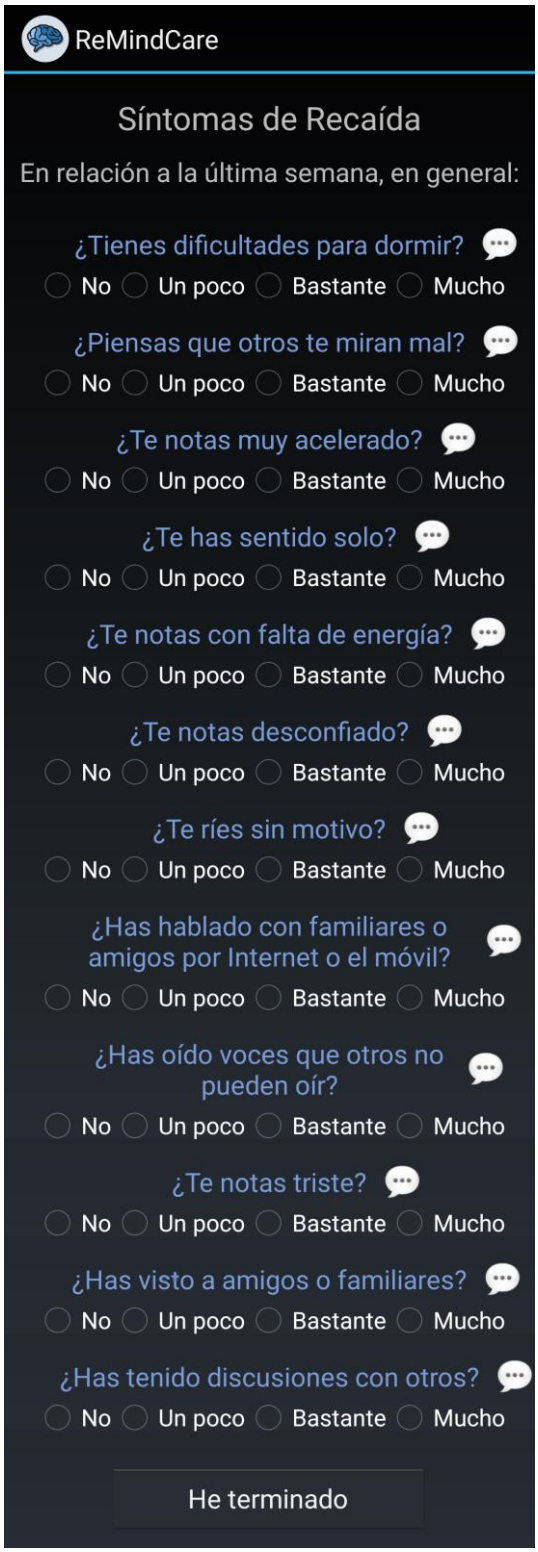
Frecuencia semanal (para agudos) o mensual (para crónicos). Tres cuestiones que evalúan la actitud del paciente hacia la toma de medicación antipsicótica.



Actitud ante la medicación

Síntomas prodrómicos de recaída

Frecuencia semanal (para agudos) o mensual (para crónicos). Cuestiones que evalúan la presencia de síntomas que puedan ser precursores de una recaída o empeoramiento en el estado de salud del paciente.



Síntomas prodrómicos de recaída

7.4. Visualización de Gráficos de Evolución

Los pacientes pueden visualizar sus respuestas a los cuestionarios accediendo a la opción de “Gráficos de evolución” que se muestra en la pantalla principal de la app. Al pulsar en el botón, se mostrará un conjunto de gráficos similar al que el clínico tiene acceso a través de la página web.

Botón de gráficos de evolución

Gráficos de evolución

7.5. Petición de consulta urgente

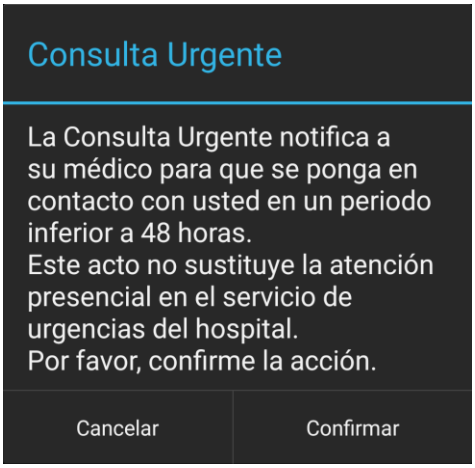
En la pantalla principal de la app, el paciente dispone de un botón de “Consulta Urgente”.

En caso de que el paciente pulse este botón, el clínico deberá ponerse en contacto con paciente en un plazo máximo de 48 horas.

Es importante que el paciente comprenda que se trata de un botón que debe pulsar en caso de notar que su estado clínico está empeorando significativamente y que debe adelantar su cita habitual con el clínico.

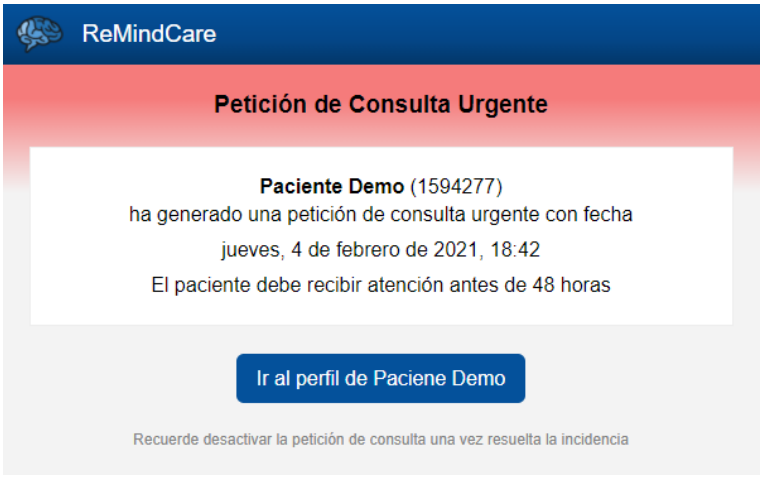
No obstante, el psiquiatra debe informar al paciente de que en caso de que su estado clínico variara de forma extrema y su estado de salud empeorará bruscamente, debe acudir a los servicios de urgencia hospitalarios.

Botón de petición de consulta urgente



Confirmación de petición de consulta urgente

Tan pronto como se realiza una petición de consulta urgente, se envía un correo electrónico a todos los clínicos que estén asociados a ese paciente, informándolos de la situación. El mail tendrá un aspecto parecido al siguiente:



Email de petición de consulta urgente

Además, tal y como se ha explicado en los apartados 2.2. Consulta urgente y 4.1. Paneles resumen de actividad, en la página web se podrá visualizar la petición y sus detalles.

7.6. Alertas

El sistema puede generar 3 tipos de alertas de forma automática vinculadas a las respuestas que el paciente ha proporcionado a los cuestionarios de la app.

Este tipo de alertas son:

a. Inactividad prolongada: Esta alerta surge cuando la app no da señales de vida durante un periodo de una semana. Esto puede ser causado porque el paciente desinstaló la app, porque tiene el móvil estropeado o porque ha decidido comprarse uno nuevo y la app todavía reside en el antiguo, el cual está apagado.

b. Compromiso bajo: Esta alerta aparece cuando el paciente contesta un porcentaje inferior al 35% en las últimas dos semanas.

c. Cambio brusco: Esta alerta se genera cuando el sistema detecta una variación superior o igual a dos puntos en las respuestas que el paciente ha proporcionado a los cuestionarios de evaluación del estado de ánimo y síntomas prodrómicos de recaída.

Al activarse una alerta, y al igual que ocurre con las peticiones de consulta urgente, se envía un correo electrónico a todos los clínicos que estén asociados a ese paciente, informándolos de la alerta. El mail tendrá un aspecto parecido al siguiente:

Email de alerta

También, como se ha explicado en los apartados 2.3. Alertas y 4.1. Paneles resumen de actividad, en la página web se podrá visualizar la alerta y sus detalles.

ANEXO I. EJEMPLO DE INFORME

DEPARTAMENT DE SALUT DE VALÈNCIA
CLÍNIC-LA MALVA-ROSA

GENERALITAT VALENCIANA
CONSELLERIA DE SANITAT UNIVERSAL I SALUT PÚBLICA

INCLIVA
Instituto de Investigación Sanitaria

SERVICIO DE PSIQUIATRÍA
UNIDAD DE PRIMEROS EPISODIOS PSICÓTICOS

Informe ReMindCare

Fecha de creación del informe: 12/06/2019 10:45

Nombre del paciente: Paciente Demo

SIP del paciente: 1594277

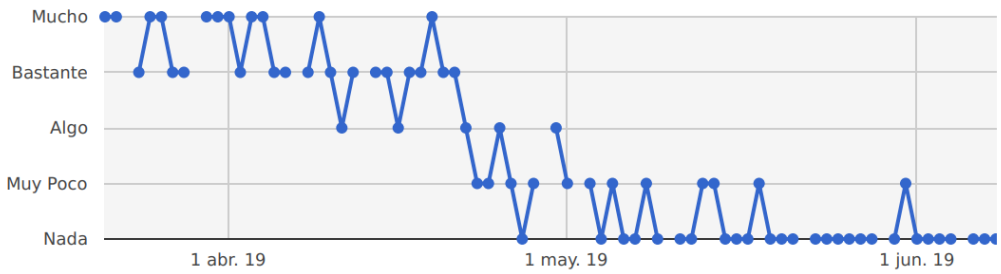
Intervalo de los datos: del 21/03/2019 al 08/06/2019

Compromiso total: 89% (419 de 471 preguntas respondidas)

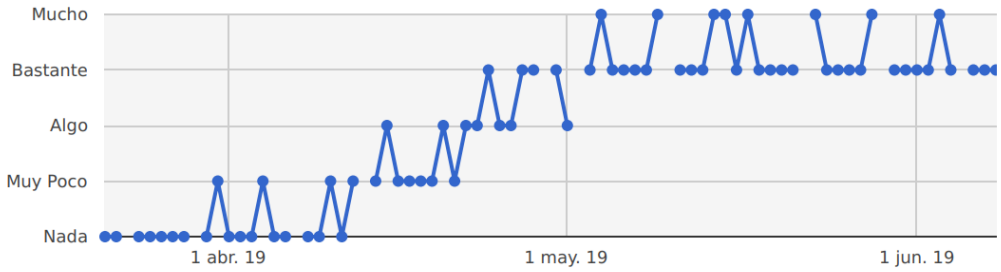
Consultas urgentes generadas: 2

Alertas generadas: 4

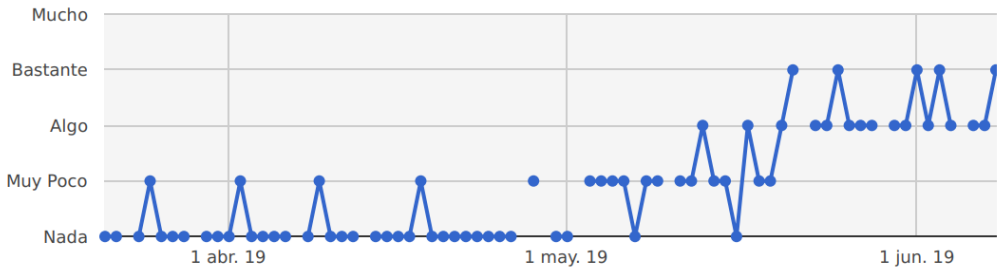
¿Te sientes deprimido? (Eval. Diaria)



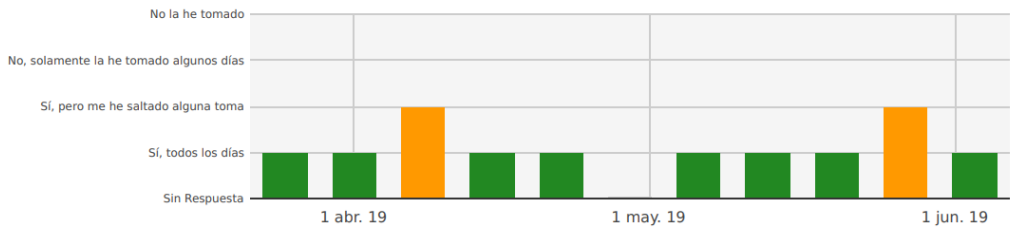
¿Te sientes nervioso? (Eval. Diaria)



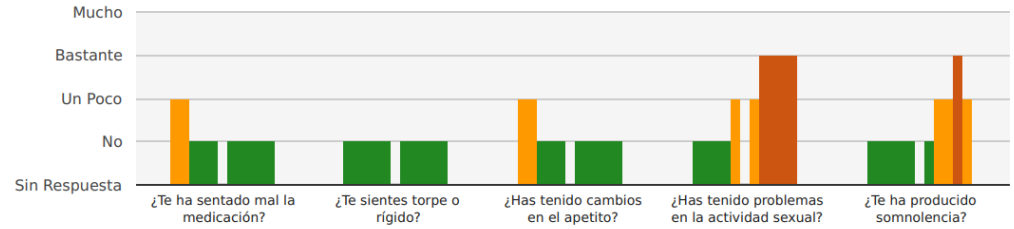
¿Te enfadas con facilidad? (Eval. Diaria)



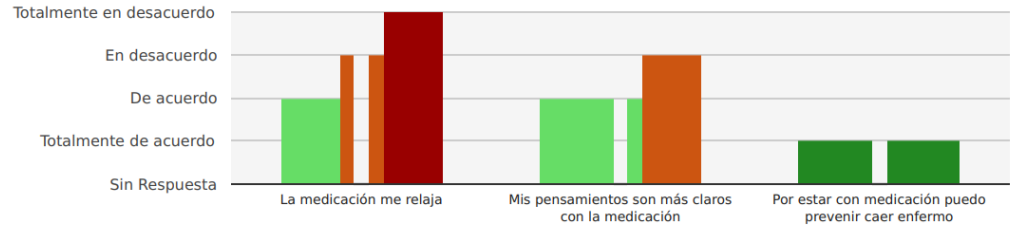
Adherencia al Tratamiento (Eval. Semanal)



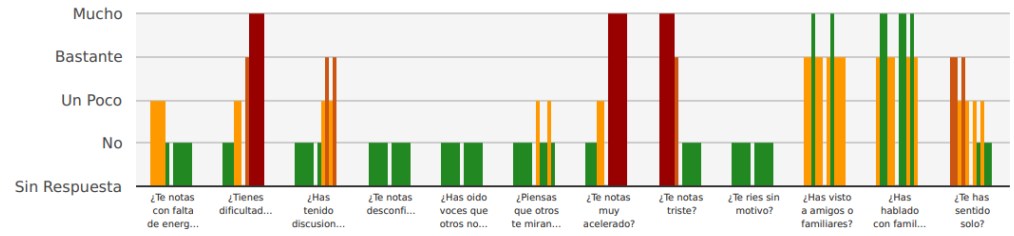
Efectos Secundarios (Eval. Semanal)



Actitud ante la Medicación (Eval. Semanal)



Síntomas Prodrómicos de Recaída (Eval. Semanal)



Historial de Consultas urgentes

Día	Hora
martes, 16 de abril de 2019	0:32
jueves, 2 de mayo de 2019	19:08

Historial de Alertas

Alerta	Desde	Hasta
Cambio Drástico en Síntomas Prodrómicos de Recaída - ¿Te notas muy acelerado?	06/05/2019	22/04/2019
Cambio Drástico en Síntomas Prodrómicos de Recaída - ¿Te notas triste?	06/05/2019	22/04/2019
Cambio Drástico en Evaluación - ¿Te sientes nervioso?	28/04/2019	21/04/2019
Cambio Drástico en Evaluación - ¿Te sientes deprimido?	26/04/2019	19/04/2019

APÉNDICE IV:

Manual de usuario breve de la aplicación ReMindCare

para el paciente.

REMINDCARE APP

MANUAL DE USUARIO

Versión para el paciente

Manual de uso de la app ReMindCare para pacientes

App desarrollada por la Unidad de Psiquiatría del Hospital Clínico de Valencia en colaboración con la Universidad Politécnica de Valencia.

Dirigida a pacientes con diagnóstico de Trastorno Psicótico con el fin de mejorar la evaluación del estado clínico del paciente y la comunicación entre paciente y médico.

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INCLIVA Instituto de Investigación Sanitaria
UNIVERSITAT POLITÈCNICA DE VALÈNCIA
i3M Instituto de Instrumentación para Imagen Molecular

0. DESCRIPCIÓN DE LA APP:

ReMindCare es una app que realiza registros diarios del estado de salud de pacientes con trastorno psicótico con el fin de mejorar la evaluación de su estado clínico y la comunicación entre paciente y médico.

1. INSTALACIÓN DE LA APP EN SU SMARTPHONE:

Una vez su clínico le haya registrado en el sistema, deberá:

1. Acceder a la app ReMindCare en Google Play, escribiendo el nombre de la app en el buscador de Google Play.
2. Descargar la app
3. Acceder a la app una vez descargada en el escritorio del móvil.
4. Hacer click en “Seleccionar hospital” y pulsar en “Hospital Clínico Universitario de Valencia”
5. Introducir su SIP y pulsar el botón de “comenzar”.

2. FUNCIONAMIENTO DE LA APP:

Tras registrarse en el sistema pulsando el botón de “comenzar” empezará a recibir las notificaciones para responder a los cuestionarios de forma automática.

2.1. Activación de los cuestionarios:

- **Evaluaciones diarias:** Todos los días a partir de las 20:00h
- **Evaluaciones semanales:** Lunes a partir de las 20:00h

*** IMPORTANTE**: **TODOS** los días debe recibir una notificación para contestar a los cuestionarios. En caso de no recibirla, no se preocupe, los cuestionarios se activan igualmente a partir de las 20h. Por lo que a partir de ese momento, puede acceder a la app y contestarlos. En caso de que tenga problemas con la app, por favor contacte con su médico de referencia.

2.2. Rango de respuesta:

- **Evaluaciones diarias:** Dispone de 8h desde la presentación del aviso para responder a los cuestionarios (20:00h-4:00h)
- **Evaluaciones semanales:** Dispone de 24h desde la presentación del aviso para responder a los cuestionarios.

2.3. Cuestionarios:

Estas notificaciones, tienen el objetivo de recordarle que debe acceder a la app para responder a unos cuestionarios en los que se evalúa su estado clínico. En ellos, aparecen unas preguntas que deberá responder en la medida en que se ajusten a su propia experiencia marcando en cada cuestión el ítem que mejor le represente (1=Nada, 2=Muy poco, 3=Algo, 4=Bastante, 5=Mucho).

Los cuestionarios que se presentan son los siguientes:

a) ***Evaluación diaria del estado de ánimo***: 3 cuestiones dirigidas a evaluar de forma breve su estado de salud mental general.
b) ***Evaluación semanal de adherencia a la medicación***: Única pregunta que evalúa la adherencia a la toma de medicación antipsicótica.
c) ***Evaluación semanal de efectos secundarios a la toma de medicación***: Evaluación de la presencia de síntomas secundarios a la toma de la medicación antipsicótica.
d) ***Evaluación semanal de la actitud hacia la medicación:*** Tres cuestiones que evalúan su actitud hacia la toma de medicación antipsicótica.
e) ***Evaluación semanal de síntomas prodrómicos de recaída:*** Cuestiones que evalúan la presencia de síntomas que puedan ser precursores de una recaída o empeoramiento en su estado de salud.

Como podrá ver, al lado de cada cuestión aparece un símbolo blanco (💬) Al pulsar en este icono verá que se le abre un desplegable en el que puede introducir texto. Esta opción le permite incorporar comentarios a las respuestas que desee, de esta forma puede personalizar más sus respuestas y comentarlas en la cita con su médico.

En caso de que se detecten grandes variaciones en sus respuestas o que se detecte un periodo de inactividad superior a dos semanas, podrá ser contactado telefónicamente por los servicios médicos.

Puede visualizar sus respuestas pulsando el botón que se encuentra en la pantalla principal “Gráficos de evolución”.

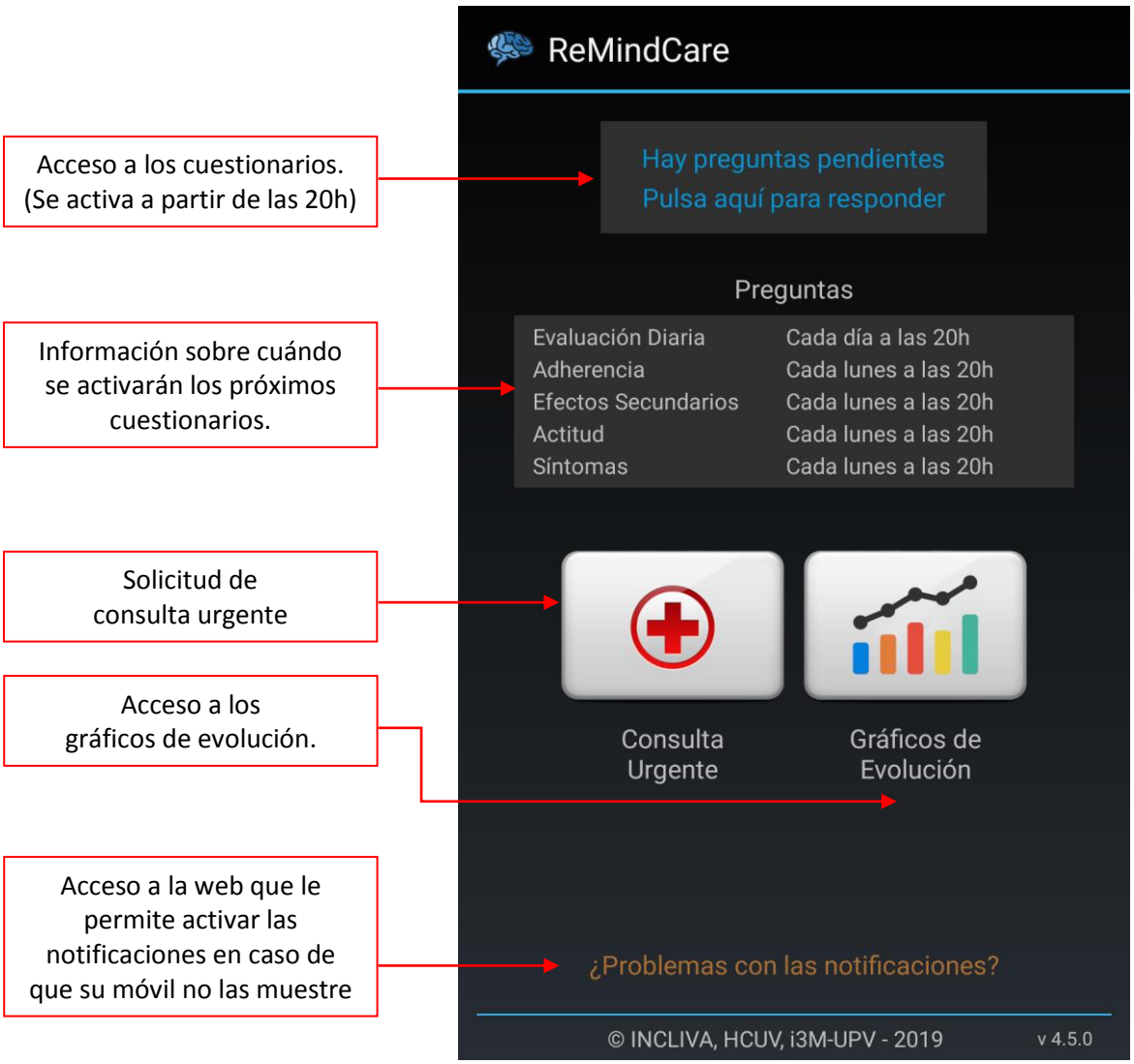
2.4. Consulta urgente:

Al acceder a la app en su dispositivo, dispone de un botón en el que se indica “Consulta urgente”. En caso de que pulse este botón, el clínico debe ponerse en contacto con usted en un plazo máximo de 48 horas.

Es importante que comprenda que se trata de un botón que debe pulsar en

caso de notar que su estado clínico está empeorando significativamente y que debe adelantar su cita habitual con el clínico. No obstante, en caso de que su estado de salud empeorará bruscamente, debe acudir a los servicios de urgencia hospitalarios.

ESQUEMA DE LA PANTALLA PRINCIPAL DE REMINDCARE APP



APÉNDICE V:

Bonet L, Llacer B, Hernandez M, Arce D, Blanquer I, Cañete C et al. T59. Filling the gap between research and clinical practice: a new app for patients with first episode of psychosis. *Schizophr Bull*. 2019;45(Suppl 2):S226.

T58. DEVELOPMENT OF AN AL-BASED WEB DIAGNOSTIC SYSTEM FOR PHENOTYPING PSYCHIATRIC DISORDERS

Yu-Wei Chang*[,1], Shih-Jen Tsai[1], Albert Yang[2]
[1]Taipei Veterans General Hospital; [2]Beth Israel Deaconess Medical Center

Background: The technique of phenotyping psychiatric disorders with neuroimaging data (e.g. MRI, PET) allows physicians to not only better diagnose but also introduce early interventions if necessary than traditional approaches. Recently, there is an increasing interest initiating AI-based medical diagnostic applications for oncology and pathology. One distinguished explainable DNN (EDNN) framework is currently presented for identifying key structural deficits related to the known structural pathology of schizophrenia [1].
As a consequence, this project aims to develop an Al-based web diagnostic system under this latest EDNN framework for diagnosing probability of schizophrenia with 3D visualization of subjects' neuroimaging dataset.
Methods: The Al-based web diagnostic system consists of three main components: the website, the server and the database.
The website is served up as HTML and JavaScript (js) files, both of which have become enormously popular in web development. All the data will be converted for graphical preparations and visualizations at this level through user's local computing resources and WebGL for the graphical abilities.
The server is constructed with Node.js, a platform on Chrome's JavaScript runtime for building scalable network applications. Node.js has been tested to yield better efficiency than PHP and Python-Web [2]. On server side, the EDNN framework is deployed to communicate with the database.
The database is the data storage for all the dataset to be viewed and to be added. For the verification of the applied EDNN framework, the diagnostic system is validated in respect of accuracy with structural brain magnetic resonance (MR) images. The structural MR images were obtained from 200 schizophrenic patients and 200 age- and sex-matched healthy control subjects recruited at Taipei Veterans General Hospital, Taiwan.
Results: Using the EDNN algorithm, our Al-based web diagnostic system achieves 80% accuracy rate in schizophrenia classification and is capable of predicting a schizophrenia probability for reference. In addition, our system can display subjects' 3D MRI image with specifically highlighted brain voxels identified by EDNN framework, enabling users to efficiently evaluate the imaging data and to phenotype schizophrenia.
Discussion: The current developing Al-based web diagnostic system makes the EDNN framework really accessible to both scientific and clinical community. Our next step is to extend the applicability of this diagnostic system from schizophrenia to other major psychiatric disorders (e.g. schizoaffective disorder, psychotic bipolar disorder, and Alzheimer's disease), making it a powerful and practical diagnosis tool in future medical applications.

T59. FILLING THE GAP BETWEEN RESEARCH AND CLINICAL PRACTICE: A NEW APP FOR PATIENTS WITH FIRST EPISODE OF PSYCHOSIS

Lucia Bonet*[,1], Blanca Llacer[2], David Arce[3], Ignacio Blanquer[3], Miguel Hernandez[4], Carlos Cañete[5], Julio Sanjuán[6]
[1]University of Valencia; [2]CIBERSAM, Valencia; [3]Universidad Politecnica de Valencia; [4]Clinic Hospital Valencia, CIBERSAM; [5]Clinic Hospital, Valencia INCLIVA,CIBERSAM [6]Research Institute of Clinic University Hospital of Valencia (INCLIVA), Center for Networking Biomedical Research in Mental Health (CIBERSAM), Clinic University Hospital, University of Valencia School of Medicine

Background: In spite of promising results of mobile Health (mHealth) interventions for patients with psychosis, integration of these appliances into clinical practice remains a significant challenge (Bonet et al. 2017). Moreover, some studies have pointed out that percentages between 19–38% of patients have had negative experiences related to internet or cell phone usage, which may increase the risk of psychotic relapses (Bonet et al. 2018). In order to address these issues, we have developed an app called "ReMindCare" whose main objective is being simple, useful and automatically integrated into clinical practice.
Methods: ReMindCare is an app that collects the following information: a) Three daily questions regarding anxiety, sadness and irritability b) 18 weekly questions about: 1. level of adherence to medication, 2. presence of medication side-effects, 3. prodromal psychotic symptoms and 4. attitude towards medication. Answers to these questions are displayed following a Likert scale (1 to 5). In addition, patients are able to contact clinicians by clicking an "urgent consultation" tab. All this information is summarized in a clinical report which is given to patients and uploaded at their electronic medical record at the hospital database, being accessible for consultation for any clinician involved in treatment of the patient. Exclusion criteria are: presence of severe mental disability, language barriers and not to sign the informant consent. All patients from the First Episode of Psychosis Unit are being offered the use of ReMindCare as a part of their usual treatment.
Results: 56 patients have been offered the app (from 26 September to 26 November). Mean age 32.96 (SD=8.82), 78.6% are male, 87,5% Caucasian, 80.4% single, 80% have medium education level (until 16 years old) or more and 98.2% are taking antipsychotic medication. From this sample, 38 patients (67.9%) accepted using the app. Significant differences were found between users and no-users regarding: previous suicidal attempts (None of no-users have had previous suicidal attempts while 37.8% of users have) ($\chi 2$= 8.23 p=.004), years of illness (65.8% of users have less than 3 years of illness compared to 38.9% of no-users) ($\chi 2$= 3.61 p=.005) and in GAF punctuations (50% of users have punctuations between 100–60 in GAF compared to 33.3% of no users, and 13.2% have punctuations lower than 50 compared 50% of no-users) ($\chi 2$=9.03 p=.01). No differences were found in other clinical and demographic factors.
Discussion: To our knowledge, this is the first attempt to integrate the use of mHealth technologies into daily practice and electronic clinical records. Rate of acceptance is high, however some clinical differences regarding years of illness and GAF punctuations, may indicate that chronic patients are less willing to use ReMindCare. On the contrary, patients who have had previous suicide attempts are very interested in using the app. This can be due to the "urgent consultation" function which would allow them to contact clinicians in case of mood aggravation. ReMindCare is being especially useful in order to detect deception into medication intake in some patients. Encouraging feedback is being received for patients and clinicians, especially in regards of improvement of quality of interview and clinical alliance.
References:
Bonet L, Izquierdo C, Escartí MJ, Sancho JV, Arce D, Blanquer I et al. Utilización de tecnologías móviles en pacientes con psicosis: una revisión sistemática. Rev Psiquiatr Salud Ment 2017 Jul-Sept; 10(3): 168–78.
Bonet L, Llácer B, Hernandez-Viadel M, Arce D, Blanquer I, Cañete C et al. Differences in the Use and Opinions About New eHealth Technologies Among Patients with Psychosis: Structured Questionnaire. JMIR Ment Health. 2018 Jul;5(3):e51.

T60. SOCIAL MEDIA AND SOCIAL FUNCTIONING IN PSYCHOSIS: A SYSTEMATIC REVIEW

Jone Bjornestad*[,1], Wenche ten Velden Hegelstad[2], Henrik Berg[3], Larry Davidson[4], Inge Joa[2], Jan Olav Johannessen[2], Ingrid Melle[5], Helen J. Stain[6], Ståle Pallesen[3]
[1]University of Stavanger; [2]TIPS – Centre for Clinical Research in Psychosis, Stavanger University Hospital; [3]University of Bergen; [4]Yale University; [5]NORMENT KG Jebsen Centre for Psychosis

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FILLING THE GAP BETWEEN RESEARCH AND CLINICAL PRACTICE: A NEW APP FOR PATIENTS WITH FIRST EPISODE OF PSYCHOSIS.

Lucia Bonet [1], David Arce[2] , Ignacio Blanquer [2], Julio Sanjuán[1,3,4]

[1] Department of Clinic Medicine, School of Medicine, University of Valencia, Valencia, Spain, [2] Institute of Instrumentation for Molecular Imaging (I3M), Joint Centre CSIC & Universitat Politècnica de València, Valencia, Spain, [3] Centre of Biomedical Investigation in Mental Health (CIBERSAM), Spanish Government Carlos III Health Institute, Valencia, Spain, [4]Department of Mental Health, Sanitary Research Institute of Valencia (INCLIVA), Hospital Clinic of Valencia, Valencia, Spain

BACKGROUND:

In spite of promising results of mobile Health (mHealth) interventions for patients with psychosis (Ben-Zeev et al. 2018), integration of these appliances into clinical practice (Bonet et al. 2017) and engagement of patients (Torous et al. 2018) remains a significant challenge. Moreover, some studies have pointed out that percentages between 19-38% of patients have had negative experiences related to internet or smartphone usage, which may increase the risk of psychotic relapses (Bonet et al. 2018). In order to address these issues, we have develop an application (app) for smartphone called "**ReMindCare**" whose **main objective is simplicity, usability and automatic integration into clinical practice.**

METHODS:

App development: The process of design and testing the app can be divided into different phases. As show in **Figure 1**.

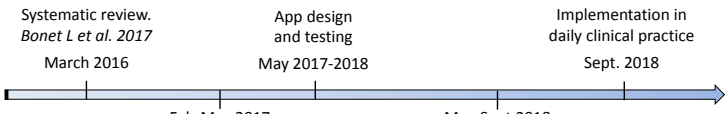


Figure 1. App development process

Participants: Patients from first episode of psychosis unit. Criteria for exclusion are: presence of severe mental disability, language barriers and not to sign the informant consent. All patients from the unit are being offered the use of ReMindCare as a part of their usual psychiatric treatment since 26th September 2018.

Instrument and procedure: The app collects the following information: a) 3 daily questions regarding anxiety, sadness and irritability b) 18 weekly questions about: 1.level of adherence to medication, 2.presence of medication side-effects, 3. prodromal psychotic symptoms and 4. attitude towards medication. This information is depicted in **Images 1-3**. Answers are displayed following a Likert scale (1 to 5) and can be consulted by clinicians in the ReMindCare´s private website. In addition, patients are able to contact clinicians by clicking an "urgent consultation" button. All this information is summarized in a clinical report which is given to patients and uploaded at their electronic medical record at the hospital database, being accessible for consultation for any clinician involved in treatment of the patient.

Image 1. Screenshot of ReMindCare app´s main menu

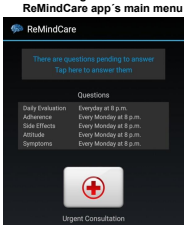


Image 2. Screenshot of the app´s weekly assessments

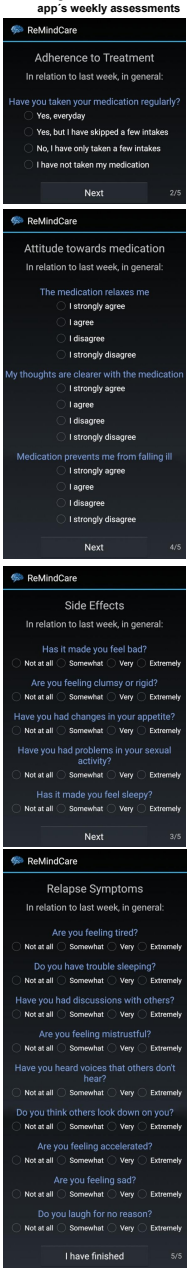
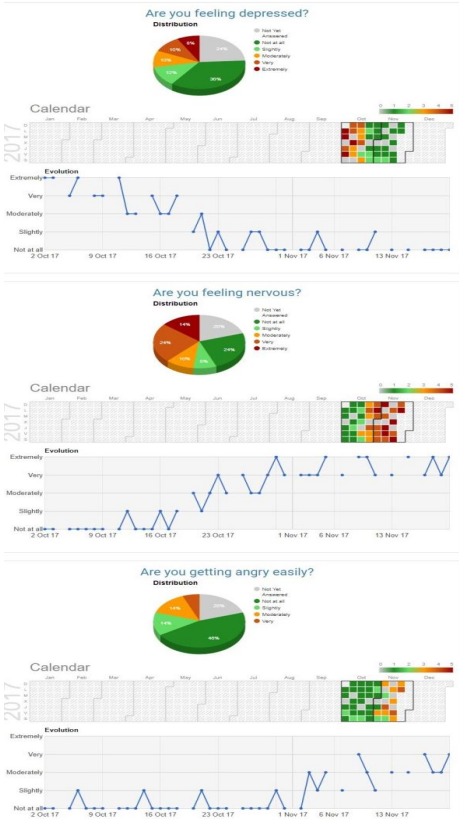
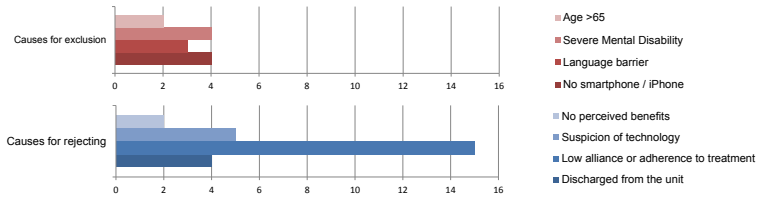


Image 3. Screenshot of daily assessments displayed on ReMindCare website



RESULTS:

A total of 81 patients were eligible for inclusion; 47/81 (58%) are app participants and 34/81 (42%) not. From no-participant sample: 13/81 (16%) meet exclusion criteria and 21/81 (26%) refused to use of the app. Causes for exclusion and rejection are depicted in **Graphic 1**.



Graphic 1. Causes for no participating

Mean age of the sample is 32,69(SD=9,01), 80.2% are men, 88,9% Caucasian, 80,2% single and 54,3% are not employed. No significant differences were found between participants and no participants in any demographic or clinical measures. Except for CGI_SI punctuations and previous suicidal attempts, as displayed in **Table 1.**

	Participants	No participants	
	n/ %	n/ %	X^2 / p
CGI_SI			**6.62/.037***
Mild (1-3)	8/ 17	7/20.6	
Moderate (4-5)	38/ 80.9	21/61.8	
Severe (>5)	1/ 2.1	6/17.6	
Suicidal attempts			**4.42/.036***
Yes	13/ 27.7	3/8.8	
No	34/ 72.3	31/91.2	
Total=81	47/ 58	34/ 42	

Table 1. Clinical statistical significant differences

CONCLUSIONS:

To our knowledge, this is the first attempt to integrate the use of mHealth technologies **as a tool into daily clinical practice and electronic clinical records**.

Rate of participation among patients in the unit is moderately high (58%) and only 26% of patients explicitly refused to use the app. No demographic differences were found between participants and no participants. However, some clinical differences regarding CGI_SI punctuations, may indicate that more severe patients are less willing to use ReMindCare. On the contrary, patients who have had previous suicide attempts are more interested in using the app, than those who have not. This can be due to the "urgent consultation" function which would allow them to contact clinicians in case of mood aggravation.

Preliminary perceptions suggest that ReMindCare is being particularly useful in order to **assess side effects of medication** and improvement of patients insight about the illness. Encouraging feedback is being received for patients and clinicians, especially in regards of **improvement of quality of interview and alliance between patient and clinician**.

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- Torous J, Nicholas J, Larsen ME, Firth J, Christensen H. Clinical review of user engagement with mental health smartphone apps: evidence, theory and improvements. Evid Based Ment Health. 2018 Aug; 21 (3): 116-9. PMID: 29871870

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APÉNDICE VI:

Bonet L, Arce D, Blanquer I, Llacer B, Julio S. S114. The efficacy of "urgent consultation request"; preliminary analysis of a real-world app (remidcare) for early psychosis

Schizophr Bull. 2020;46 (Suppl 1):S77-S78.

S112. ELUCIDATING THE CHRONOLOGY OF FLUCTUATIONS IN BASIC SYMPTOMS, EARLY SIGNS AND PSYCHOTIC SYMPTOMS IN ESTABLISHED PSYCHOSIS USING REPEATED MEASURES DATA GATHERED USING A SMARTPHONE APP

Emily Eisner*[1], Richard Drake[1], Richard Emsley[2], Christine Barrowclough[1], Sandra Bucci[1]
[1]University of Manchester; [2]King's College London

Background: Psychosis relapses are common, have profound adverse consequences for patients, and are costly to health services. 'Early signs' (e.g. anxiety; insomnia) have been used to predict relapse, in the hope of prevention or mitigation, with moderate sensitivity and specificity. Recent studies have provided preliminary prospective evidence that assessing 'basic symptoms' (e.g. vivid colour vision; disturbances in expressive speech) in addition to conventional early signs improves relapse prediction.
Basic symptoms are assumed to be one of the earliest, most basic subjective expressions of the underlying neurobiological disruption preceding the development of psychosis. There is some empirical evidence from ultra-high risk groups suggesting that basic symptoms do indeed emerge prior to other risk indicators during the prodromal period. However, no studies to date have examined the relative timing of increases in basic symptoms, conventional early signs and psychotic symptoms in individuals with established psychosis. In the current study, we used time-lagged, repeated measures, prospective data to test whether increased basic symptoms would precede increased conventional early signs, and in turn increased psychotic symptoms.
Methods: Individuals who had experienced a relapse of psychosis within the past year (n=18) were asked to use a smartphone app ('ExPRESS') weekly for six months to report early signs, basic symptoms and psychotic symptoms. Participants completed 65% of app assessments over the 6 month follow-up period, providing >200 observations in total. These data were analyzed using mixed effects models to account for clustering within individuals and to allow for missing data.
Results: App items showed high concurrent validity with researcher-rated psychotic symptoms (ρ range 0.80 to 0.87, $p<0.001$) and basic symptoms (ICC=0.76, $p<0.001$) over six months. The results of the mixed effects analyses described above will be presented in full, and their theoretical and clinical implications will be discussed.
Discussion: We anticipate that the findings of this study will be of theoretical interest. Within the socio-developmental-cognitive model (Howes & Murray, 2014), it would be logical to equate basic symptoms with the initial 'anomalous experiences' that are proposed to occur as a result of a disrupted dopamine system. Conventional early signs may then either occur later in the deterioration process laid out in the model or, as a heterogeneous group, may relate to more than one stage of the process. The results of the current study may help to elucidate the place of basic symptoms and conventional early signs within the socio-developmental-cognitive model. The findings may also lend support to the idea that basic symptoms are dopaminergic in origin.

S113. TELE-PSYCHIATRIC AFTER CARE (TAC) CLINIC FROM INDIA: PATTERN OF CONTINUITY OF CARE OF PATIENTS WITH SEVERE MENTAL DISORDERS

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Background: In India, follow up rates of persons with severe mental disorders are as low as 30%, necessitating the development of alternative models to ensure continuity of care (COC). Telepsychiatry is one such promising avenues that use audio-visual communication to provide effective services at affordable cost and convenience. A pilot study from the telepsychiatry aftercare (TAC) clinic has shown promising results in terms of acceptability, feasibility, clinical effectiveness and cost-saving benefits. This study aimed at evaluating the pattern of services of TAC clinic for patients with severe mental disorders
Methods: This study was conducted at TAC Clinic, Tele Medicine Centre of National Institute of Mental health and Neurosciences, Bengaluru. This study was approved by the institute's ethics committee. TAC is a psychiatrist-based clinic for follow-up in a videoconference mode for patients who are stable and unlikely to have psychiatric /medical emergencies. Chart review was done for all patients who availed services of TAC clinic between October 2016 to September 2019
Results: We reviewed charts of 90 patients. Primary psychiatric diagnosis were: Schizophrenia 34 (17 males, 17 females), bipolar disorder in 35 (23 males, 12 females), Psychosis NOS 21 (6 males, 15 females). The mean age was 38.84± (16.28) years; 82% of patients belonged to the middle socio-economic status and 65.1% were from an urban background. 242 TAC appointments were given during the study period. Among them, 9 got canceled (7 technical reasons, 2 non-availability of the patient), and 2 were aborted due to active suicidal tendencies. A total of 231 TAC consultations successfully completed i.e sessions were conducted successfully. Among these 85.29% sessions were successful in schizophrenia, 94.28% in BPAD, and 95.23 % psychosis NOS. Minimum of 1 to 3 consultations were done in 67.77% of the patients,13.33% had between 4–6 consultations and 18.7% had more than 7 consultations. The average duration of each session was 18.33 (±6.40) minutes. The total mean duration for all consultation for each patient was 101.40 (±160.61) minutes. Patients avoided an average of 1702.18(±1900) KM one-sided travel. In terms of psychopathology, 94.4% of patients with Schizophrenia, 81.71% with BPAD and 95.23%with psychosis NOS showed good improvement in their clinical condition. Common reasons for choosing TAC were: long-distance 51(48.1%), the convenience of using technology 21(19.8%), and cost of care 18(17%).
Discussion: Logistic issues were of significant concern among the patients and the families in our study, the high success rate and good improvement during TAC depict high acceptability and feasibility.
There are a felt need and demand to provide continuous specialist services bypassing all the logistic barriers. The TAC service in our facility is one such method that has started to ensure the continuity of care for patients with severe mental illness.

S114. THE EFFICACY OF "URGENT CONSULTATION REQUEST"; PRELIMINARY ANALYSIS OF A REAL-WORLD APP (REMIDCARE) FOR EARLY PSYCHOSIS

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Background: Patients are clamming for more personalized and closer clinical attention (Bonet et al. 2018). To this end, we developed RemindCare app. The app conducts daily and weekly assessments and this information is used to prevent relapses, to improve the therapeutic alliance and it is automatically included at the electronic clinical record of the hospital. Moreover, patients can contact clinicians by an "Urgent Consultation Request" (UCR), which is answered by a phone call in a period of 24-48h. This app was introduced in clinical practice in October 2018. Since then, 81 patients met criteria for inclusion and 57/81 (71%) started using the app. The aim of this study is to analyze the efficacy of this UCR to determine if this function can improve the real-world treatment of patients with early psychosis.
Methods: RemindCare app, is offered as an extra-service to the usual psychiatric care of patients in an Early Psychosis Program (EPP) at the Clinic Hospital of Valencia, Spain (Bonet et al. 2019). No remuneration is offered to any patient or clinician to use the app. Data of 57 patients diagnosed with a psychotic disorder was analyzed: the 26.3% (15/57) used the UCR (UCR group) and the 73.7% (42/57) did not (Non-UCR group). Mean age of the sample was 31.5 (SD=9.3), 56.1% were male, 87.7% caucasian and 82.5% were single. Mean years of illness was 3.5 (SD=2.8), CGI mean 4.1 (SD=0.9), GAF mean 60.5 (SD=12.3) and PANSS mean 56.6 (SD=12.2).
Results: Mean of months using the app was 8.4 (SD=4.5), 38.6% (22/57) of patients used the app for more than a year (12–13 months) and mean of engagement was 84.3 (SD=18.9). No significant differences were found between UCR and Non-UCR group in terms of demographic and clinical characteristics. However, there was a difference between groups in terms of engagement to the app ($\chi2$= 6.3, p=0.04). The 93.3% of the UCR group had a percentage of engagement to the app between 81–100% compared to the 66.7% in the Non-UCR group and the number of visits to the Urgent Care Units (UCU) was also higher in the UCR group ($\chi2$= 4.4, p=0.03). Additionally, only the 13.3% (2/15) of patients used the UCR for a psychotic symptom´s aggravation, the 33.3% (3/15) used it to inform of anxiety symptoms and another 33.3% (3/15) to change the clinical appointment. Moreover, the 66.7% (4/6) of patients who attended to UCU had previously made an UCR and they went to the UCU before that period of 24-48h of clinical response ended. Finally, there were no differences in terms of hospital admissions ($\chi2$= 1.1, p=0.3) and psychotic relapses ($\chi2$= 0.08, p=0.8) between groups. However, patients who stopped using the app had more relapses than patients who continued using it ($\chi2$= 15.3, p<0.000).
Discussion: To our knowledge, this is the first e-Health intervention systematically introduced in clinical practice. Rates of acceptance and engagement are high (71%; 84.3%) and nearly 40% of the sample is using the app for more than a year. Mean of engagement with the app, was extremely high among patients who used the UCR (93.3%; engagement between 81–100%) and although this UCR service was the most required in our previous survey (Bonet et al. 2018), these preliminary results suggest ¡ that the use of this alarm is not related to psychotic relapse detection. However, patients who use RemindCare app had less relapses than the ones who discontinue its use, which highlights the efficacy of the app. This, along with the high engagement and the positive feedback received, suggests that an improvement in real-world treatment of patients with early psychosis may be found in upcoming analysis.

S115. EVALUATION OF THE CLINICAL UTILITY OF SYMPTOM DIMENSIONS ON LONG-TERM CLINICAL AND FUNCTIONAL OUTCOMES IN FIRST EPISODE PSYCHOSIS

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Background: Current clinical utility of diagnostic categories in patients with psychosis is in debate. Alternatively, symptom-based dimensional approaches are suggested, but research on their utility and longitudinal stability is at its early phases, showing lack of consistencies. The aims of this prospective study are: 1) to test the stability of structure of symptom dimensions in first episode psychosis patients; 2) to explore the utility of symptom dimensions in predicting clinical and functional outcomes.
Methods: This study included a total of 208 with first episode of psychosis-spectrum disorders aged 18–65 years who presented to psychiatric services in South London, recruited as part of the Genetics and Psychosis Outcome (GAP) case-control study and EU-GEI multicentre case-control study. A subsample of 114 patients were traced after a mean of 6.5 years. Psychopathology was assessed at baseline and at follow-up using OPCRIT and tested with bifactor model, encompassing one general psychosis dimension and five specific symptom dimensions (positive, negative, disorganisation, mania, and depression). Follow up measures on functional outcome (assessed with GAF scale) and clinical outcomes (number and total length of hospitalisations) were derived from clinical records. Predictor role of baseline symptom dimensions was tested by multiple linear regression to predict global functioning; and by negative binomial regression for length of hospitalisation and number of hospital admissions.
Results: Factor loadings of disorganisation dimension were most likely to change longitudinally while loadings of positive dimension were most stable. Regarding dimension stability over time, all positive, disorganised and depressive symptoms significantly improved over time while manic and negative symptoms did not significantly differ. In terms of prediction of outcome, baseline manic symptoms were associated with reduced risk of hospitalisation (adj OR 1.56; 95% CI 1.01–2.38), reduced length of hospitalisation (adj IRR= 0.73; 95% CI 0.56–0.95) and better global functioning (β=5.21; 95% CI 2.46–7.95) at follow up. Similarly, depressive symptoms were associated with reduced length of hospitalisation (adj IRR= 0.77; CI 0.61–0.97). On the other hand, baseline positive symptoms were associated with increased risk of hospitalisation (adj OR 1.93; 95% CI 1.25–2.96). No other significant associations were found between the rest of symptom dimensions and outcomes.
Discussion: This study provides new evidence on the longitudinal stability of bifactor model of psychosis and, shows that all except manic and negative symptoms significantly improved over time. Whereas affective symptoms (including mania and depression) were associated with good prognosis, positive symptoms seem to predict poor clinical outcomes. The particular and different influence of affective and psychotic symptoms on long-term functional and clinical outcomes may have therapeutic implications and support the potential clinical utility of incorporating symptom-based approach in further outcome research.

S116. PRAGMATIC COMPREHENSION IN SCHIZOPHRENIA: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background: Individuals with schizophrenia (SCZ) frequently show a severe and widespread impairment in the communicative-pragmatic domain. They exhibit difficulties in the comprehension of a wide range of

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THE EFFICACY OF URGENT CONSULTATION REQUEST:

Preliminary analysis of a real-world app for early psychosis

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BACKGROUND:

Patients are clamming for more personalized and closer clinical attention (Bonet et al. 2018). To this end, we developed RemindCare app. The app conducts daily and weekly assessments and this information is used to prevent relapses, to improve the therapeutic alliance and it is automatically included at electronic clinical record of the patient. Moreover, patients can contact clinicians by an "Urgent Consultation Request" (UCR), which is answered by a phone call in maximum period of 24-48h. This app was introduced in clinical practice in October 2018. Since then, 81 patients met criteria for inclusion and 57/81 (acceptance=71%) started using the app.

The **aim** of this study is to **analyze the efficacy of this UCR to determine if this function can improve the real-world treatment of patients with early psychosis**.

RESULTS:

There was a difference between groups in terms of engagement to the app ($\chi2$= 6.3, p=0.04) which was higher on the UCR group. The number of visits to the Urgent Care Units (UCU) was also higher in the UCR group ($\chi2$= 4.4, p=0.03). No significant differences were found between groups in terms of demographic and clinical characteristics and in terms of hospital admissions ($\chi2$= 1.1, p=0.3) and psychotic relapses ($\chi2$= 0.08, p=0.8) **(Table 1).**

	TOTAL (N=57)	UCR (N=15)	NON-UCR (N=42)	X (p)
App status, n(%)				1.9 (0.4)
Using	43 (75.4)	13 (86.7)	30 (71.4)	
Discontinued	10 (17.5)	2 (13.3)	8 (19.0)	
Recovered (Discharged FEPP)	4 (7.0)	0 (0)	4 (9.5)	
Months using app, mean (SD)	8.4 (4.5)	8.6 (5.12)	9.3 (4.2)	10.9 (0.5)
Engagement, mean (SD)	84.3 (18.9)			6.3 (0.04)*
<40%	2 (3.5)	1 (6.7)	1 (2.4)	
41-80%	13 (22.8)	0 (0)	13 (31)	
81-100%	42 (73.7)	14 (93.3)	28 (66.7)	
Visits UCU, n (%)	12 (21)	6 (40.0)	6 (14.3)	4.4 (0.03)*
Hospital Admission, n (%)	7 (12.3)	3 (20.0)	4 (9.5)	1.1 (0.3)
Psychotic relapses, n(%)	10 (17.5)	3 (20.0)	7 (16.7)	0.08 (0.8)

Table 1. Use of the app significant differences between UCR and NON-UCR groups.

From the **UCR group**: Only the 13.3% used the UCR to inform of a psychotic relapse, the 33.3% used for anxiety symptoms and 33.3% to change the clinical appointment. The 66.7% of patients who attended to UCU, had previously made an UCR and they went to the UCU before that period of 24-48h of clinical response ended **(Table 2).**

	TOTAL (n=57)
Patients UCR, n (%)	15 (26.3)
Reason UCR, n (%)	
• Psychotic relapse	2 (13.3)
• Suicidal thoughts	2 (13.3)
• Anxiety	3 (20)
• Medication side effects complains	2 (13.3)
• Change clinical appointment	3 (20)
• Others	3 (20)
Visit UCU[1], n (%)	6 (40.0)
UCR pre-visit to UCU[1], n (%)	4 (66.7)

Table 2. Analysis of UCR characteristics.

	PSYCHOTIC RELAPSES N=10 / 57	NO N= 47 / 57	X (p)
App status, n(%)			15.3 (0.00)*
Using	4 (40.0)	39 (83.0)	
Discontinued	6 (60.0)	4 (8.5)	
Recovered	0 (0)	4 (8.5)	

Table 3. Analysis of the use of the app status and the presence of psychotic relapses among the total of patients.

However, patients who stopped using the app had more relapses than patients who continue using it ($\chi2$=15.3, p<0.000) (Table 3).

METHODS:

Study setting: RemindCare app, is offered as an extra-service to the usual psychiatric care in an Early Psychosis Program (EPP) at the Clinic Hospital of Valencia, Spain. No remuneration is offered to any patient or clinician.

Participants: Data of 57 patients diagnosed with a psychotic disorder was analyzed. Mean age of the sample was 31.5 (SD=9.3), 56.1% were male, 87.7% Caucasian and 82.5% were single. Mean years of illness was 3.5 (SD=2.8), CGI mean 4.1 (SD=0.9), GAF mean 60.5 (SD=12.3) and PANSS mean 56.6 (SD=12.2).

Measures: Information displayed on the dashboard of physicians in relation to the use of the UCR was analyzed. As a result, two study groups were created: (1)UCR Group, 15/57 (26.3%) and (2) Non-UCR group, 42/57 (73.7%).

** (Further information about this naturalistic and real-world intervention, can be found on the study protocol (Bonet et al. 2020)) **

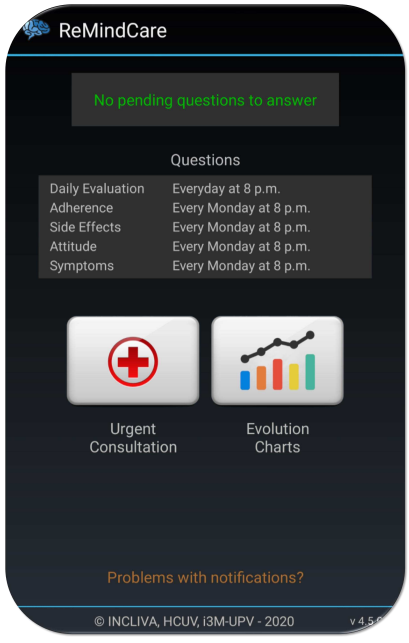

Image 1. Screenshot of the home screen of the app.

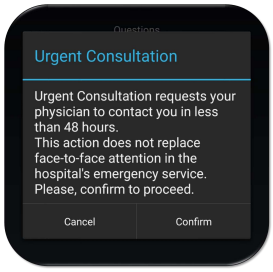

Image 3. Screenshot of the automahic message that appears after cliking on the UCR

CONCLUSIONS:

To our knowledge, this is the first e-Health intervention **systematically introduced in clinical practice**. Rates of acceptance and engagement are high (71%; 84.3%) and nearly 40% of the sample is using the app for more than a year. Mean of engagement with the app, was extremely high among patients who used the UCR (93.3%; engagement between 81-100%) and although this UCR service was the most required in our previous survey (Bonet et al. 2018), these preliminary results suggest that the use of this alarm is not related to psychotic relapse detection. However, patients who use RemindCare app had less relapses than the ones who discontinue its use, which highlights the potential efficacy of the app. This, along with the high engagement and the positive feedback received, suggests that an improvement in real-world treatment of patients with early psychosis may be found in upcoming analysis.

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APÉNDICE VII:

Bonet L, Torous J, Arce D, Blanquer I, Llacer B, Julio S. ReMindCare for early psichosis: Real-world intervention during the COVID-19 outbreak. *Schizophr Bull*. 2021. [Pendiente de publicación]

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ReMindCare APP for early psychosis

Real-world intervention during the COVID-19 outbreak

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BACKGROUND:

Since the COVID-19 crisis started, many authors have expressed their concerns about the negative effects of this unprecedent situation on mental health. Recent studies found higher rates of anxiety, depression and stress in general population, and some studies have claimed that this risk of psychological decompensating is increased for those with severe mental illness. Since telemedicine has shown its potential benefits to increase the quality of mental health interventions, the development of this digital interventions has surged as the access to health services was restricted. In this regard, ReMindCare is a smartphone application (Bonet et al. 2020a) whose development was based on two previous studies (Bonet et al. 2017-2018). This app, showed its positive clinical outcomes after 19 months of implementation in a First Episode of Psychosis Program (FEPP) for patients with early psychosis (EP) (Bonet et al. 2020b).

The objective of this study was to analyze the clinical impact of the COVID-19 outbreak in the group of patients followed in a FEPP and the impact of the use of ReMindCare app during this period.

METHODS:

Rates of incidence, relapse and hospitalizations were analyzed from patients in the FEPP at the Clinic Hospital of Valencia from the 1st of March of 2019 to the 28th of February of 2021. The impact of the use of the app during the first year of the COVID-19 outbreak (March 2020) was also analyzed.

RESULTS:

The number of patients included in the FEPP during COVID-19 outbreak increased 26.6% (X2= 6.29, p=0.012) compared to the same period in 2019 **(Table 1).**

The incidence during this period increased 107.14% (X2= 4.10, p=0.04) when we compared to data from the same period in 2019. However, no significant differences were found in terms of number of relapses (X2= 1,67, p=0.19) and hospitalizations (X2= 0.32, p=0.57) in both periods **(Table 2).**

Table 1. FEPP follow-up patients from March to February 2020-2021.

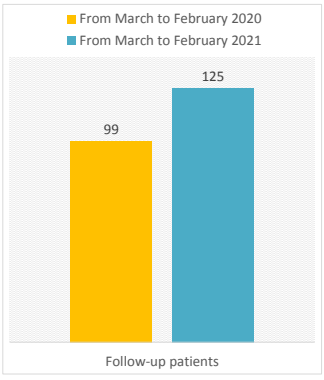
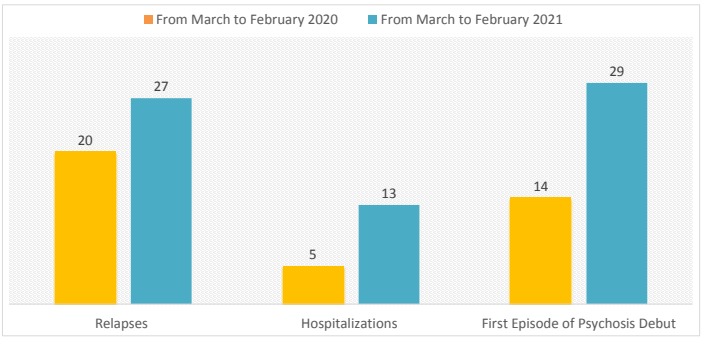


Table 2. Clinical data from FEPP patients from March February 2020-2021.



RESULTS:

53 patients used the app during the COVID-19 outbreak (March to February 2021) and only 9,4% had a relapse during this period, compared to the 25,6% of the 86 patients who did not use the app (Treatment as usual, TAU) (X2= 5,46, p=0.019). Moreover, only one patient using the app had a hospitalization during this period while 14% of patients who did not use the app had (X2= 5,63, p=0.018) **(Table3).**

Table 3, Clinical diffreneces between ReMindCare patients and TAU during the Covid-19 outbreak

	TOTAL	RC GROUP	TAU	X^2 (p)
Gender (Male), N (%)	99 (71,2)	35 (66,0)	64 (74,4)	1,12 (0,28)
Age, mean (SD)	34,17 (11,8)	32,64 (1,39)	35,12 (1,37)	49,06 (0,18)
Relapses, mean (SD)	27 (19,4)	5 (9,4)	22 (25,6)	5,46 (0,019)
Hospitalizations, mean (SD)	13 (9,4)	1 (1,9)	12 (14)	5,63 (0,018)
Total	139	53	86	

In addition, in regards of the use of the app during the months of March to October 2020, mean rate of engagement with the app was 85,7 (SD=16,4) and mean of moths using the app were 16.8 (SD=8.4).

CONCLUSIONS:

The use of ReMindCare app during the COVID-19 outbreak was correlated to fewer relapses and hospitalizations. In addition, we found an increase in the number of the EP patients in our FEPP when we compare data from March to October from 2019 to 2020. These data highlight the relevance of developing digital interventions to prevent the negatives effects of the pandemic crisis and the social isolation.

To the best of our knowledge, ReMindCare app was the **first e-Health** intervention which was **daily being used since the beginning of the COVID-19** outbreak and the first app for patients with psychosis that has obtained **positive clinical outcomes during this period**.

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APENDICE VIII:

Cuestionario de feedback de ReMindCare

Resultados del análisis de datos para la publicación: Bonet L, Arce D, Blanquer I, Llacer B, Julio S. Resultados del análisis de las experiencias de los usuarios de ReMindCare tras 12 meses de intervención [Pendiente de publicación].

NOMBRE Y APELLIDOS:
NÚM. TELEF:
FECHA:

ESCALA DE VALORACIÓN DE LA APP REMINDCARE

VERSIÓN PARA USUARIOS

Con el fin de mejorar nuestros servicios, te pedimos que rellenes este cuestionario sobre tus opiniones tras el uso de la App ReMindCare. Te rogamos la máxima sinceridad, nos interesa conocer tú verdadera opinión, ya sea positiva o negativa.

Esta información va a ser tratada de forma anónima y confidencial y con fines académicos e investigadores orientados a la mejora de la atención sanitaria que tú y otros pacientes recibís.

INSTRUCCIONES: *A continuación, se van a presentar una serie de preguntas con diferentes respuestas posibles. Marca con una "X" la casilla de la respuesta que más te convenga.* ***Marca solo una casilla por pregunta.***

A. CALIDAD DE LA APP:

1. **FACILIDAD DE USO. ¿Te ha resultado fácil aprender a utilizar la App una vez ha sido instalada?**
   - ☐ Muy difícil. Requiere mucho tiempo y esfuerzo aprender a utilizarla.
   - ☐ Algo difícil. Me costó un poco de tiempo aprender a utilizarla.
   - ☐ Fácil. Tras la explicación que me dieron ya supe cómo utilizarla.
   - ☐ Muy fácil. Incluso sin la explicación, habría sabido cómo utilizarla.

2. **FUNCIONAMIENTO. ¿Cómo te ha funcionado la App (Aparición de avisos de respuesta a test, acceso y cumplimentación de test, envio de alertas al clínico, etc.)?**
   - ☐ Muy mal. He tenido muchos problemas utilizando la App.
   - ☐ No muy bien. He tenido algunos problemas al utilizar la App pero se han resuelto rápidamente o no eran muy graves.
   - ☐ Bien. En general la App no me ha dado problemas, aunque hay algunas funciones que mejorar.
   - ☐ Muy bien. La App me ha funcionado perfectamente y no hay nada que mejorar.

3. **APARIENCIA. ¿Te resulta atractiva visualmente la App?**
   - ☐ Nada atractiva. Debe cambiar por completo la apariencia de la App.
   - ☐ Muy poco atractiva: diseño pobre / mal uso de los colores / es aburrida.
   - ☐ Atractiva. En general me gusta el diseño de la App, se adapta a su objetivo.
   - ☐ Muy atractiva. Me encanta el diseño de la App, sus colores, etc.

B. CALIDAD DE LA INTERVENCIÓN:

1. **UTILIDAD. ¿Crees que es útil la App para mejorar la atención psiquiátrica que recibes?**
   - ☐ Nada útil. Considero que el uso de la App no ha supuesto ninguna mejora en la atención sanitaria que recibo.
   - ☐ Poco útil. El uso de la App me ha generado pocos beneficios con respecto a la atención sanitaria convencional.
   - ☐ Bastante útil. He notado una diferencia en la atención sanitaria que he recibido utilizando la App frente a cuando no la utilizaba.
   - ☐ Muy útil. Siento que la atención sanitaria que he recibido al utilizar la App ha mejorado mucho.

2. **SATISFACCIÓN. ¿Estás satisfecho/a con la atención sanitaria que se te ha proporcionado al utilizar la App?**
   - ☐ Nada satisfecho/a. Siento que no se han valorado mis respuestas a la App, que el clínico no ha respondido a mis avisos, etc.
   - ☐ Poco satisfecho/a. Siento que no siempre se han respondido a mis demandas y/o avisos.
   - ☐ Bastante satisfecho/a. Siento que generalmente los test que enviaba eran valorados por mi psiquiatra, que normalmente se han respondido a mis avisos, etc.
   - ☐ Muy satisfecho/a. Los test que rellenaba siempre eran valorados por mi psiquiatra, siempre se ha respondido adecuadamente a mis avisos, etc.

3. **RECOMENDACIÓN. ¿Recomendarías esta App a otros pacientes de la unidad?**
   - ☐ No. No recomendaría esta App a ningún otro paciente.
   - ☐ En general no recomendaría esta App, salvo a pacientes con unas características muy específicas.
   - ☐ Si. Algunos pacientes podrían beneficiarse de su uso.
   - ☐ Si. Todos los pacientes con psicosis podrían beneficiarse de su uso.

C. EXPERIENCIA USO APP:

En general el uso de la App me hace sentir / me ha hecho sentir… (Marca la casilla correspondiente):

	Totalmente de acuerdo	Bastante de acuerdo	Algo en desacuerdo	Totalmente en desacuerdo
Más **relajado/a**. Saber que la App detecta mi estado de salud me ha hecho sentir más tranquilo/a.	☐	☐	☐	☐
Agobiado/a. Me angustia tener que responder todos los días a los cuestionarios.	☐	☐	☐	☐
Preocupado/a. Me preocupa que la App recoja tanta información privada sobre mí.	☐	☐	☐	☐

	Totalmente de acuerdo	Bastante de acuerdo	Algo en desacuerdo	Totalmente en desacuerdo
Preocupado/a. El uso de la App me hace estar pensando todo el día en mi enfermedad.	☐	☐	☐	☐
Atendido/a. He sentido que si empeoraba, rápidamente sería atendido/a por mi médico.	☐	☐	☐	☐
Aburrido/a. Rellenar los test me resulta muy pesado.	☐	☐	☐	☐
Más **próximo/a** a mi médico. Gracias a la App siento que ha mejorado la relación con mi médico.	☐	☐	☐	☐

¿Alguna sugerencia o comentario que quieras añadir?
¿Cuál es tu opinión general tras utilizar la App ReMindCare?
(Ventajas, desventajas, aspectos a mejorar, etc.)

Gracias por tu colaboración

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FREQUENCIES VARIABLES=Facilidad_uso Funcionamiento Apariencia Utilidad Satisfacción Recomend
  /BARCHART PERCENT
  /ORDER=ANALYSIS.
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Frecuencias

Notas

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	Casos utilizados	Los estadísticos se basan en todos los casos con datos válidos.
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Estadísticos

		Facilidad_uso	Funcionamiento	Apariencia	Utilidad	Satisfacción
N	Válidos	28	28	28	28	28
	Perdidos	0	0	0	0	0

Estadísticos

		Recomendación	Exp_Relajado	Exp_Agobiado	Exp_PreocupadoPrivacidad	Exp_PreocupadoEnfermedad
N	Válidos	28	28	28	28	28
	Perdidos	0	0	0	0	0

Estadísticos

		Exp_Atendido	Exp_Aburrido	Exp_Próximo
N	Válidos	28	28	28
	Perdidos	0	0	0

Tabla de frecuencia

Facilidad_uso

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Fácil	6	21,4	21,4	21,4
	Muy fácil	22	78,6	78,6	100,0
	Total	28	100,0	100,0	

Funcionamiento

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	No muy bien	4	14,3	14,3	14,3
	Bien	13	46,4	46,4	60,7
	Muy bien	11	39,3	39,3	100,0
	Total	28	100,0	100,0	

Apariencia

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Nada atractiva	1	3,6	3,6	3,6
	Muy poco atractiva	6	21,4	21,4	25,0
	Atractiva	20	71,4	71,4	96,4
	Muy atractiva	1	3,6	3,6	100,0
	Total	28	100,0	100,0	

Utilidad

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Poco útil	3	10,7	10,7	10,7
	Bastante útil	12	42,9	42,9	53,6
	Muy útil	13	46,4	46,4	100,0
	Total	28	100,0	100,0	

Satisfacción

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Poco satisfecho	1	3,6	3,6	3,6
	Bastante satisfecho	10	35,7	35,7	39,3
	Muy satisfecho	17	60,7	60,7	100,0
	Total	28	100,0	100,0	

Recomendación

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Si. Algunos pacientes	11	39,3	39,3	39,3
	Si. Todos pacientes psicosis	17	60,7	60,7	100,0
	Total	28	100,0	100,0	

Exp_Relajado

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Totalmente de acuerdo	11	39,3	39,3	39,3
	Bastante de acuerdo	15	53,6	53,6	92,9
	Algo en desacuerod	1	3,6	3,6	96,4
	Totalmente en desacuerdo	1	3,6	3,6	100,0
	Total	28	100,0	100,0	

Exp_Agobiado

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Totalmente de acuerdo	1	3,6	3,6	3,6
	Bastante de acuerdo	5	17,9	17,9	21,4
	Algo en desacuerod	7	25,0	25,0	46,4
	Totalmente en desacuerdo	15	53,6	53,6	100,0
	Total	28	100,0	100,0	

Exp_PreocupadoPrivacidad

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Bastante de acuerdo	6	21,4	21,4	21,4
	Algo en desacuerod	7	25,0	25,0	46,4
	Totalmente en desacuerdo	15	53,6	53,6	100,0
	Total	28	100,0	100,0	

Exp_PreocupadoEnfermedad

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Bastante de acuerdo	3	10,7	10,7	10,7
	Algo en desacuerod	9	32,1	32,1	42,9
	Totalmente en desacuerdo	16	57,1	57,1	100,0
	Total	28	100,0	100,0	

Exp_Atendido

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Totalmente de acuerdo	14	50,0	50,0	50,0
	Bastante de acuerdo	10	35,7	35,7	85,7
	Algo en desacuerod	3	10,7	10,7	96,4
	Totalmente en desacuerdo	1	3,6	3,6	100,0
	Total	28	100,0	100,0	

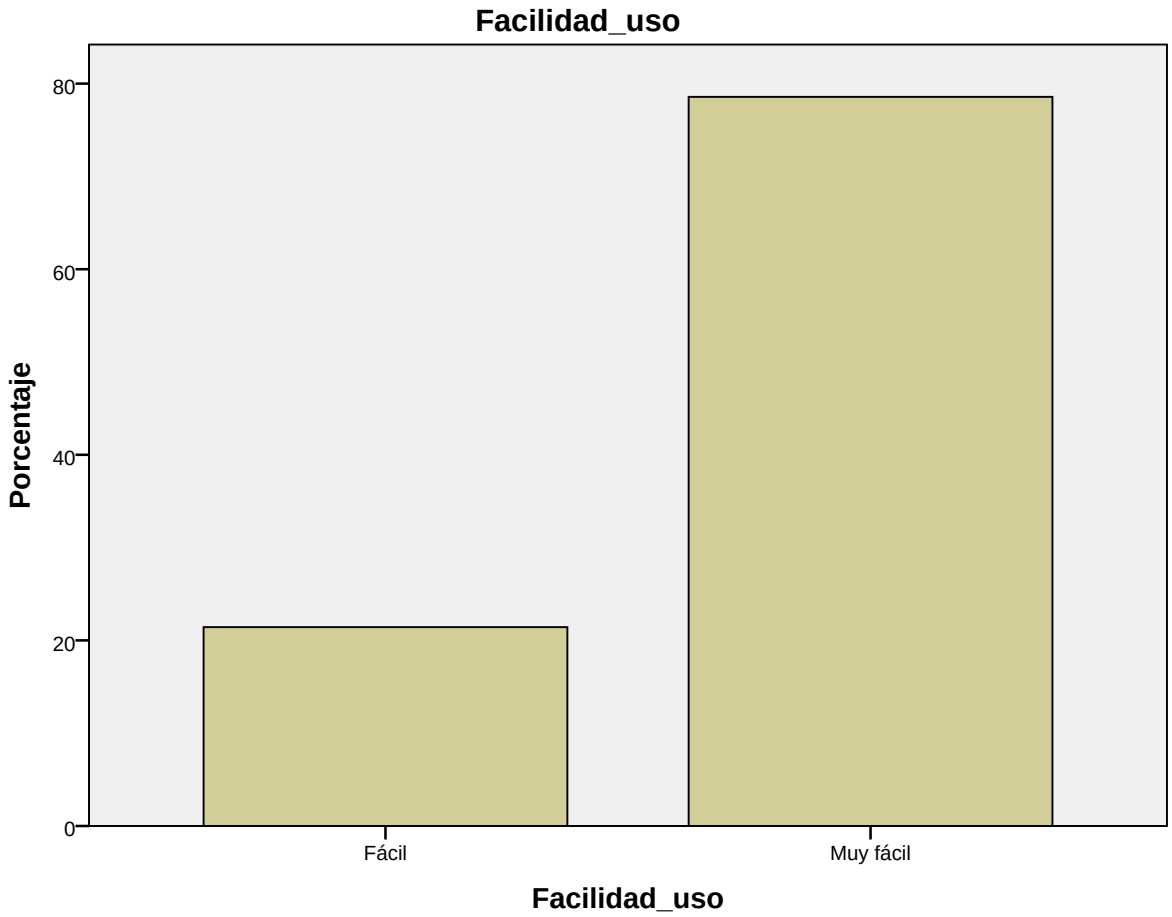
Exp_Aburrido

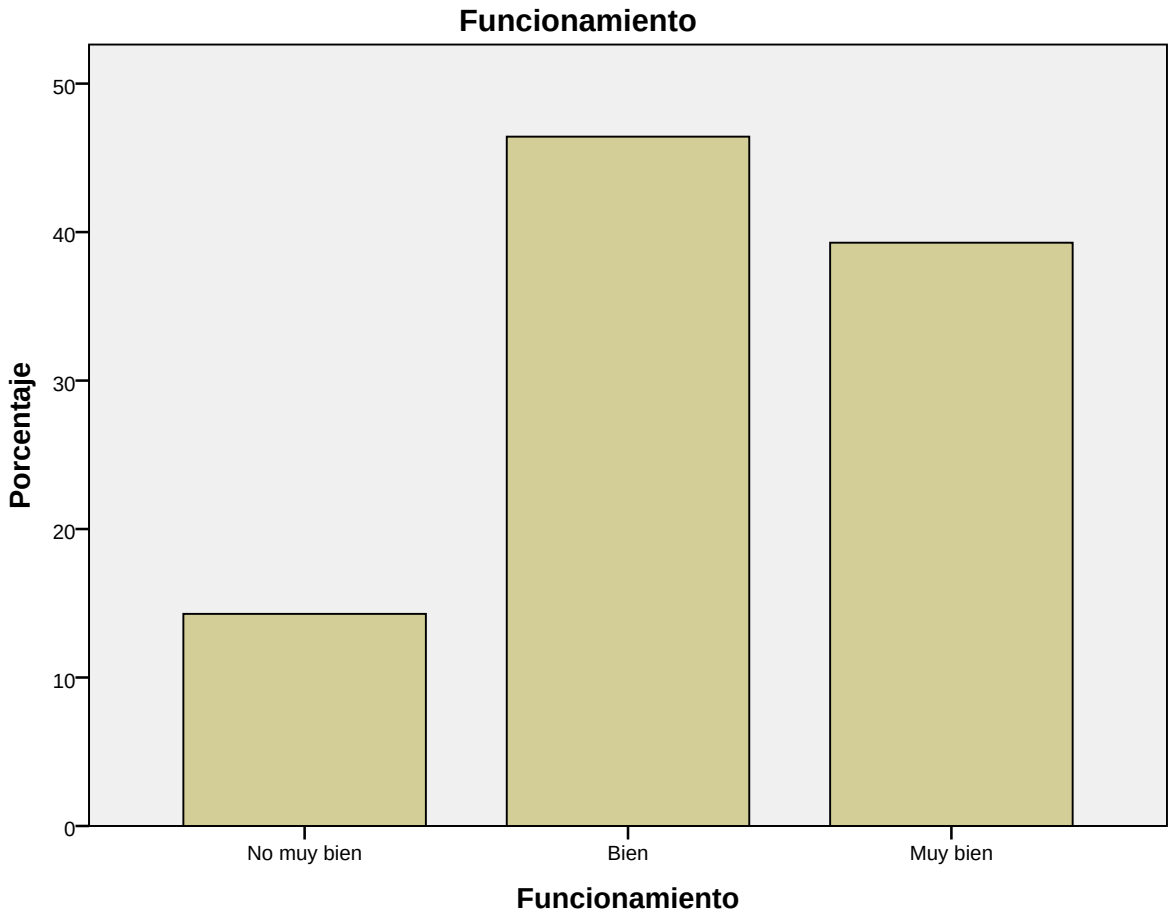
		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Totalmente de acuerdo	1	3,6	3,6	3,6
	Bastante de acuerdo	5	17,9	17,9	21,4
	Algo en desacuerod	14	50,0	50,0	71,4
	Totalmente en desacuerdo	8	28,6	28,6	100,0
	Total	28	100,0	100,0	

Exp_Próximo

		Frecuencia	Porcentaje	Porcentaje válido	Porcentaje acumulado
Válidos	Totalmente de acuerdo	12	42,9	42,9	42,9
	Bastante de acuerdo	12	42,9	42,9	85,7
	Algo en desacuerod	3	10,7	10,7	96,4
	Totalmente en desacuerdo	1	3,6	3,6	100,0
	Total	28	100,0	100,0	

Gráfico de barras

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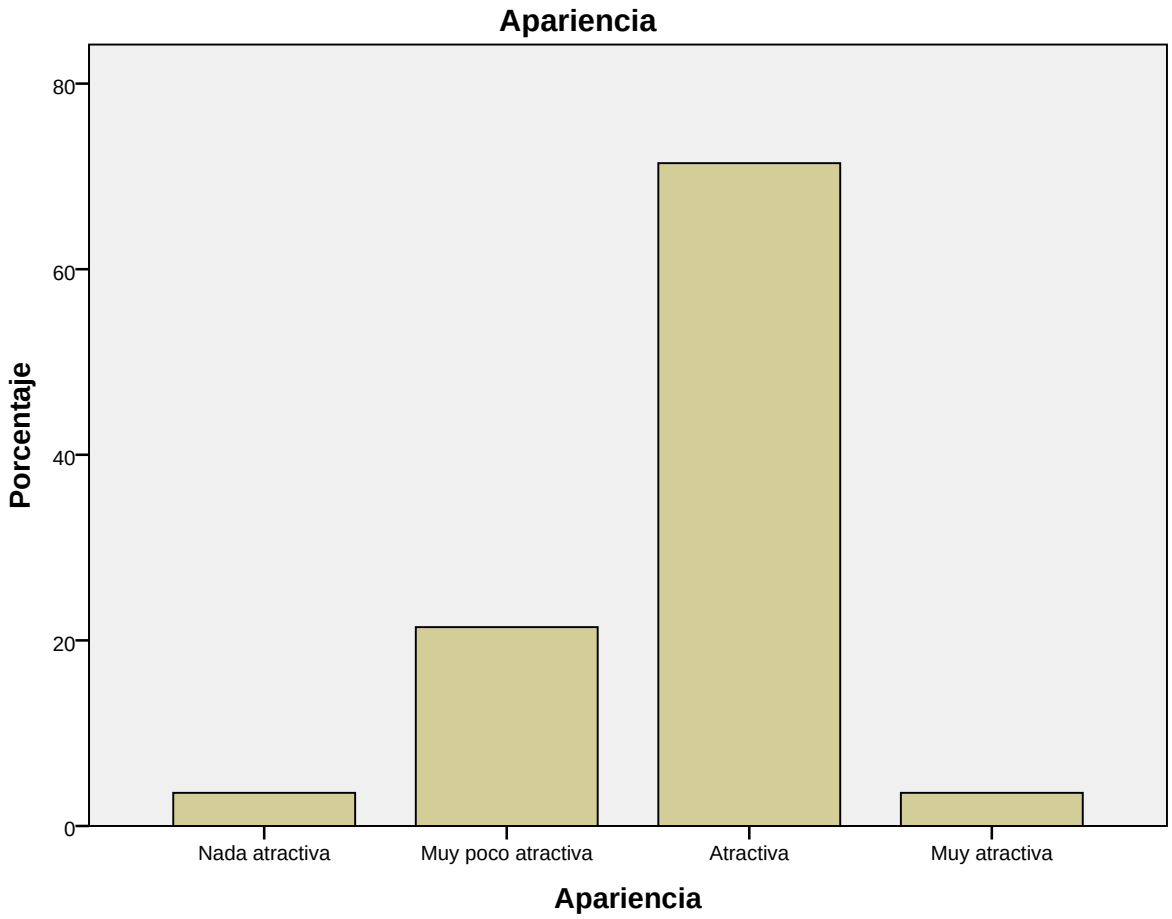
Porcentaje
50
40
30
20
10
0
No muy bien
Bien
Muy bien
Funcionamiento


Apariencia
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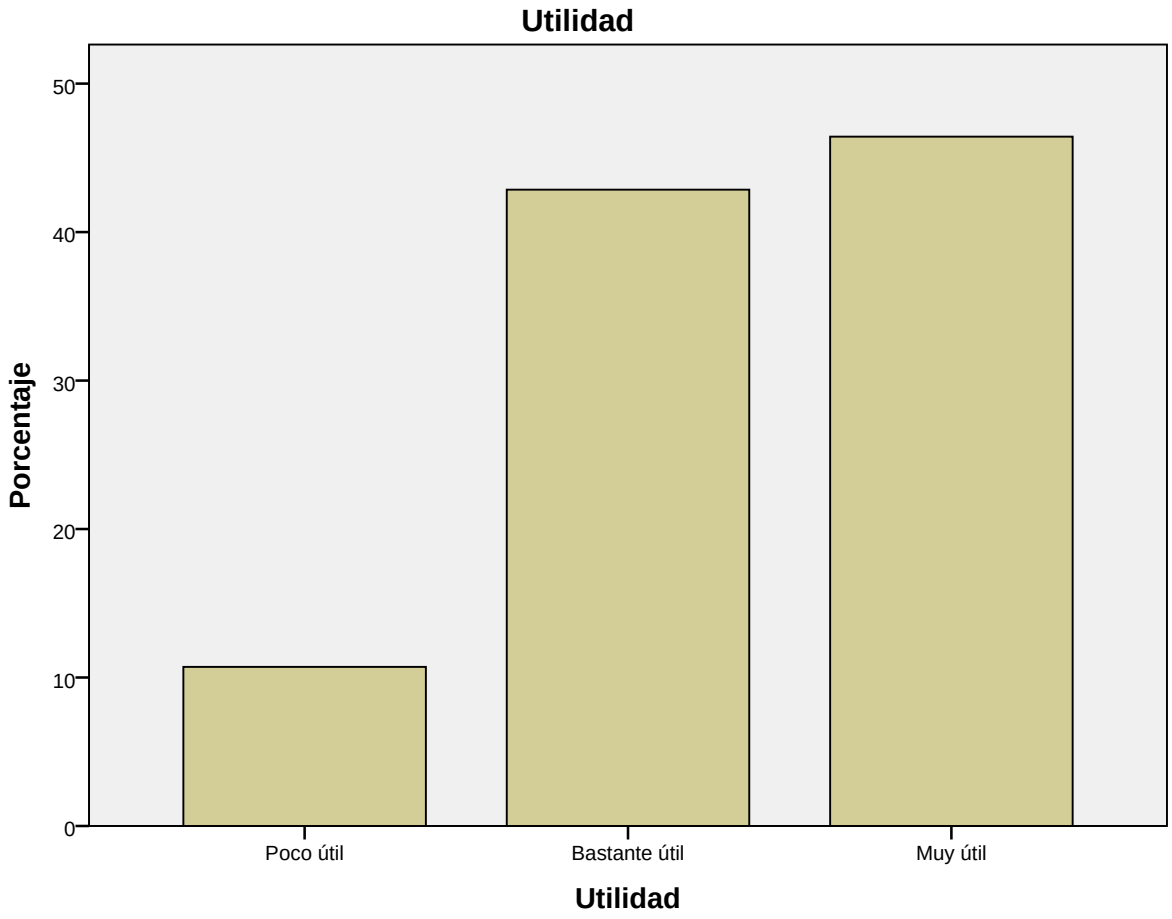
60
40
20
0
Porcentaje
Nada atractiva
Muy poco atractiva
Atractiva
Muy atractiva
Apariencia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Porcentaje
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20
10
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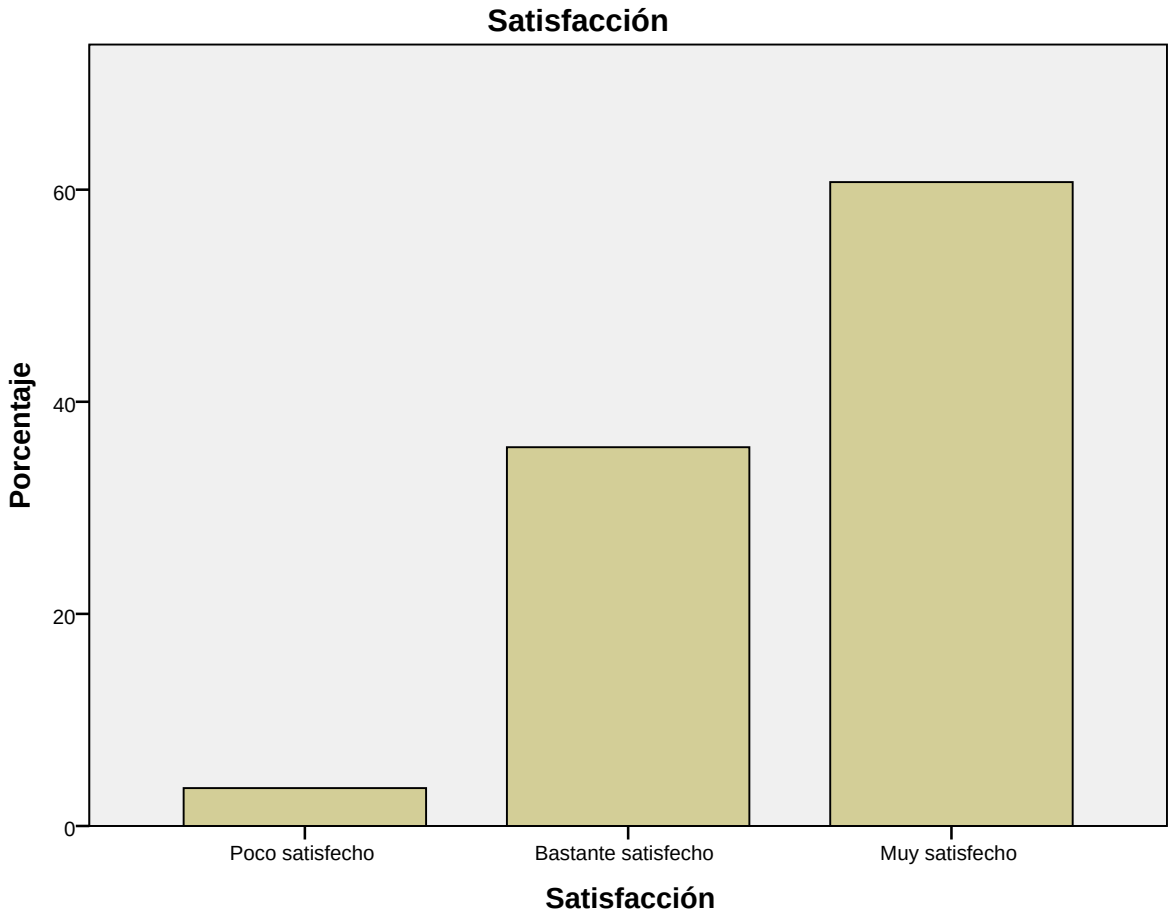
Poco útil
Bastante útil
Muy útil
Utilidad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Porcentaje
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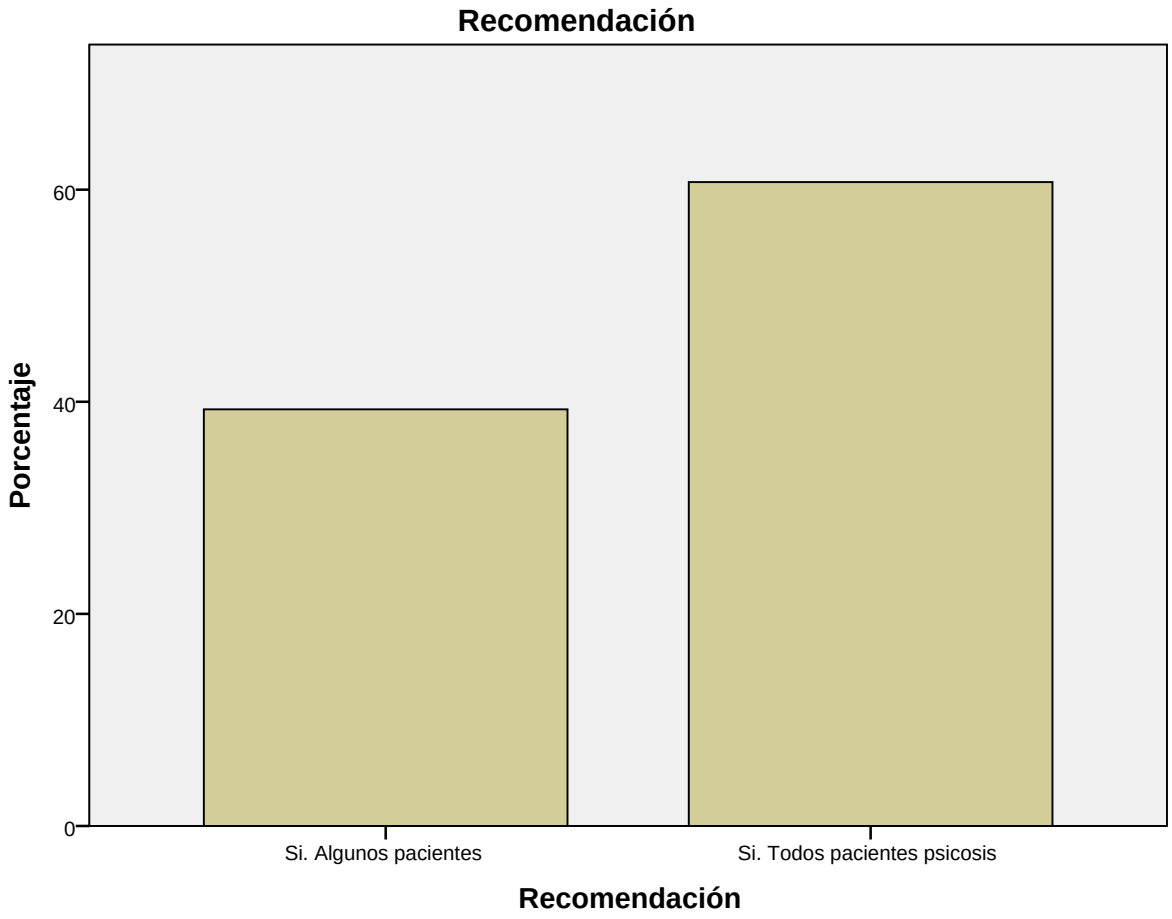
40
20
0
Poco satisfecho
Bastante satisfecho
Muy satisfecho
Satisfacción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Porcentaje
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40
20
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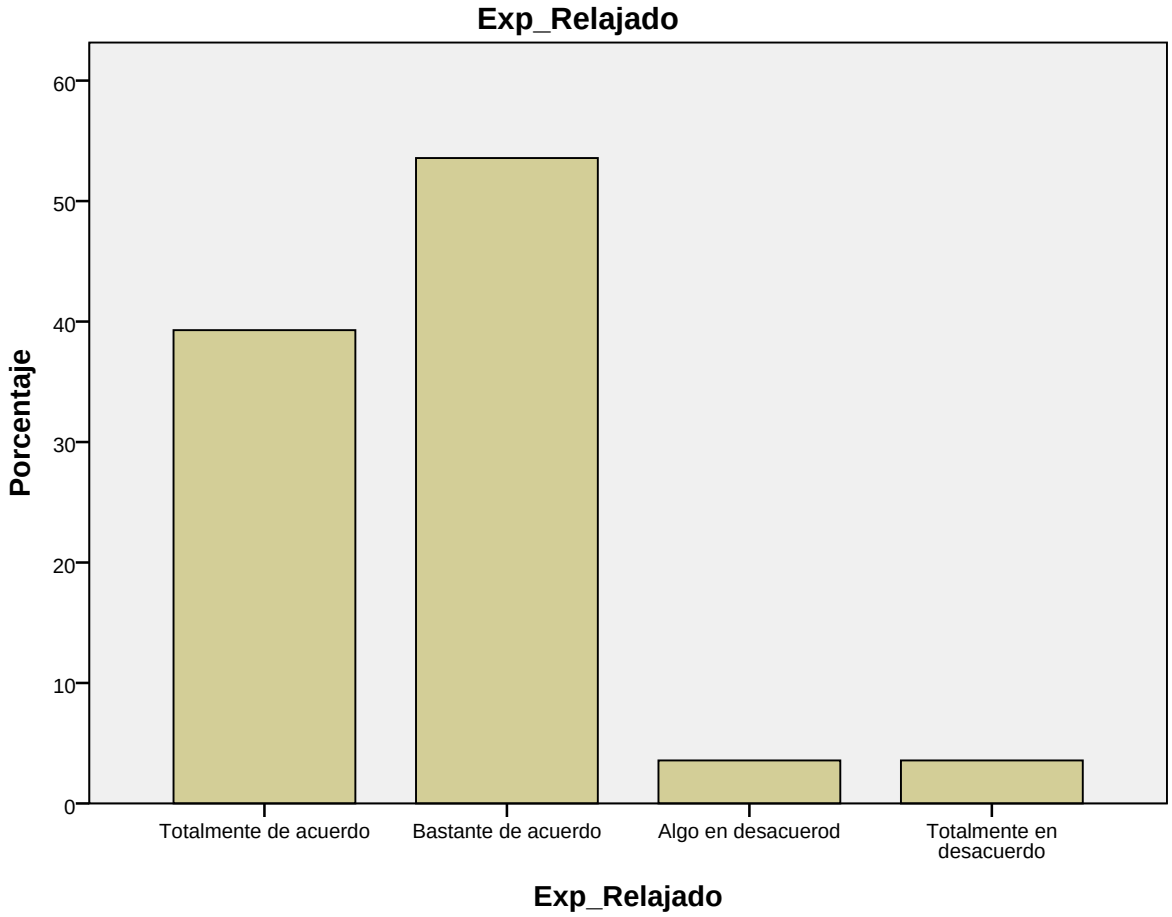
Si. Algunos pacientes
Si. Todos pacientes psicosis
Recomendación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Porcentaje
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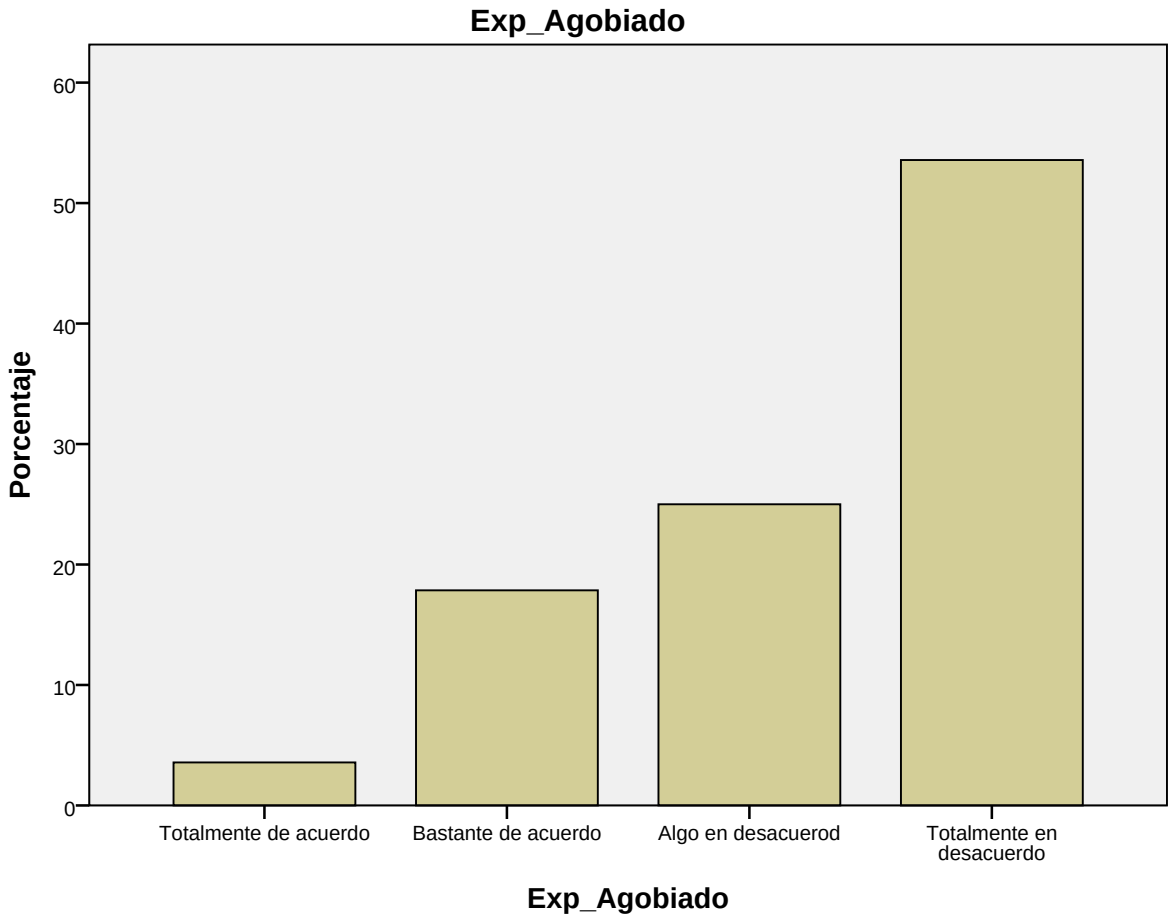
Bastante de acuerdo
Algo en desacuerod
Totalmente en desacuerdo
Exp_Relajado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Porcentaje
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Bastante de acuerdo
Algo en desacuerod
Totalmente en desacuerdo
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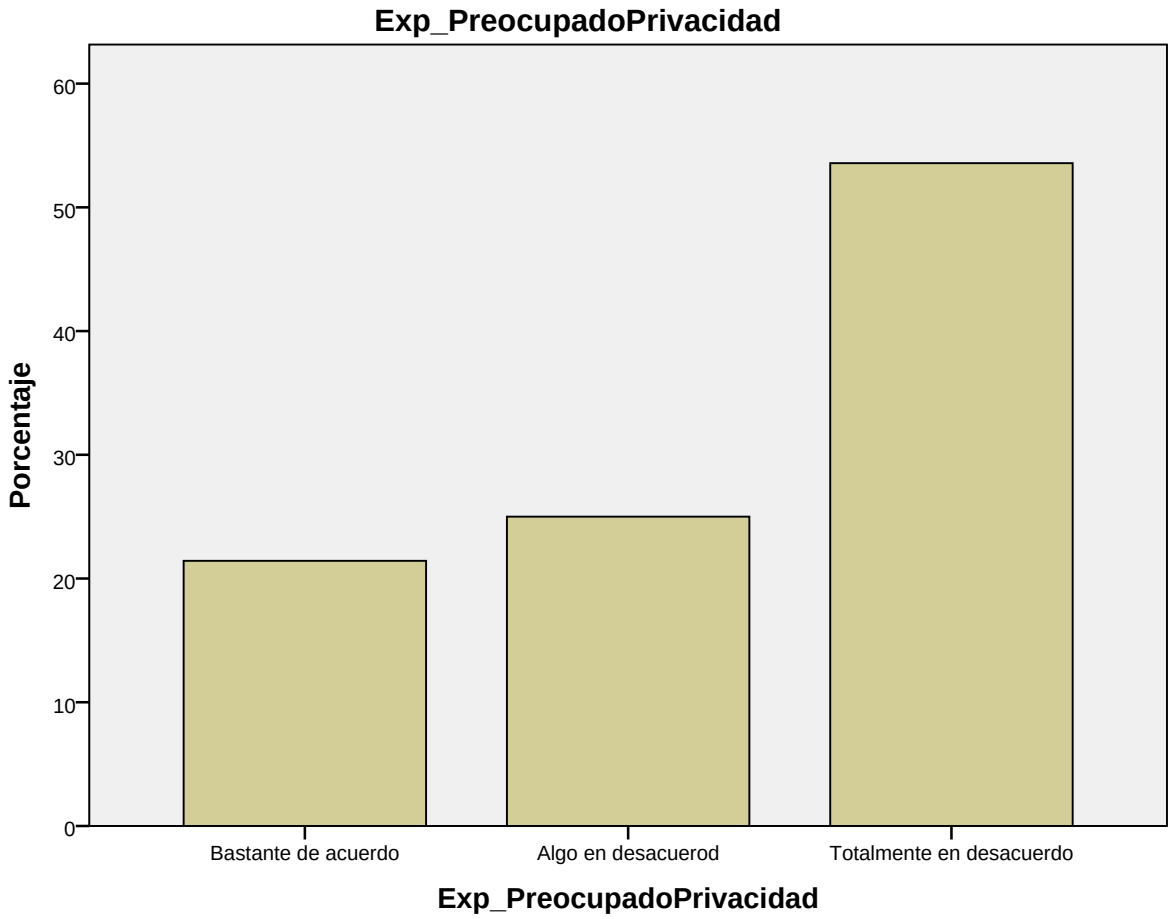
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Porcentaje
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20
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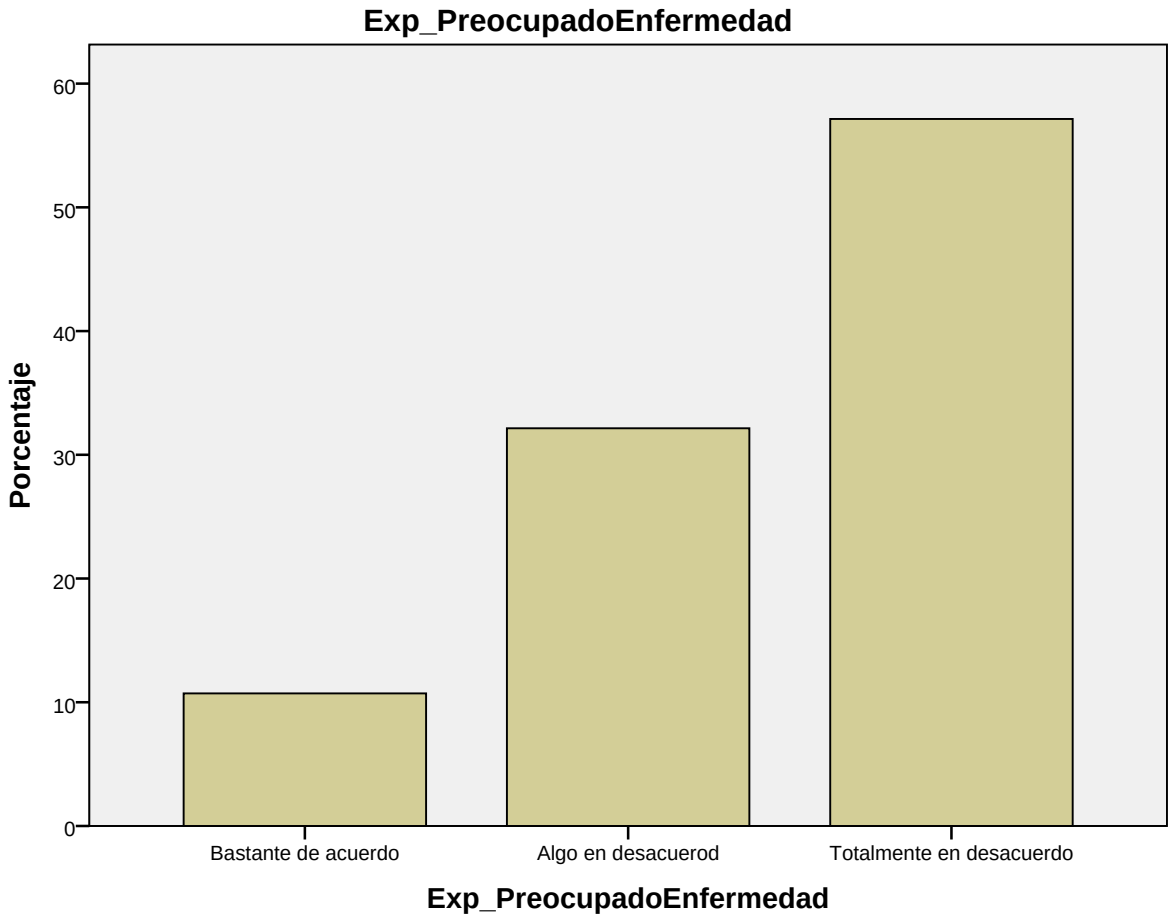
Bastante de acuerdo
Algo en desacuerod
Totalmente en desacuerdo
Exp_PreocupadoPrivacidad


Exp_PreocupadoEnfermedad
Porcentaje
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Algo en desacuerod
Totalmente en desacuerdo
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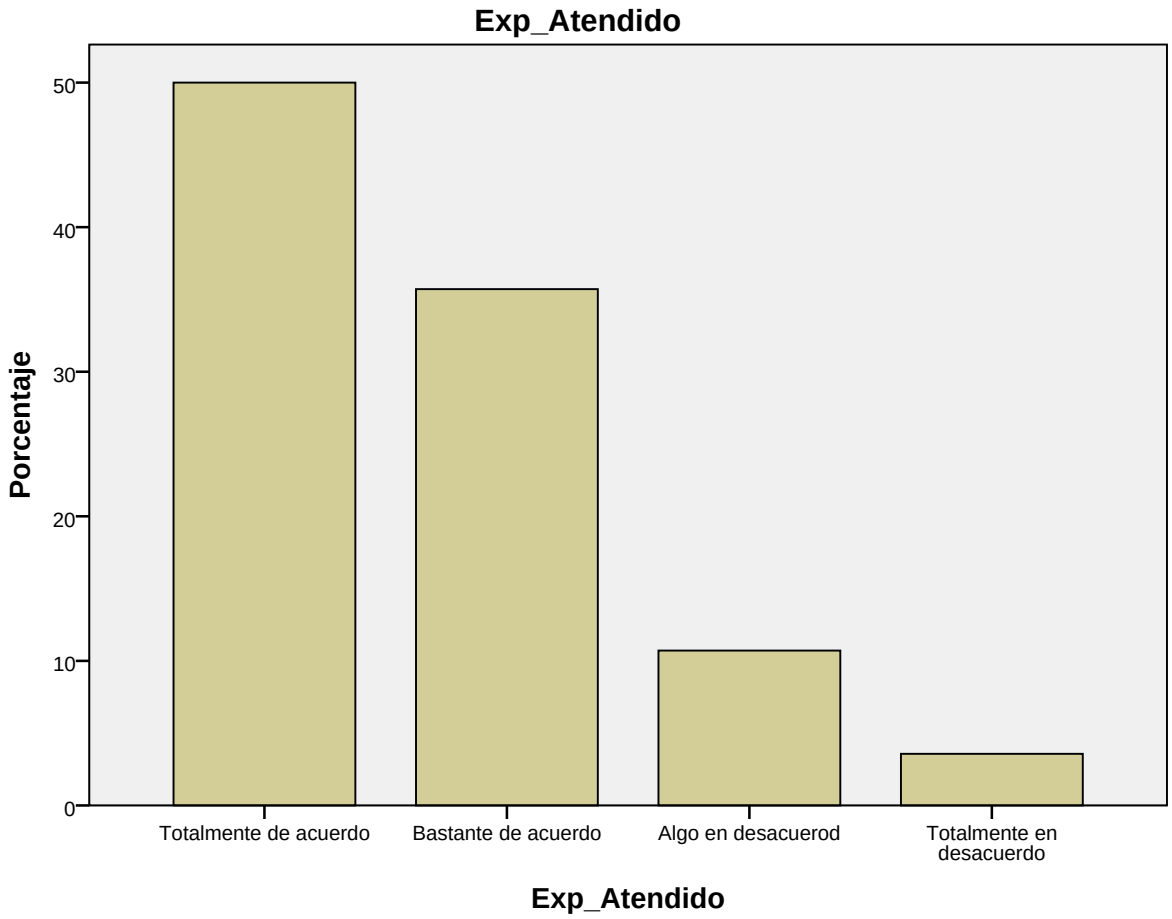
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Algo en desacuerod
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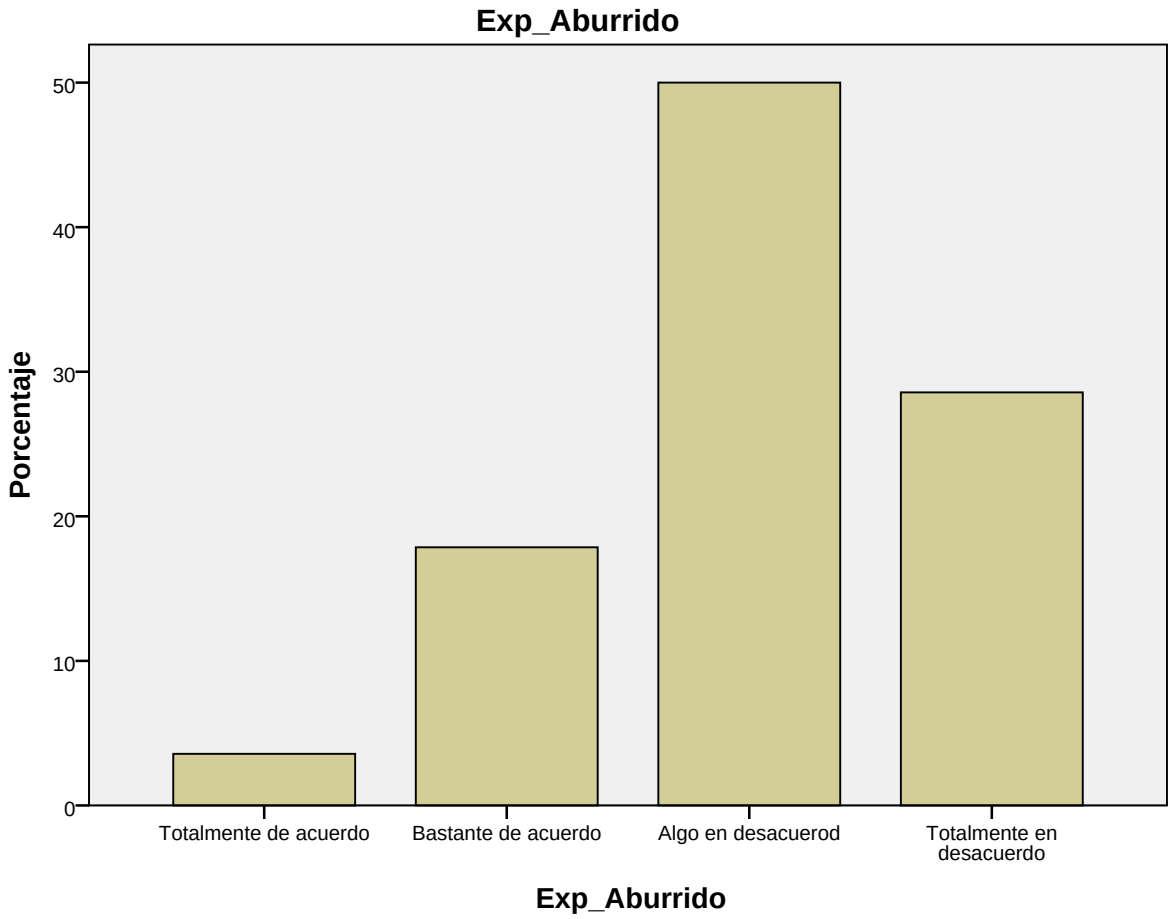
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Porcentaje
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Algo en desacuerod
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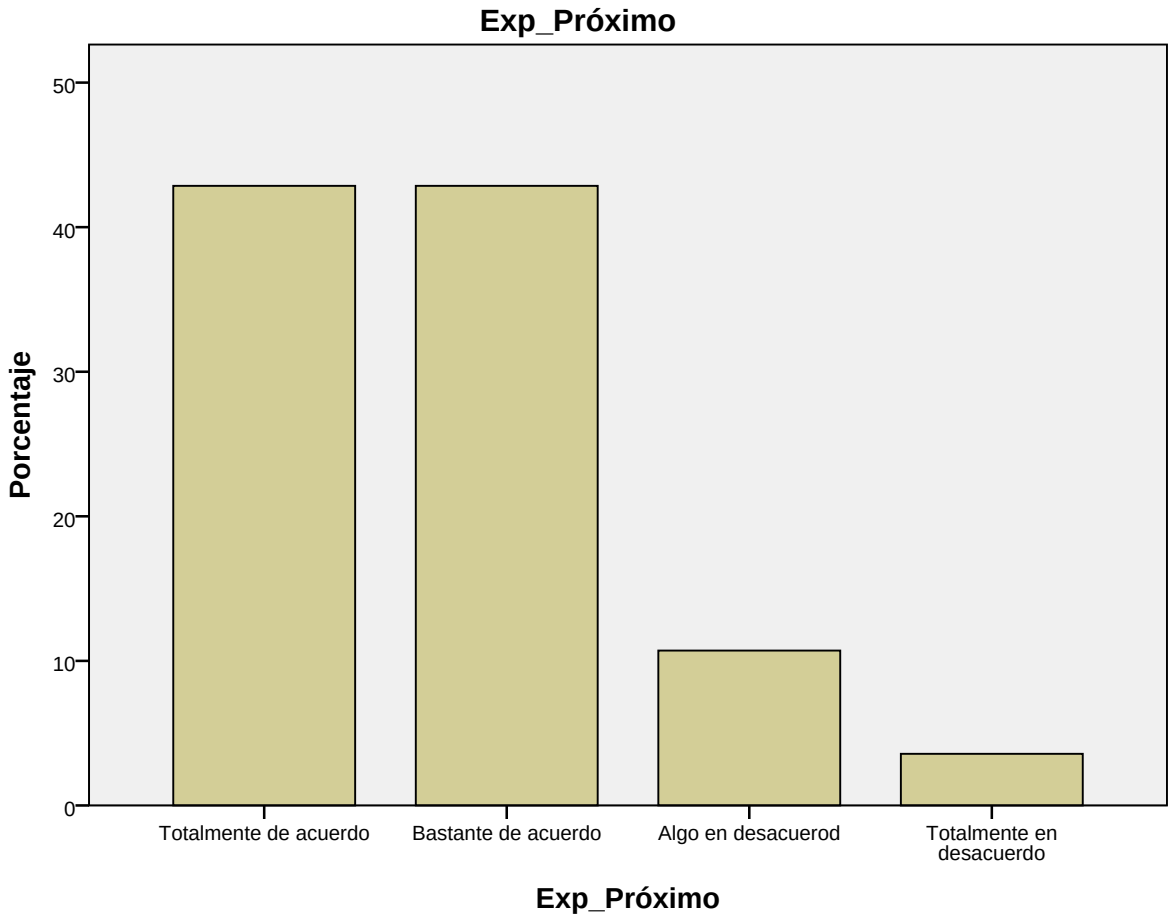
Exp_Aburrido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Porcentaje
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Bastante de acuerdo
Algo en desacuerod
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Exp_Próximo